GARIS PANDUAN

ETIKA PENYELIDIKAN

GUIDELINES FOR

RESEARCH ETHICS

PUSAT PENGURUSAN PENYELIDIKAN & INOVASI

CENTRE FOR RESEARCH & INNOVATION MANAGEMENT

UNIVERSITI PERTAHANAN NASIONAL MALAYSIA

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[SEMENTARA]

[PROVISIONAL]

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PENGENALAN

Garis Panduan Etika Penyelidikan Universiti Pertahanan Nasional Malaysia (UPNM) ini telah dibangunkan bagi menyediakan satu sistem kawalan kepatuhan terhadap etika penyelidikan bagi cadangan penyelidikan yang menggunakan subjek manusia dan haiwan yang dilakukan di premis milik UPNM ataupun oleh kakitangan dan pelajar UPNM. Selaras dengan perkembangan UPNM dalam membangunkan dan merancakkan aktiviti penyelidikan dalam bidang pertahanan dan keselamatan, garis panduan ini diharapkan dapat menjadi rujukan utama kepada para penyelidik sebelum memulakan sesuatu projek penyelidikan.

Penyelidikan secara amnya ditakrifkan sebagai suatu aktiviti sistematik dan berdisiplin yang dijalankan untuk mewujud dan mengembangkan ilmu pengetahuan. Ia melibatkan kaedah yang boleh merentasi pelbagai disiplin dan menggunakan proses analisis kritikal bagi membuktikan penemuan dalam bidang saintifik dan sosial, membuat ciptaan baru, memperluaskan pemahaman atau membaiki konsep, teori, dan teknik. Ciri-ciri umum penyelidikan merangkumi metodologi yang sistematik dan berdisiplin, komitmen terhadap penerbitan hasil daripada penemuan dan ulasan kesepakaran yang setanding. Unsur penerbitan penyelidikan juga berbeza mengikut disiplin dan boleh meliputi penerbitan hasil penyelidikan di dalam jurnal atau monograf atau buku sehinggalah persembahan komposisi kreatif.

Etika pula ditakrifkan sebagai prinsip-prinsip perilaku yang baik yang dikenali juga sebagai prinsip akhlak yang didasarkan pada sistem nilai yang diterima dalam sesuatu peradaban. Dalam konteks penyelidikan di Universiti, etika dikenal pasti sebagai perilaku yang baik yang patut diikuti berdasarkan sistem nilai Universiti berkenaan yang menolak perilaku yang buruk dalam menjalani kehidupan dan kerjaya sebagai kakitangan akademik dan juga penyelidik.

Garis panduan ini akan sentiasa dikemaskini dan ditambah baik dari semasa ke semasa bagi menjamin mutu dan etika penyelidikan UPNM sentiasa berada di tahap yang terbaik. Semoga dengan adanya panduan ini, warga penyelidik UPNM terus menjaga kualiti penyelidikan supaya penyelidikan di UPNM setanding tarafnya dengan piawaian antarabangsa dan diiktiraf.

Garis panduan ini telah diluluskan oleh Senat ke 46 Bil. 2/2015 yang telah bersidang pada 31 Mac 2015.

BAB I

ETIKA PENYELIDIKAN

1. Latar Belakang

1.1 Semua kakitangan akademik di Universiti Awam (UA) di Malaysia perlu menjalankan penyelidikan dan aktiviti kesarjanaan di samping menerbitkan hasil penyelidikan mereka atau mempatenkannya. Sehubung itu semua penyelidik dikehendaki memohon dana penyelidikan bagi membiayai penyelidikan yang ingin mereka laksanakan. Malah menjalankan penyelidikan adalah salah satu keperluan dalam perkembangan kerjaya kakitangan akademik UA.

1.2 Penyelidikan yang dijalankan mungkin melibatkan subjek manusia, haiwan, tumbuh-tumbuhan, bentuk-bentuk hidup yang lain, alam sekitar, jentera dan struktur, hal-hal politik dan sosial. Secara umumnya, apa-apa penyelidikan yang dijalankan oleh kakitangan (akademik dan sokongan) dan/atau pelajar hendaklah mematuhi etika dan disiplin penyelidikan yang ditentukan oleh Universiti di dalam atau di luar negara, oleh mana-mana kerajaan dan mana-mana pihak ketiga yang memberi penajaan kepada penyelidikan tersebut.

1.3 Kepentingan penjagaan hak asasi manusia telah diberi penekanan di peringkat antarabangsa di mana satu Pengisytiharan Universal Hak Asasi Manusia *(Universal Declaration of Human Rights*) telah diterima pakai oleh Perhimpunan Umum Pertubuhan Bangsa-bangsa Bersatu (PBB) *(General Assembly of the United Nations)* pada tahun 1948. Pada tahun 1966, demi memberi kuasa perundangan dan moral terhadap Pengisytiharan ini, Perhimpunan Umum PBB telah menerima pakai '*the International Covenant on Civil and Political Rights*'. Bahagian 7 *Covenant* ini menyatakan "*No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation".* Melalui kenyataan ini masyarakat umum mengkehendaki nilai asas kemanusiaan hendaklah digunakan untuk mentadbir semua penyelidikan yang melibatkan subjek manusia khususnya memastikan perlindungan hak dan kebajikan semua subjek manusia yang terlibat dalam uji kaji saintifik.

2. Nilai-Nilai Dan Prinsip Penyelidikan Beretika

2.1. Terdapat empat prinsip yang menjadi landasan kepada tingkah laku penyelidikan yang beretika, iaitu: menghormati setiap manusia (respect for persons); berfaedah dan tidak mendatangkan kemudaratan (beneficence); keadilan (justice); dan, merit serta integriti penyelidikan (research merit and integrity). Setiap prinsip ini di huraikan di bawah:

a. **Menghormati Setiap Insan**.

Prinsip menghormati setiap insan berasaskan kesedaran bahawa setiap insan mempunyai nilai diri mereka tersendiri. Penyelidik perlu menerima hakikat ini dan mesti menghormati maruah mereka yang dilibatkan dalam penyelidikan.

Bagi penglibatan mana-mana peserta penyelidikan, aspek moral yang ditekankan adalah penghormatan terhadap setiap manusia mestilah dilandaskan setiap penyelidik menerima hakikat bahawa setiap peserta penyelidikan merupakan seorang insan yang mempunyai hak autonominya tersendiri dan penyelidik hendaklah sentiasa melindungi insan yang tertimpa keadaan autonomi yang tersekat atau terkurang. Adalah menjadi kewajipan penyelidik untuk mendapatkan persetujuan yang berpengetahuan (informed consent) daripada setiap peserta penyelidikan dan untuk mengekalkan kerahsiaan bagi pihak mereka. Penyelidik perlu memberi peluang kepada mereka untuk membuat keputusan sendiri secara sukarela sepanjang proses penyelidikan di jalankan. Jika peserta tidak mampu membuat keputusan mereka sendiri atau mempunyai masalah kekurangan kapasiti untuk berbuat sedemikian maka, demi terus menghormati mereka, perlu ada proses memberi kuasa kepada mereka di mana mungkin dan penyediaan kaedah perlindungan bagi mereka ini mengikut keadaan mereka. Penyelidik perlu sentiasa menghormati privasi, kerahsiaan, sensitiviti dan budaya peserta penyelidikan dan jika berkaitan, komuniti mereka. Jika terdapat apa-apa perjanjian yang dibuat dengan peserta penyelidikan ataupun masyarakat mereka, perjanjian tersebut perlu dilunaskan.

b. **Berfaedah dan Tidak Mendatangkan Kemudaratan**.

Prinsip ini merupakan gandingan di antara manfaat dan bahaya yang berkaitan dengan penyertaan dalam penyelidikan. Manfaat dari penyelidikan mestilah wajar dengan risiko, bahaya atau ketidak selesaan yang mungkin terjadi akibat penyelidikan tersebut. Risiko dan bahaya ini melibatkan bukan sahaja individu dalam penyelidikan tetapi turut dipanjangkan kepada masyarakat dari mana mereka datang. Penyelidik mempunyai kewajipan untuk memaksimumkan faedah mungkin dan mengurangkan risiko kemudaratan. Khususnya para penyelidik adalah bertanggungjawab untuk:

- mengolah reka bentuk penyelidikan supaya mengurangkan risiko kecederaan dan ketidakselesaan kepada peserta;
- menjelaskan kepada peserta penyelidikan akan manfaat dan risiko yang mungkin terbit dari penyelidikan tersebut, dan
- menjaga kebajikan peserta penyelidikan sepanjang kajian dijalankan.

Dalam keadaan di mana tiada faedah secara langsung mungkin diperolehi oleh peserta penyelidikan, prinsip etika yang perlu diguna pakai adalah risiko yang dihadapi peserta haruslah lebih rendah daripada faedah yang boleh diperolehi dari penyelidikan seumpama yang lain.

c. **Keadilan**.

Prinsip keadilan ini berasaskan kesaksamaan di mana setiap individu mempunyai kesamaan tertentu yang beliau berkongsi dengan individu yang lain sehinggalah setiap individu menerima layan yang sama rata dalam kehidupan mereka. Prinsip ini membawa maksud bahawa beban dan faedah penyelidikan diagihkan secara saksama, dan merangkumi layanan yang adil dalam pengambilan peserta penyelidikan dan di dalam perlaksanaan

penyelidikan. Penyelidik perlu memastikan golongan yang vulnerable tidak dieksploitasi dan bahawa calon peserta penyelidikan yang layak serta boleh mendapat manfaat daripada penyertaan tidak dikecualikan tanpa alasan yang munasabah. Prinsip ini memerlukan setiap penyelidikan mematuhi perkara berikut:

- Kriteria pemilihan, pengecualian dan seterusnya kemasukan setiap peserta penyelidikan dalam sesuatu projek penyelidikan dilakukan secara adil dan maklumat penghuraian kriteria-kriteria ini dimaklumkan dengan tepat di dalam laporan penyelidikan.
- Proses merekrut/memilih peserta adalah dilakukan dengan adil.
- Pemilihan peserta penyelidikan tidak dibebankan ke atas golongan calon peserta tertentu sahaja secara tidak adil.
- Pengagihan manfaat dari penyertaan dalam penyelidikan hendaklah dibuat secara saksama.
- Tidak berlaku eksploitasi terhadap peserta penyelidikan semasa perlaksanaan kerja penyelidikan tersebut.
- Capaian ataupun akses kepada faedah penyelidikan disediakan dengan saksama.
- Hasil penyelidikan hendaklah boleh diakses oleh peserta penyelidikan tersebut.

d. **Merit Serta Integriti Penyelidikan**.

Penglibatan sebarang peserta dalam mana-mana penyelidikan adalah tidak beretika melainkan jika penyelidikan yang dicadangkan mempunyai merit dan penyelidiknya mempunyai integriti. Penyelidikan yang mempunyai merit:

- hendaklah mempunyai potensi manfaat yang wajar, samada dari segi sumbangan kepada pengetahuan, kefahaman, kemahiran atau kepakaran bagi para penyelidik dan/atau peningkatan dalam kebajikan serta faedah sosial dan/atau kesejahteraan individu;
- direka bentuk dengan menggunakan kaedah yang sesuai bagi mencapai matlamat penyelidikan;
- hendaklah berasaskan kajian kepustakaan terhadap pengetahuan semasa dan lampau terhadap persoalan kajian. Namun ini tidak menolak cadangan penyelidikan yang *novel* di mana terdapat maklumat yang terhad atau ketiadaan maklumat, ataupun penyelidikan itu diperlukan bagi menyediakan maklum balas yang pantas bagi menangani sesuatu situasi yang tidak diduga;
- direka bentuk agar penghormatan maruah peserta tidak terjejas oleh matlamat penyelidikan, cara penyelidikan itu dilaksanakan, atau oleh keputusannya;

- hendaklah dijalankan atau diselia oleh orang atau kumpulan yang berpengalaman, berkelayakan dan mempunyai kecekapan yang sesuai untuk penyelidikan tersebut; dan
- hendaklah dijalankan dengan menggunakan kemudahan dan sumber yang bersesuaian dengan penyelidikan tersebut.

2.2. Terdapat keperluan khusus bagi pematuhan kepada kod etika antarabangsa bagi penyelidikan yang menggunakan subjek manusia ataupun haiwan. Bagi penyelidikan yang menggunakan subjek manusia dokumen Perisytiharan Helsinki (*Helsinki Declaration*) terbitan Persatuan Perubatan Sedunia (WMA) dan Garis Panduan Etika Antarabangsa bagi Penyelidikan Bioperubatan Yang Melibatkan Subjek Manusia terbitan *Council for International Organizations of Medical Sciences* (CIOMS) dengan kerjasama *World Health organization* (WHO). Manakala bagi haiwan pula digunakan standard yang diterbitkan oleh Pertubuhan Kesihatan Haiwan Sedunia (*Organisation Mondiale de la Santê Animale)* (OiE).

2.3. Setiap penyelidikan yang menggunakan subjek manusia hendaklah mematuhi etika dan disiplin penyelidikan seperti berikut:

a. mematuhi prinsip etika dan prosedur yang standard bagi penyelidikan yang berkaitan dengan manusia seperti ditetapkan oleh Pertubuhan Kesihatan Sedunia (WHO) atau lain-lain badan yang diiktiraf;

b. menghormati maruah manusia;

c. mendapatkan kebenaran bertulis atau persetujuan daripada peserta penyelidikan;

d. meminimumkan kemudaratan dan memaksimumkan manfaat kepada manusia; dan

e. mendapatkan kelulusan daripada Jawatankuasa Etika Penyelidikan Universiti (JKEP) atau mana-mana jawatankuasa lain yang diiktirafkan oleh Universiti.

2.4. Manakala penyelidikan yang melibatkan haiwan pula hendaklah mematuhi etika dan disiplin penyelidikan seperti berikut:

a. mematuhi standard etika yang ditetapkan oleh Pertubuhan Kesihatan Haiwan Sedunia (*Organisation Mondiale de la Santê Animale* -OiE) atau mana-mana badan lain yang diiktiraf;

b. dilaksanakan atau diselia oleh kakitangan akademik, pelajar atau kakitangan lain yang kompeten dan terlatih;

c. menjaga kebajikan haiwan, termasuk:

- mengurangkan rasa lapar dan dahaga yang terlampau;
- mengurangkan kesakitan dan kecederaan;
- mengurangkan ketakutan dan penderitaan; dan

- membenarkan haiwan menunjukkan tingkah laku semula jadi mereka.

d. mendapatkan kebenaran bertulis daripada agensi-agensi yang berkaitan bagi haiwan-haiwan yang terlindung di bawah undang-undang kebangsaan dan antarabangsa;

e. mengurangkan bilangan haiwan yang digunakan untuk penyelidikan dan menggantikan penggunaan haiwan, jika boleh, dengan alternatif lain;

f. menggunakan kaedah penyelidikan yang sesuai untuk haiwan yang digunakan dalam penyelidikan; dan

g. mendapat kebenaran daripada Jawatankuasa Etika Penyelidikan Universiti atau mana-mana badan lain yang diiktiraf oleh Universiti.

2.5. Seterusnya setiap penyelidikan yang melibatkan organisma diubah suai secara genetik hendaklah mematuhi etika dan disiplin penyelidikan seperti berikut:

a. mematuhi ketetapan dalam Akta Bio-keselamatan (2007) atau mana-mana akta dan peraturan yang dikuat kuasakan berkaitan dengan organisma yang diubahsuai secara genetik; dan

b. mendapat kebenaran daripada Jawatankuasa Etika Penyelidikan Universiti atau mana-mana badan lain yang diiktiraf oleh Universiti.

3. Skop Etika Penyelidikan

3.1. Penyelidikan terhadap subjek manusia termasuklah apa-apa kaedah penyelidikan yang dijalankan dengan atau mengenai orang, data atau spesimen biologi, termasuk:

a. kaji selidik atau temubual;

b. pengujian atau perawatan psikologi, fisiologi dan perubatan;

c. pemerhatian oleh penyelidik;

d. akses kepada dokumen peribadi mereka atau bahan-bahan maklumat mereka yang lain;

e. pengumpulan dan penggunaan organ, tisu atau cecair tubuh mereka (contohnya: kulit, darah, air kencing, air liur, rambut, tulang, tumor, dan spesimen biopsi lain); atau

f. capaian kepada maklumat peribadi mereka (samada dalam bentuk yang dikenali secara individu [*individually identifiable*], boleh dikenal pasti-semula [re-identifiable] atau tidak boleh dikenal pasti [*nonidentifiable*]) yang merupakan sebahagian daripada sumber maklumat yang pernah diterbitkan atau sebahagian suatu pangkalan data.

3.2. Manakala penyelidikan menggunakan subjek haiwan termasuklah apa-apa penyelidikan yang dijalankan dengan atau mengenai haiwan, data atau spesimen biologi. Ini termasuk mengkaji subjek haiwan melalui:

a. pengujian atau perawatan psikologi, fisiologi dan perubatan;

b. pemerhatian oleh penyelidik;

c. akses kepada rekod dan dokumen berkenaan haiwan tersebut atau bahan-bahan maklumat yang lain yang berkaitan; atau

d. pengumpulan dan penggunaan organ, tisu atau cecair tubuh haiwan (contohnya: kulit, darah, air kencing, air liur, rambut, tulang, tumor, dan spesimen biopsi lain).

BAB II

JAWATANKUASA ETIKA PENYELIDIKAN

4. Peranan, Keahlian dan Pengurusan Jawatankuasa Etika Penyelidikan Institusi (EC)

4.1. Peranan, keahlian dan pengurusan sesebuah jawatankuasa etika penyelidikan institusi (EC) dihuraikan di dalam Garis Panduan Operasi Jawatankuasa Etika Yang Meneliti Penyelidikan Bioperubatan (terbitan WHO). Petikan dari garis panduan tersebut menghuraikan:

a. Tujuan kewujudan suatu EC adalah bagi meneliti permohonan penyelidikan bioperubatan bagi memastikan bahawa maruah, hak, keselamatan, dan kesejahteraan semua peserta kajian samada peserta sebenar atau yang berpotensi menjadi peserta. Prinsip asas dalam penyelidikan yang melibatkan peserta manusia adalah 'menghormati maruah manusia'. Matlamat penyelidikan, walaupun penting, tidak boleh dibenarkan membelakangkan kesihatan, kesejahteraan, dan penjagaan kesihatan peserta penyelidikan. EC juga perlu mengambil kira prinsip keadilan. Prinsip ini memerlukan faedah dan beban yang terakibat dari penyelidikan diagihkan secara adil di kalangan semua kumpulan dan kelas dalam masyarakat, dengan mengambil kira umur, jantina, status ekonomi, budaya, dan kumpulan etnik.

b. Ia perlu membuat penilaian etika tidak memihak kepada mana-mana kepentingan, kompeten, dan tanpa melengah terhadap cadangan penyelidikan yang dimukakan. EC perlu bebas dari sebarang campur tangan politik, institusi, profesional, dan pengaruh pasaran dalam semua aspek fungsinya termasuk keahliannya, prosedurnya, dan keputusan yang di buat. Ia turut mestilah kompeten dan cekap dalam melakukan fungsinya.

c. EC bertanggungjawab bagi membuat penilaian terhadap cadangan penyelidikan sebelum penyelidikan tersebut dimulakan. Pemantauan berkala perlu juga dilakukan terhadap etika penyelidikan dalam cadangan penyelidikan yang telah diluluskan.

d. Ia bertanggungjawab melaksanakan fungsinya secara prihatin terhadap kepentingan peserta penyelidikan dan masyarakat yang terlibat, dan dengan mengambil kira kepentingan dan keperluan penyelidik, serta mematuhi keperluan undang-undang dan peraturan yang berkuat kuasa dari agensi-agensi kawal selia yang berkaitan.

5. Penubuhan EC

5.1. Sesuatu EC perlu ditubuhkan bagi memastikan setiap cadangan penyelidikan yang diterima dinilai sewajarnya dari aspek etika penyelidikan dan untuk memastikan

bahawa tugas EC boleh dilaksanakan bebas daripada sebarang pengaruh dan tindakan berat sebelah yang boleh menjejaskan kebebasan EC tersebut.

5.2. EC hendaklah dibentuk supaya dianggotai ahli dari pelbagai disiplin dan sektor, termasuklah kepakaran saintifik, dan keahliannya turut diimbangi dari segi taburan umur dan jantina, serta mempunyai ahli yang sesuai yang mewakili kepentingan dan kebimbangan masyarakat.

5.3. EC hendaklah ditubuhkan mengikut undang-undang dan peraturan negara berkenaan dan selaras dengan nilai-nilai dan prinsip-prinsip masyarakat di mana mereka berkhidmat.

5.4. EC perlu mewujudkan prosedur operasi standard yang boleh di capai oleh orang ramai yang menyatakan kuasa penubuhan EC tersebut, fungsi dan tugasnya, syarat dan terma rujukan keahlian, penempatan pejabatnya, struktur organisasinya, prosedurnya, dan kuorum penilaiannya. EC sebaiknya menerbitkan laporan tahunan yang menyenaraikan aktivitinya.

6. Keahlian EC

6.1. Prosedur yang jelas perlu diwujudkan bagi mengenal pasti atau merekrut calon ahli EC. Suatu kenyataan perlu disediakan berkaitan keperluan pencalonan yang mempunyai senarai tugas-tugas dan tanggungjawab anggota EC.

6.2. Syarat keahlian perlu diwujudkan yang meliputi perkara berikut:

a. Pihak yang bertanggungjawab membuat pelantikan;

b. Tatacara pemilihan ahli, termasuk kaedah untuk pelantikan;

c. Tatacara mengawal konflik kepentingan juga perlu diwujudkan termasuk aspek ketelusan mengenai kepentingan tersebut.

d. Sistem giliran menjadi ahli perlu dipertimbangkan demi mengekalkan kesinambungan dan menyokong pembangunan dan pengekalan kepakaran di dalam EC serta membenarkan input berterusan idea dan pendekatan baru.

e. Syarat lantikan haruslah menetapkan tempoh lantikan, dasar pembaharuan lantikan, prosedur hilang kelayakan, prosedur peletakan jawatan dan prosedur penggantian.

6.3. Ahli yang dilantik hendaklah memenuhi syarat pelantikan seperti berikut:

a. ahli perlu bersedia untuk nama penuh beliau, profesion dan kepentingan profesional beliau didedahkan secara terbuka;

b. semua bayaran balik untuk kerja dan perbelanjaan, jika ada, di dalam atau yang berkaitan dengan EC hendaklah direkod dan disediakan untuk orang ramai atas permintaan; dan

c. ahli perlu menandatangani perjanjian kerahsiaan mengenai perbincangan mesyuarat, permohonan dan cadangan penyelidikan, maklumat mengenai peserta kajian, dan perkara-perkara lain yang berkaitan.

d. keperluan kerahsiaan ini turut terpakai bagi semua kakitangan pentadbiran EC. Mereka perlu menandatangani perjanjian kerahsiaan seperti ahli EC.

7. Jawatankuasa Etika Penyelidikan Universiti Pertahanan Nasional Malaysia (UPNM)

7.1. Bagi memudahcara dan memangkinkan penyelidikan yang menggunakan subjek manusia dan haiwan, Mesyuarat Senat Ke-46 Bil. 2/2015 yang telah bersidang pada 31 Mac 2015 telah bersetuju dan meluluskan penubuhan **Jawatankuasa Etika Penyelidikan UPNM (JKEP).**

7.2. JKEP hendaklah memberi perhatian khusus kepada penyelidikan yang boleh mengeksploitasi golongan tertentu seperti, tetapi tidak terhad kepada, cadangan penyelidikan yang:

a. melibatkan kanak-kanak, banduan/orang tahanan, anggota pasukan keselamatan dan orang dewasa yang tidak kompeten untuk memberikan persetujuan;

b. melibatkan subjek haiwan;

c. melibatkan penggunaan bahan genetik; dan

d. boleh mengenakan suatu kemudaratan yang tidak wajar kepada peserta.

8. Terma Rujukan JKEP

8.1. Terma Rujukan JKEP adalah seperti berikut:

a. Meluluskan, menolak atau mengubah suai penyelidikan berdasarkan pertimbangan yang berkaitan dengan perlindungan subjek manusia dan haiwan.

b. Memastikan penyelidikan dijalankan berdasarkan skop penyelidikan yang telah diluluskan.

c. Memastikan undang-undang dan peraturan UPNM secara khasnya dan negara Malaysia secara amnya yang berkaitan dan relevan dengan penyelidikan dikenalpasti dan dipatuhi pada setiap masa material.

d. Memantau laporan semasa bagi penyelidikan yang telah diluluskan.

e. Menggantung atau menamatkan kelulusan yang telah diberikan kepada penyelidik jika melanggari syarat-syarat kelulusan JKEP dan/atau undang-undang dan peraturan UPNM dan Malaysia yang berkenaan.

8.2. JKEP hendaklah menerima pakai kelulusan yang telah diperolehi daripada Jawatankuasa Etika lain seperti *Medical Review & Ethics Committee,* Kementerian Kesihatan Malaysia, Jawatankuasa Etika Penyelidikan universiti tempatan dan jawatankuasa etika agensi penyelidikan yang telah diiktiraf oleh Biro Pengawalan Farmaseutikal Kebangsaan (BPFK), Kementerian Kesihatan Malaysia. Oleh itu, secara umumnya, cadangan penyelidikan yang telah menerima kelulusan etika penyelidikan daripada jawatankuasa seperti dinamakan di atas tidak memerlukan

kelulusan yang baru daripada JKEP. Walau bagaimanapun, jika projek penyelidikan tersebut melibatkan pelajar pra-siswazah atau pasca-siswazah, kemudahan dan/atau dana UPNM, JKEP mempunyai hak untuk meneliti dan menilai semula kelulusan tersebut serta menetapkan syarat tambahan jika perlu.

8.3. Sebarang pelanggaran syarat kelulusan JKEP yang mempunyai unsur salahlaku akademik hendaklah dirujukkan oleh JKEP kepada Jawatankuasa Penyelidikan dan Inovasi Universiti (JPIU) untuk tindakan seterusnya.

8.4. JKEP boleh membangunkan kaedah dan prosedur bagi membantu penyelidik membuat permohonan kelulusan JKEP. Kaedah serta prosedur tersebut perlu dikemukakan kepada JPIU terlebih dahulu dan disyorkan sebelum di bawa ke Senat untuk kelulusan.

8.5. Pelaksanaan penilaian terhadap cadangan penyelidikan hendaklah dilakukan tanpa lengah dan perlu disegerakan agar penyelidik tidak menghadapi kelewatan dalam memulakan kerja-kerja penyelidikan. JKEP hendaklah bertindak memberi nasihat kepada penyelidik bagi cadangan penyelidikan yang tidak menepati keperluan etika penyelidikan. Sebarang cadangan yang tidak diluluskan hendaklah diberi penjelasan kepada penyelidik yang memohon berkenaan ketidak patuhan etika yang terdapat dalam cadangan mereka dan seterusnya di beri nasihat bagaimana cadangan beliau boleh diperbaiki.

9. Keahlian JKEP

9.1. JKEP adalah terdiri dari sekurang-kurangnya 16 ahli dan melibatkan sekurangnya 5 ahli yang bukan dari disiplin sains perubatan. Keahlian JKEP juga haruslah seimbang dari segi jantina dan umur.

9.2. Secara amnya, JKEP mempunyai ahli seperti berikut:

a. Bagi ahli disiplin sains perubatan, sekurangnya seorang perlu ada pengalaman dengan penyiasatan klinikal (*clinical trials*) dan penglibatan ahli dari disiplin pembedahan, perubatan, pra-klinikal, kesihatan kemasyarakatan, biologi molekul, genetik, dan obstetrik & ginekologi hendaklah dibuat apabila kepakaran mereka mempunyai kaitan dengan cadangan penyelidikan.

b. Sekurang-kurangnya seorang ahli yang merupakan seorang saintis bukan jurusan sains perubatan.

c. Sekurang-kurangnya seorang ahli adalah saintis yang mempunyai pengalaman dengan penyelidikan menggunakan subjek haiwan.

d. Sekurang-kurangnya seorang ahli ialah pegawai veterinar dengan pengalaman pengendalian haiwan penyelidikan.

e. Sekurang-kurangnya seorang ahli adalah orang awam yang tidak terlibat dengan sebarang kerja-kerja perubatan, saintifik, perundangan, jagaan haiwan ataupun akademik.

f. Sekurang-kurangnya seorang ahli hendaklah mempunyai kelulusan perundangan (namun bukan peguam yang dilantik oleh UPNM untuk mewakili UPNM dalam perkara-perkara perundangan).

g. Sekurang-kurangnya seorang ahli hendaklah mempunyai pengalaman dan pengetahuan dalam bidang jagaan kesihatan dan/atau kaunseling.

h. Sekurang-kurangnya seorang ahli hendaklah seseorang yang mempunyai kelulusan dalam bidang keagamaan.

9.3. Secara khususnya senarai keahlian JKEP adalah seperti di bawah:

a. Pengerusi.

b. Wakil Disiplin Pembedahan.

c. Wakil Disiplin Perubatan.

d. Wakil Disiplin Obstetrik & Ginekologi.

e. Wakil Disiplin Kesihatan Kemasyarakatan.

f. Wakil Disiplin Pra-klinikal (merangkumi biologi molekul dan genetik).

g. Wakil Disiplin Sains Kejuruteraan.

h. Wakil Disiplin Sains Tulen

i. Wakil Disiplin Sains Gunaan.

j. Wakil Disiplin Sains Veterinar (ahli yang berpengalaman mengendalikan haiwan penyelidikan).

k. Wakil Disiplin Sains Sosial.

l. Wakil Orang Awam (ahli yang tidak terlibat dengan sebarang kerja-kerja perubatan, saintifik, perundangan, jagaan haiwan ataupun akademik).

m. Wakil Perundangan (ahli yang mempunyai kelulusan perundangan namun bukan peguam yang dilantik oleh UPNM untuk mewakili UPNM dalam perkara-perkara perundangan).

n. Wakil Bidang Jagaan Kesihatan dan/atau Kaunseling.

o. Wakil Keagamaan (seseorang yang mempunyai kelulusan dalam bidang keagamaan).

p. Ahli-ahli lain yang difikirkan sesuai (tiada bilangan yang ditetapkan tetapi keahlian JKEP hendaklah sekurangnya 16 orang).

10. Pengerusi dan Ahli JKEP

10.1. Pengerusi JKEP hendaklah dilantik dari kalangan ahli akademik UPNM dan mempunyai persijilan Amalan Perubatan Yang Baik (*Good Clinical Practice*).

10.2. Pelantikan bagi Pengerusi dan semua Ahli adalah bagi tempoh dua tahun dan semua ahli layak di lantik semula selepas tempoh lantikan asal tamat.

10.3. Ahli yang gagal hadir ke mesyuarat yang ditetapkan secara tiga kali berturut-turut tanpa alasan yang munasabah boleh dilucutkan keahliannya dalam JKEP.

10.4. Ahli boleh meletak jawatan dengan mengemukakan alasan yang munasabah kepada pihak berkuasa yang melantik dan salinan di sampaikan kepada Pengerusi JKEP.

10.5. Semua ahli JKEP dan kakitangan pentadbiran yang terlibat dengan JKEP hendaklah menandatangani perjanjian atau akujanji kerahsiaan dan pengisytiharan konflik kepentingan berkaitan tugas dan tanggungjawab mereka di dalam jawatankuasa ini.

BAB III

PENYELIDIKAN YANG MEMERLUKAN KELULUSAN ETIKA PENYELIDIKAN

11. Jenis Penyelidikan Yang Memerlukan Kelulusan Etika Penyelidikan

11.1. Secara amnya semua penyelidikan (termasuk *clinical* trial) yang melibatkan subjek manusia, sama ada pesakit atau sukarelawan yang sihat (termasuk bahan-bahan biologi dan / atau data pesakit) dan subjek haiwan memerlukan penilaian dan kelulusan oleh JKEP sebelum kajian dimulakan.

11.2. Penyelidikan yang dimaksudkan termasuk:

a. Semua ujian klinikal dan penyelidikan bioperubatan bertujuan:

i. mengetahui atau mengesahkan kesan klinikal, farmakologi, dan / atau farmako-dinamik sesuatu produk penyiasatan.

ii. untuk mengenal pasti apa-apa kesan sampingan terhadap sesuatu produk penyiasatan.

iii. untuk mengkaji penyerapan, pengedaran, metabolisme dan perkumuhan produk penyiasatan dengan tujuan:

(a) menentukan keselamatan dan / atau keberkesanannya.

(b) menilai *utility* apa-apa dadah atau prosedur yang masih belum diterima dalam amalan perubatan rutin.

b. Semua penyelidikan yang memerlukan prosedur tambahan dibuat pada subjek manusia. Ini merujuk kepada penyelidikan yang memerlukan ujian tambahan penyiasatan, atau prosedur invasif tambahan, atau ubat-ubatan tambahan yang melebihi amalan perubatan standard (biasa), walaupun ujian atau prosedur atau ubat yang terlibat bukannya sesuatu yang baru.

c. Semua kajian soal selidik yang melibatkan pesakit atau saudara-mara mereka. Ini adalah untuk melindungi keresahan yang boleh dihindarkan dan ketidakselesaan kepada pesakit.

d. Semua kajian menggunakan data pesakit luar jagaan profesional penyelidik terlibat. Ia difahami bahawa setiap pengamal perubatan sudah terikat dengan Kod Etika Profesional Majlis Perubatan Malaysia untuk melindungi integriti dan kerahsiaan rekod pesakit yang mereka merawat, dan Kod ini masih terpakai apabila mana-mana data mengenai pesakit beliau termasuk dalam sesuatu penyelidikan. Oleh itu, penyelidikan yang berdasarkan semata-mata kepada data rutin dari pesakit yang di rawat sendiri oleh seseorang pengamal perubatan tidak memerlukan kelulusan JKEP. Walau bagaimanapun, jika penyelidik berhasrat untuk menilai maklumat dari rekod-rekod pesakit selain dari pesakitnya sendiri, maka cadangan penyelidikan tersebut mesti diluluskan JKEP.

e. Penyelidikan yang telah diluluskan tetapi kemudiannya memerlukan perubahan yang signifikan dalam protokol asal atau dalam mengumpul, menyimpan, menganalisis, atau melaporkan data; atau penyelidikan di mana isu-isu etika telah timbul.

f. Penyelidikan yang dijalankan oleh penyelidik dan pelajar-pelajar bukan UPNM, samada di peringkat sarjana muda atau lepasan ijazah yang ingin mengakses pelajar, kakitangan atau pesakit UPNM (termasuk bahan-bahan biologi dan / atau data pesakit) sebagai subjek kajian dalam cadangan-cadangan penyelidikan yang telah diluluskan di institusi lain.

g. Semua penyelidikan yang melibatkan keadaan kecemasan berkaitan kesihatan yang melibatkan ciri-ciri samada fizikal atau psikologi, mesti mematuhi garis panduan yang ditetapkan oleh JKEP.

BAB IV

PENYELIDIKAN YANG TIDAK MEMERLUKAN PENILAIAN DAN KELULUSAN JKEP

12. Jenis Penyelidikan Yang Tidak Memerlukan Penilaian Dan Kelulusan Oleh JKEP

12.1. Penyelidikan yang tidak memerlukan penilaian dan kelulusan oleh JKEP adalah disenaraikan di bawah:

a. Penyelidikan tentang seorang individu yang masih hidup yang terlibat dalam arena awam, atau sebagai seorang artis, berdasarkan maklumat secara eksklusif yang diperolehi dari domain awam.

b. Prosedur penyelidikan, prosedur temuduga dan pengumpulan data dalam domain awam.

c. Penyelidikan semata-mata melibatkan penggunaan ujian pendidikan (kognitif, diagnostik, kebolehan, pencapaian).

d. Pengujian yang berkaitan dengan keperluan pendidikan dan latihan biasa.

e. Kajian jaminan kualiti.

f. Penilaian prestasi yang dijalankan sebagai sebahagian daripada aktiviti yang rutin.

g. Prosedur diagnostik dan terapeutik yang diterima pakai sebagai amalan semasa dalam perawatan pesakit dan diiktiraf umum oleh profesion perubatan.

h. Aktiviti yang terdiri dari latihan amalan profesional (contohnya, guru-dalam-latihan; doktor-dalam-latihan).

i. Perundingan dengan rakan-rakan yang bukan merupakan sebahagian daripada projek penyelidikan.

BAB V

MEMOHON PENILAIAN DAN KELULUSAN OLEH JKEP

13. Prosedur Permohonan Kelulusan Etika Penyelidikan

13.1. Permohonan bagi penilaian sesuatu cadangan penyelidikan ataupun penggunaan haiwan dalam pengajaran hendaklah dikemukakan kepada JKEP dengan menggunakan borang yang telah ditetapkan (Borang ini adalah dilampirkan di Kembaran G, H dan I).

13.2. Permohonan penilaian etika penyelidikan setiap cadangan penyelidikan yang dikemukakan kepada JKEP hendaklah disemak terlebih dahulu oleh Jawatankuasa Penyelidikan Fakulti dan pandangan serta syor jawatankuasa tersebut dikemukakan kepada JKEP bersama cadangan penyelidikan berkenaan.

13.3. Pemohon perlu mengemukakan dokumen berikut kepada JKEP:

a. Cadangan penyelidikan di mana cadangan perlu menghuraikan reka bentuk kajian dan metodologi perolehan data.

b. Borang Permohonan Kelulusan Etika (Borang JKEP 01 / 2015 atau yang terkini) perlu disertakan.

c. Borang Keizinan Bermaklumat (samada bagi Kajian Klinikal ataupun Kajian Kualitatif).

d. Lembaran Maklumat Pesakit/Subjek Manusia (jika berasingan dari borang keizinan bermaklumat).

e. Jika kajian melibatkan subjek kanak-kanak, Borang Persetujuan Bermaklumat bagi Subjek Kanak-kanak dan Borang Keizinan Bermaklumat Ibubapa perlu disertakan.

f. Bagi kajian melibatkan penggunaan instrumen soal selidik, instrumen tersebut perlu dikemukakan.

g. Jika kajian menggunakan subjek haiwan, Permohonan Kelulusan Etika Penyelidikan Menggunakan Haiwan (Borang JKEP 02 / 2015) perlu disertakan.

13.4. Contoh ataupun templat bagi Borang Keizinan Bermaklumat adalah dipaparkan di Kembaran A. Templat ini adalah dalam Bahasa Inggeris dan merupakan templat yang telah di sediakan oleh Jawatankuasa Penyelidikan Beretika (ERC) Pertubuhan Kesihatan Sedunia (*World Health Organisation* – WHO). Setiap dari templat ini memberi penghuraian terperinci mengenai isi kandungan sesuatau Borang Keizinan Bermaklumat dan Lembaran Maklumat untuk Subjek sesuatu kajian.

13.5. JKEP akan meminta pemohon untuk menyediakan maklumat tambahan jika diperlukan bagi membolehkan sesuatu cadangan diberi pertimbangan yang sewajarnya.

14. Prosedur Permohonan Kelulusan Etika Bagi Penggunaan Haiwan Dalam Pengajaran

14.1. Bagi permohonan bagi kelulusan etika bagi penggunaan haiwan dalam aktiviti pengajaran, pensyarah terbabit perlu memajukan permohonan menggunakan Borang Permohonan Kelulusan Etika Haiwan Bagi Penggunaan Haiwan Dalam Pengajaran (Borang JKEP 03 / 2015).

15. Proses Penilaian oleh JKEP

15.1. Setelah sesuatu permohonan diterima, Sekretariat JKEP akan menyemak dokumen yang dikemukakan dan jika lengkap akan disenaraikan di dalam agenda mesyuarat JKEP.

15.2. Lazimnya JKEP hendaklah bersidang sebulan sekali namun jika terdapat permohonan yang banyak, mesyuarat ini boleh diadakan dengan lebih kerap. Umumnya, mesyuarat JKEP hendaklah bersidang tidak lewat dari 30 hari selepas satu permohonan penilaian cadangan penyelidikan yang lengkap di kemukakan.

15.3. Bagi permohonan yang tidak lengkap, pemohon akan dimaklumkan dan permohonan akan di bawa kepada mesyuarat JKEP yang seterusnya selepas semua maklumat yang diperlukan dilengkapkan.

15.4. Apabila mesyuarat JKEP bersidang, jika permohonan adalah lengkap dan cadangan tersebut memenuhi keperluan etika penyelidikan, JKEP akan meluluskan cadangan tersebut. Pengerusi JKEP menerbitkan Sijil Kelulusan Etika Penyelidikan dengan menggunakan Borang JKEP 04/2015 sebagai bukti kelulusan. JKEP akan menggunakan format penilaian di Kembaran G bagi penilaian setiap permohonan kelulusan JKEP.

15.5. Namun jika terdapat perkara yang bercanggah dengan keperluan etika penyelidikan, JKEP akan mengemukakan maklum balas bertulis kepada pemohon yang menerangkan percanggahan yang diperhatikan dan mencadangkan langkah penambah baikan yang diperlukan bagi membolehkan permohonan tersebut mematuhi prinsip etika penyelidikan. Pemohon hendaklah membuat pembetulan dan penambah baikan yang diperlukan dan mengemukakan dokumen tersebut kembali ke JKEP untuk kelulusan.

15.6. JKEP boleh meluluskan sesuatu permohonan secara bersyarat dengan penambahbaikan dibuat ataupun boleh memerlukan permohonan tersebut dibuat pertimbangan semula di peringkat mesyuarat bulanan JKEP mengikut budibicara Pengerusi JKEP. Jika penambahbaikan tersebut dibuat mengikut syor dari JKEP, maka Pengerusi JKEP boleh menerbitkan Sijil Kelulusan Etika Penyelidikan dengan menggunakan Borang JKEP 04/2015.

15.7. JKEP boleh menolak sesuatu permohonan yang tidak mematuhi keperluan etika penyelidikan namun, pemohon perlu dimaklumkan secara bertulis dengan dinyatakan sebab-sebab penolakan permohonan dan penjelasan di mana permohonan bercanggah dengan keperluan etika penyelidikan.

15.8. Bagi memperkukuhkan amalan penyelidikan yang beretika, khususnya yang menggunakan subjek manusia dan haiwan, JKEP turut memainkan peranan sebagai penasihat kepada para penyelidik UPNM dan perlu memberi nasihat atas reka

bentuk kajian dan metodologi pengumpulan maklumat yang beretika selain dari bertindak meneliti permohonan kelulusan etika penyelidikan.

16. Mesyuarat dan Kuorum JKEP

16.1. Kehadiran dan kekerapan mesyuarat JKEP adalah ditentukan oleh Pengerusi JKEP mengikut jenis permohonan penilaian cadangan penyelidikan yang diterima.

16.2. Kuorum mesyuarat adalah sekurangnya 5 ahli yang hendaklah seboleh mungkin mengandungi ahli seperti berikut:

a. Pengerusi (samada Pengerusi JKEP sendiri ataupun ahli lain yang ditetapkan oleh Pengerusi JKEP untuk mempengerusikan mesyuarat berkenaan).

b. Seorang ahli yang memiliki kelulusan perundangan (namun bukan peguam yang dilantik oleh UPNM untuk mewakili UPNM dalam perkara-perkara perundangan).

c. Seorang ahli yang berpengalaman dengan jenis penyelidikan yang dicadangkan.

d. Jika melibatkan subjek haiwan, seorang pegawai veterinar.

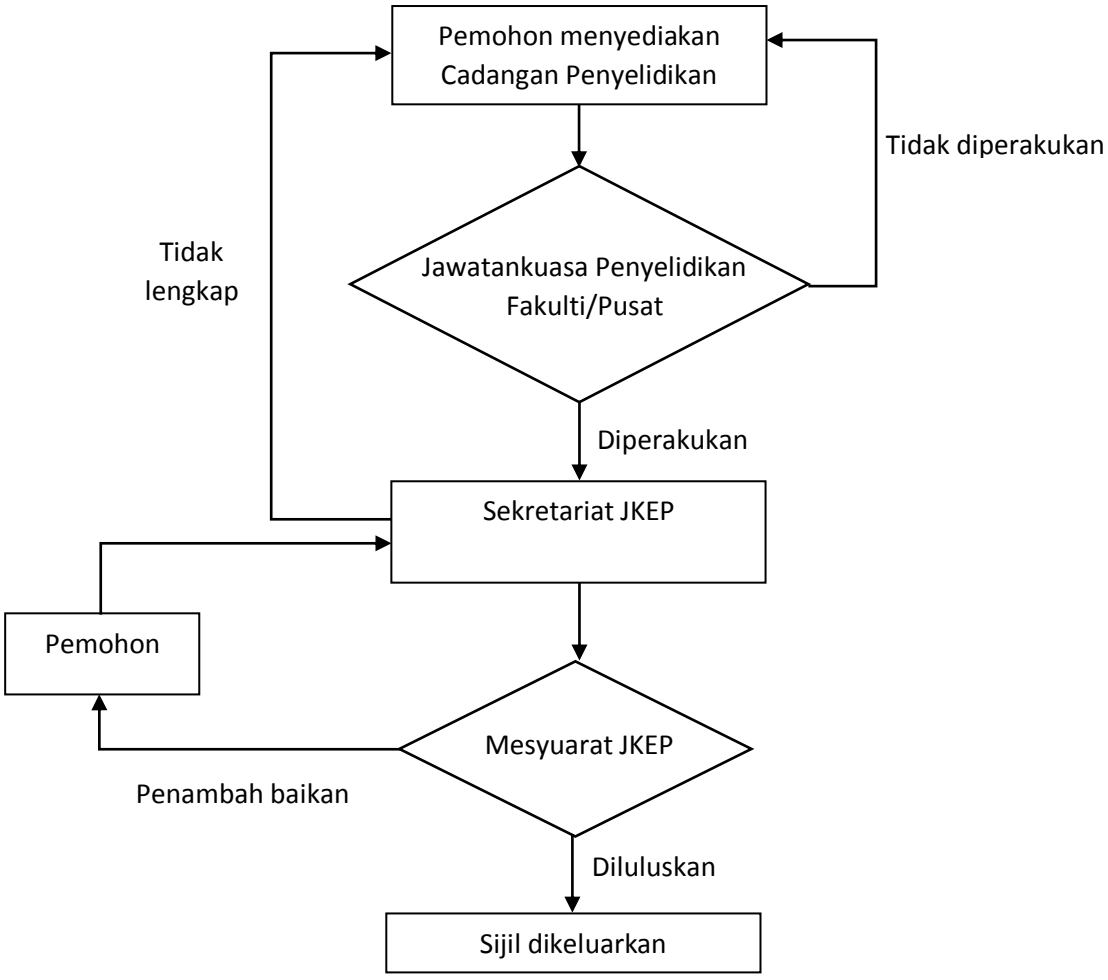
e. Seorang ahli saintis yang bukan dari disiplin penyelidikan yang dicadangkan.

f. Mana-mana ahli lain yang difikirkan sesuai oleh Pengerusi JKEP dari segi pengalaman, kemahiran ataupun pengetahuan.

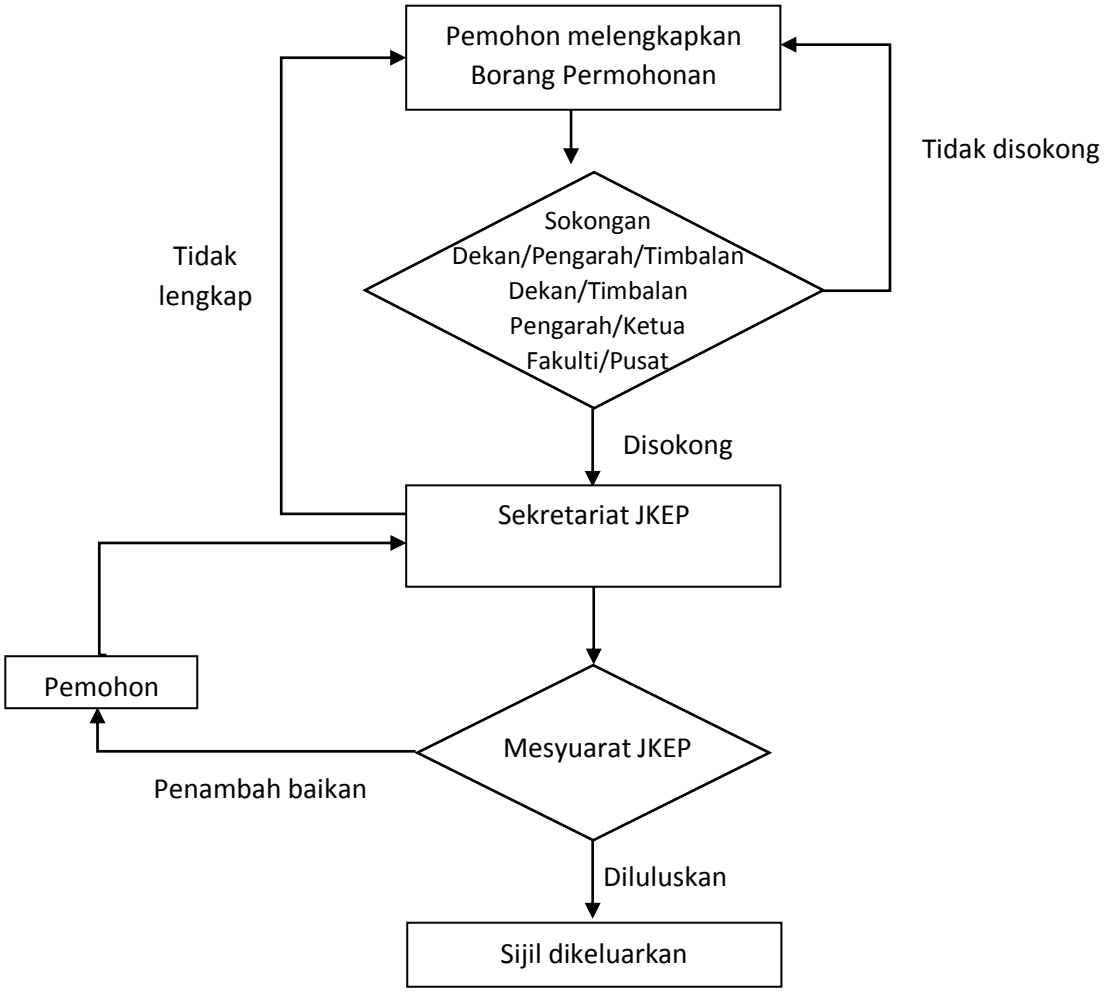
17. Rayuan Oleh Pemohon

17.1. Jika sesuatu permohonan kelulusan tidak diluluskan oleh JKEP, pemohon boleh mengemukakan rayuan kepada Pengarah, Pusat Pengurusan Penyelidikan dan Inovasi UPNM (PPPI) secara bertulis dengan menyatakan sebab-sebab kenapa rayuan di buat. Pengarah PPPI hendaklah membincangkan rayuan ini dengan Pengerusi JKEP dan menyediakan maklumbalas kepada perayu. Maklumbalas ini akan dikemukakan kepada Timbalan Naib Canselor Penyelidikan & Inovasi UPNM (TNC P & I) terlebih dahulu sebelum disampaikan kepada perayu. Keputusan TNC P&I dalam perkara ini adalah muktamad.

Rajah 1. CARTA ALIR PROSES PERMOHONAN KELULUSAN ETIKA PENYELIDIKAN BAGI CADANGAN PENYELIDIKAN



Rajah 2. CARTA ALIR PROSES PERMOHONAN KELULUSAN ETIKA BAGI PENGGUNAAN SUBJEK HAIWAN DALAM PENGAJARAN



BAB VI

ETIKA PENYELIDIKAN TERHADAP HAIWAN

18. Perlindungan Etika Penyelidikan Yang Melibatkan Penggunaan Haiwan

18.1. Maksud “haiwan” di dalam bab ini meliputi mana-mana makhluk hidup yang menjadi anggota alam haiwan iaitu; mamalia; burung; reptilia; amfibia; ikan (bertulang atau berawan); invertebrate dan mana-mana anggota alam haiwan yang akan diumumkan dari semasa ke semasa, termasuk sebarang janin mamalia. Ia tidak termasuk manusia dan mana-mana haiwan pada peringkat pranatal, pratetas, larva, atau lain-lain peringkat perkembangan yang sepertinya kecuali seperti mana yang dinyatakan.

18.2. Dalam sebarang penyelidikan terhadap haiwan atau yang menggunakan haiwan penyelidikan, semua orang yang terlibat adalah bertanggungjawab ke atas kesejahteraan haiwan termasuklah setiap penyelidik dan semua mereka yang ada kaitan dengan sesuatu projek penyelidikan (staf akademik/penyelidikan, pembantu penyelidik graduan [GRA]/pembantu penyelidik [RA] ataupun pelajar). Mereka ini perlu mengikuti latihan yang bersesuaian tentang teknik dan pengendalian haiwan makmal sebelum menjalankan sebarang kajian ataupun eksperimen terhadap haiwan.

18.3. Penjagaan semua haiwan yang digunakan dalam kajian meliputi jagaan, pemberian makanan dan minum serta dikendalikan dalam keadaan penjagaan kesihatan yang bersesuaian dengan keperluan-keperluan khusus sesuatu spesies haiwan itu. Ini adalah amat penting bagi mengelakkan penyebaran jangkitan di antara haiwan melalui bendasing ataupun fomit yang boleh memindahkan kuman, parasit dan lain-lain. Persekitaran fizikal tempat tinggal dan tidur haiwan di tempat haiwan tersebut dipelihara atau dibiakkan perlu kerap diperiksa dan tindakan yang sepatutnya segera diambil bagi memastikan kesejahteraan haiwan sentiasa diberi keutamaan.

19. Etika Penggunaan Haiwan Dalam Pengajaran

19.1. Umumnya, haiwan yang ingin digunakan dalam pengajaran adalah tertakluk kepada pertimbangan etika yang sama sepertimana digunakan dalam penyelidikan. Keperluan menggunakan haiwan dalam pengajaran hendaklah dibuat pertimbangan yang seperti yang dibuat bagi penggunaan haiwan dalam penyelidikan dan semua permohonan menggunakan haiwan dalam pengajaran perlu juga dikemukakan kepada JKEP. Sehinggalah ditetapkan sebaliknya, JKEP akan bertindak sebagai Jawatankuasa Institusi bagi Jagaan dan Penggunaan Haiwan (*Institutional Animal Care and Use Committee* [IACUC]) bagi UPNM.

19.2. Permohonan penggunaan haiwan bagi tujuan pengajaran memerlukan pensyarah berkenaan mengisi borang permohonan khusus (Borang UPNM/JKEP 04/2015 atau versi yang terkini) dan pemohon hendaklah mendapatkan kelulusan di peringkat fakulti/pusat sebelum dikemukakan kepada JKEP. JKEP akan meneliti permohonan tersebut dan jika cadangan tersebut menepati keperluan etika bagi penggunaan haiwan, JKEP seterusnya meluluskan permohonan tersebut secara bertulis.

20. Reka bentuk Eksperimen/Ujikaji

20.1. Dalam mereka bentuk sebarang kajian ataupun eksperimen yang menggunakan haiwan terdapat beberapa perkara yang mesti diberi perhatian oleh para penyelidik. Perkara ini termasuk:

a. Bilangan haiwan yang diperlukan

b. Jenis dan kesesuaian haiwan penyelidikan yang digunakan

c. Perolehan haiwan untuk penyelidikan

d. Tahap kesihatan haiwan

e. Pengangkutan haiwan

f. Gangguan/kecederaan fisiologi dan fizikal kepada haiwan

g. Penamatan hayat haiwan yang berperikemanusiaan

21. Bilangan Haiwan Yang Diperlukan

21.1. Eksperimen/ujikaji yang ingin dilaksanakan perlu berasaskan reka bentuk yang bersesuaian dan dilaksanakan ke atas jumlah haiwan yang paling kurang (minima).

21.2. Namun dalam mematuhi prinsip mengurangkan jumlah haiwan yang digunakan janganlah sehingga pengurangan ini mengakibatkan penderitaan yang lebih teruk ke atas haiwan secara individu.

21.3. Sebaik-baiknya, teknik dan prosedur yang diguna pakai mestilah merangkumi sistem biologi in vitro yang membolehkan penggunaan jumlah terkecil bilangan haiwan.

22. Jenis dan Kesesuaian Haiwan Penyelidikan Yang Digunakan

22.1. Haiwan yang dipilih untuk tujuan eksperimen/ujikaji perlulah dari spesis yang bersesuaian dan berkualiti. Cadangan penyelidikan perlu menyatakan jenis (spesis) haiwan secara khusus dalam cadangan penyelidikan dan menyatakan rujukan yang digunakan bagi menentukan spesies haiwan yang dipilih.

22.2. Reka bentuk penyelidikan hendaklah dinyatakan dengan jelas dalam cadangan penyelidikan termasuk menyatakan parameter pengujian yang dicadangkan yang melibatkan haiwan.

22.3. Cadangan kaedah pengesahan data dan statistik juga perlu dinyatakan dengan jelas. Bagi tujuan penelitian, cadangan penyelidikan perlu menunjukkan kaedah pengiraan ataupun penentuan saiz sampel atau kuantiti haiwan yang ingin digunakan dalam kajian tersebut. Lazimnya hanya bilangan minima haiwan yang diperlukan untuk memperoleh keputusan yang sah secara saintifik akan diberi kelulusan oleh JKEP.

23. Perolehan Haiwan Untuk Penyelidikan

23.1. Perolehan haiwan bagi tujuan penyelidikan sebaiknya adalah dari program-program pembiakan khusus. Haiwan lain yang tidak dibiak secara khusus boleh digunakan hanya jika haiwan tersebut memenuhi syarat penyelidikan, dan diperoleh secara sah dari segi perundangan.

23.2. Penangkapan haiwan liar hendaklah dielakkan dan hidupan liar tidak sepatutnya diambil dari habitat semula jadinya kecuali apabila haiwan yang dipelihara dalam kurungan sukar diperoleh atau didapati tidak sesuai bagi tujuan khusus penyelidikan tersebut. Permit yang bersesuaian perlu diperoleh daripada Pihak Berkuasa Tempatan sebelum penangkapan haiwan tersebut (hidupan liar, hutan simpan dll.) dibuat. Teknik penangkapan perlulah berperikemanusiaan serta mengambil kira soal kesihatan, kebajikan dan keselamatan manusia dan haiwan.

23.3. Jika haiwan penyelidikan tersebut adalah dari spesis terancam dan dalam bahaya, maka penggunaan haiwan adalah bergantung kepada Akta Haiwan 1953 dan undang-undang subsidiari yang berkaitan serta tertakluk kepada penyemakan semula oleh pihak berkuasa berkenaan. Cadangan penyelidikan perlu mengandungi dokumen kebenaran dari pihak berkuasa yang relevan bagi penggunaan haiwan tersebut bagi maksud penyelidikan yang dicadangkan. Spesis yang terancam hanya boleh digunakan dalam keadaan-keadaan khusus berdasarkan alasan saintifik yang kukuh bahawa keputusan yang dikehendaki /diingini tidak mungkin diperoleh jika menggunakan haiwan lain.

24. Tahap Kesihatan Haiwan

24.1. Tahap kesihatan haiwan perlulah diketahui sebelum dimulakan sesuatu penyelidikan. Apabila perlu, pemantauan rutin kesihatan haiwan, tahap mikrobiologi dan parasitologi koloni haiwan ujikaji serta usaha kewujudan program pencegahan penyakit adalah penting untuk memastikan keputusan eksprimen dapat diulang.

24.2. Para pengkaji/penyelidik dan mereka yang terlibat perlulah memastikan ada rekod pemantauan penggunaan haiwan untuk tujuan saintifik di simpan mulai dari tarikh haiwan diperolehi dan rekod tersebut tersimpan dengan sempurna sepanjang tempoh hayat projek penyelidikan berkenaan. Salinan rekod ini perlu diserahkan bersama laporan akhir projek penyelidikan berkenaan kepada PPPI UPNM. Rekod ini perlu disimpan selama sekurang-kurangnya 5 tahun.

24.3. Rekod ini perlu menyediakan butiran penuh dan tepat tentang haiwan, sumber, penggunaan, pelupusan, teknik penangkapan dan maklumat-maklumat lain yang berkaitan. Penyelidik mestilah sentiasa bersedia untuk rekod ini diperiksa apabila diminta oleh JKEP ataupun oleh Pegawai UPNM yang dipertanggungjawabkan ke atas kesihatan dan keselamatan haiwan penyelidikan.

25. Pengangkutan Haiwan

25.1. Haiwan perlu diangkut secara berperikemanusiaan serta dalam keadaan bersih seperti mana yang diperlukan oleh keperluan fisiologi dan tingkah laku haiwan tersebut. Tempoh masa yang diperlukan bagi pengangkutan haiwan perlu dipastikan sesingkat mungkin.

25.2. Proses pengangkutan perlu mengambil kira laluan dan pelan perjalanan, reka bentuk kurungan, reka bentuk kenderaan, kecekapan serta sikap pemandu dan mereka yang terlibat dalam pengangkutan, tempoh perjalanan, ciri dan kaedah penyediaan makanan dan minuman serta rancangan penyesuaian/aklimatisasi selepas pengangkutan.

25.3. Pihak pembekal mahupun penerima bekalan haiwan, kedua-duanya perlu memastikan wujud prosedur penghantaran yang memuaskan yang berakhir dengan

haiwan diterima oleh pihak yang bertanggungjawab dalam keadaan selamat dan sihat.

25.4. Para penyelidik perlu bersedia memberi maklumbalas kepada JKEP mengenai perkara ini apabila diperlukan.

26. Gangguan/Kecederaan Fisiologi Dan Fizikal Kepada Haiwan

26.1. Cadangan penyelidikan perlu menyediakan maklumat yang cukup mengenai kesan yang mungkin terjadi akibat sebarang gangguan/kecederaan ke atas fisiologi haiwan serta sebab-sebab gangguan/kecederaan tersebut berlaku.

26.2. Dalam cadangan penyelidikan tersebut, penyelidik perlu memaklumkan sebarang kemungkinan kesan sampingan, gangguan fisiologi dan kesan ke atas kebajikan/kesejahteraan haiwan yang timbul akibat gangguan fisiologi atau kecederaan.

26.3. Penyelidik perlu juga menyediakan butiran pemantauan yang akan dilakukan bagi mengesan sebarang kesan buruk yang dijangka atau yang di luar jangka yang mungkin timbul akibat gangguan/kecederaan ke atas haiwan.

26.4. Jika haiwan tersebut digunakan bagi ujian toksikologi ataupun untuk kajian melibatkan pemberikan bahan terapeutik/ujian dengan apa cara sekali pun (e.g. suntikan, makanan, minuman, salap, dan sebagainya) maka tatacara ujian dan bahan yang digunakan mestilah diterangkan dalam cadangan penyelidikan. Alasan yang khusus mesti dikemukakan bagi penggunaan haiwan dalam prosedur toksikologi yang mungkin mendatangkan kesan pada tahap yang lebih teruk daripada yang sepatutnya, dan butiran penerangannya mestilah mendapat kelulusan JKEP.

26.5. Jika bersesuaian, kalau ada terdapat kaedah ujian tanpa haiwan, maka kaedah tersebut mesti diutamakan. Khususnya, kaedah in vitro perlu digunakan untuk ujian saringan awal bila dan di mana perlu.

26.6. Titik akhir kajian toksikologi mestilah seawal yang mungkin bersesuaian dengan penilaian toksikologi yang boleh dipercayai serta mesti meminimakan tahap kesakitan dan kesusahan. Para penyelidik mesti menghalang kesakitan, kesusahan dan kelambatan kematian haiwan kecuali tiada lain pilihan penamatan yang dapat difikirkan sesuai dan matlamat projek tersebut ialah untuk pencegahan, pengurangan/pelegaan atau penyembuhan penyakit atau situasi yang mengancam nyawa manusia dan haiwan.

26.7. Jika kematian tidak dapat dielakkan pada titik akhir kajian, projek tersebut mestilah direka bentuk supaya jumlah kematian haiwan seminima yang mungkin.

26.8. Di akhir ujian ataupun kajian yang dijalankan, penyelidik perlu menyatakan kaedah pelupusan haiwan penyelidikan yang digunakan. Jika tiada keperluan untuk membunuh haiwan selepas kajian selesaikan dijalankan, maka perlu dinyatakan proses pelupusan yang akan dilakukan. Tanggungjawab penjagaan haiwan tersebut masih kekal dengan penyelidik sehinggalah proses pelupusan selesai disempurnakan.

27. Penamatan Hayat Haiwan Yang Berperikemanusiaan

27.1. Semua haiwan mestilah dibunuh mengikut kaedah yang bersesuaian. Cadangan penyelidikan perlu memberi huraian kaedah pembunuhan yang akan digunakan.

28. Kajian Yang Melibatkan Pembedahan Terhadap Haiwan

28.1. Bagi kajian yang melibatkan prosedur pembedahan terhadap haiwan terdapat beberapa perkara yang perlu diberi perhatian. Cadangan penyelidikan perlu memberi maklumat yang mencukupi dalam metodologi kajian termasuklah perkara-perkara yang dinyatakan di bawah ini:

28.2. **Pembiusan & Analgesia**. Jika diperlukan, prosedur yang dijalankan ke atas haiwan perlu disediakan kaedah bius (anaesthesia) dan/atau analgesik dan/atau lain-lain kaedah pembiusan/analgesia yang bersesuaian untuk meminimumkan kesakitan, penderitaan, kesusahan atau kemudaratan yang diakibatkan kepada haiwan berkenaan. Semua haiwan yang menjalani proses pembiusan perlu dipantau secara berterusan oleh kakitangan yang terlatih.

28.3. **Pembedahan.** Prosedur pembedahan mestilah dilakukan dengan menggunakan kaedah pembiusan yang bersesuaian samada secara setempat ataupun secara bius umum. Prosedur pembedahan mesti dilakukan oleh kakitangan yang telah menjalani latihan dan memiliki pengalaman yang bersesuaian.

28.4. **Penjagaan Pasca-pembedahan**.

a. Keselesaan haiwan mestilah diutamakan sepanjang tempoh pasca-pembedahan. Perhatian perlu diberi terhadap pemulihan haiwan tersebut dari kesan pembedahan. Penyelidik juga mestilah memastikan kebersihan, pengambilan cecair dan makanan haiwan tersebut di samping menentukan pengawalan jangkitan akibat prosedur yang dijalankan.

b. Haiwan yang sedang pulih dari kesan bius perlu ditempatkan dalam keadaan haiwan tersebut tidak boleh mencederakan dirinya melalui pergerakan yang tidak terkawal. Haiwan tersebut juga tidak boleh ditempatkan dalam sangkar/kurungan bersama-sama haiwan lain kerana ini berkemungkinan menimbulkan kemarahan spesis lain yang seterusnya bertindak menyerang atau membunuh haiwan tersebut.

29. Penggunaan Semula Haiwan

29.1. Untuk mengurangkan penderitaan, haiwan penyelidikan tidak dibenarkan menjalani prosedur yang melebihi kadar yang diperlukan untuk mencapai sesuatu objektif penyelidikan, ujian dan pengajaran. Jika ternyata haiwan itu memerlukan beberapa prosedur, maka maklumat tersebut mestilah dikemukakan untuk perhatian JKEP ketika memohon kelulusan cadangan penyelidikan.

29.2. Semasa mempertimbangkan penggunaan semula haiwan, faktor-faktor berikut perlu diambil kira oleh JKEP:

a. Kesakitan atau penderitaan serta kemungkinan kesan kumulatif jangka panjang akibat sebarang prosedur yang dijalani sebelumnya.

b. Keseluruhan tempoh penggunaan haiwan tersebut, kesakitan dan penderitaan yang mungkin diakibatkan oleh prosedur yang berikut dan seterusnya.

c. Sama ada haiwan itu sudah pulih sepenuhnya daripada prosedur yang terdahulu sebelum digunakan dalam prosedur berikutnya.

30. Pelupusan Haiwan Hidup

30.1. **Pemulangan haiwan ke tempat asal**: haiwan yang diperoleh dari ladang, pusat penetasan, rumah, dan lain-lain tidak boleh dipulangkan ke tempat asalnya kerana berisiko tinggi mencetuskan penyakit berjangkit di tempat asalnya.

30.2. **Pelepasan haiwan ke habitat liar/hutan**: haiwan yang diperoleh dari alam semula jadi perlu dipulangkan semula ke tempat asalnya hanya atas nasihat pihak berkuasa hidupan liar berkenaan. Haiwan yang bukan penghuni asal/bukan natif, sebarang jenis vertebrat yang dijinakkan serta yang dipelihara di dalam sangkar tidak boleh dilepaskan ke habitat liar/hutan.

30.3. **Pelepasan haiwan kepada pelajar**: Amalan membenarkan pelajar membawa pulang haiwan eksperimen/ujikaji (hidup atau mati) sebagai haiwan peliharaan atau untuk tujuan-tujuan lain tidak digalakkan. Perkara ini tidak sepatutnya dibenarkan atas sebab kemungkinan berlakunya penyebaran penyakit zoonotik.

31. *Euthanasia* dan Penamatan Eksperimen

31.1. Kematian haiwan mesti disahkan berlaku sebelum bangkai dilupuskan. Pembunuhan/penakaian dan pelupusan haiwan mestilah dilakukan melalui kaedah yang bersesuaian atau kaedah-kaedah lain yang telah diluluskan oleh JKEP.

31.2. *Euthanasia* perlu dilakukan oleh seseorang yang terlatih. Pemiilihan kaedah *euthanasia* bergantung kepada spesis haiwan dan projek yang menggunakan haiwan tersebut. *Euthanasia* mestilah disempurnakan secara berperikemanusiaan, bersesuaian dengan spesies tersebut, dan dengan cara yang dapat memastikan kematian segera.

31.3. Pelupusan haiwan yang telah menjalani *euthanasia* perlu disempurnakan dengan cara yang selaras dengan undang-undang dan peraturan yang berkaitan, serta selaras dengan kepentingan kesihatan, sekitaran dan estetik, dan diluluskan oleh JKEP.

32. Penyimpanan Haiwan Untuk Pencerapan

32.1. Setiap haiwan yang digunakan bagi tujuan penyelidikan hendaklah disimpan bagi tempoh masa yang paling singkat (minimum) dan selaras dengan pencapaian objektif saintifik atau pendidikan. Penyelidik, pelajar dan staf penjagaan haiwan mestilah dilatih untuk mengendalikan haiwan secara berperikemanusiaan. Latihan perlu merangkumi maklumat tentang tingkah laku normal/lazim spesis berkenaan dan kemungkinan tindak balasnya dalam tawanan.

32.2. Kawasan atau bekas untuk menyimpan haiwan mestilah selamat, tidak bising dan bersih selaras dengan piawaian semasa antarabangsa. Bagi penempatan yang merupakan kurungan tertutup seperti beg dan peti, ianya mestilah:

a. Membenarkan haiwan berehat secara selesa.

b. Mengurangkan risiko terlepas atau kecederaan.

c. Mempunyai aliran pengudaraan secukupnya.

d. Mengekalkan haiwan dalam tahap pencahayaan dan suhu sekeliling yang sesuai.

e. Menyediakan kelembapan persekitaran dalam sangkar yang bersesuaian dengan spesis berkenaan.

f. Mengurangkan risiko jangkitan penyakit.

32.3. Haiwan perlu diberi makanan yang sedap, tidak tercemar, dan seimbang dari segi khasiatnya, juga air minuman yang tidak tercemar dalam kuantiti yang secukupnya untuk keperluan harian haiwan tersebut. Sebarang perubahan dari keadaan ini perlu dinyatakan dalam cadangan penyelidikan dan hendaklah bersesuaian dengan matlamat kajian yang dicadangkan serta selaras dengan matlamat penyelidikan.

32.4. Perhatian khusus perlu diberi terhadap penyediaan jumlah bekas makanan dan minuman yang mencukupi untuk penempatan/kemudahan haiwan. Kemudahan penyimpanan haiwan hendaklah meliputi kaedah dan kelengkapan bersesuaian bagi pengisian, pengisian semula, pembersihan serta susunan atur bekas makanan dan minuman di samping mengambil kira tabiat pemakanan haiwan tersebut.

33. Isu Etika Penyelidikan Genetik dan Eksperimen Bioteknologi Penggabungan Semula Bahan DNA

33.1. Setiap cadangan yang melibatkan penggunaan bahan genetik perlu mengandungi maklumat yang mencukupi mengenai kemungkinan kesan pengenalan gen baharu, atau mengubah sifat gen sedia ada termasuklah jika program pembiakan dicadangkan. Dalam cadangan penyelidikan, penyelidik mestilah memaklumkan sebarang kemungkinan kesan sampingan manipulasi genetik yang mungkin memberi kesan negatif ke atas kesejahteraan haiwan induk atau anak-anaknya serta kaedah yang akan digunakan untuk menghadapi kemungkinan-kemungkinan tersebut.

33.2. Penyelidik perlu menyediakan maklumat yang lengkap mengenai kesan buruk yang mungkin timbul akibat modifikasi genetik yang dilakukan dalam kajian yang dicadangkan. Rekod mestilah disimpan termasuklah syarat-syarat "*biocontainment*", maklumat genetik dan fenotip, dan pengenalpastian individu bahan genetic tersebut.

34. Pemeriksaan Oleh JKEP

34.1. JKEP boleh membuat pemeriksaan terhadap kemudahan yang disediakan bagi penyimpanan dan pelaksanaan kajian yang melibatkan haiwan penyelidikan apabila diperlukan. Jika kemudahan yang disediakan tidak sesuai ataupun kurang lengkap sehinggakan mengganggu kesejahteraan dan jagaan haiwan penyelidikan, kelulusan JKEP terhadap cadangan penyelidikan tidak akan diberikan sehinggalah kekurangan atau ketidak sesuaian tersebut ditangani.

INTRODUCTION

The National Defence University Malaysia (NDUM) Guidelines for Research Ethics was developed to provide a system for ensuring compliance with research ethics for proposed research that use human and animal subjects conducted on NDUM premises or by NDUMstaff and students. In accordance with NDUM's planned development initiatives and in order to boost research activities in the fields of defense and security, these guidelines shall be among the main references for researchers before beginning a research project.

Research is generally defined as an activity carried out in a systematic and disciplined manner with the intent to explore and expand knowledge. It involves methods that may cross a range of disciplines and involve critical analysis processes to prove scientific findings in the fields of science and social studies, make new discoveries, extend understandings or improving concepts, theories, and techniques. The general characteristics of research include systematic and disciplined methodology, a commitment to the publication of the results of the research and peer review. The elements of research vary by discipline and may include the publishing of research findings in journals or monographs or books up to the presentation of creative compositions.

Ethics is defined as the principles of good behavior, and is also known as the moral principles that are based on values accepted civilised society. In the context of research at a University, ethics is identified as the good behavior that should be followed based on the University's value system that rejects reprehensible behavior in both the life and careers of academic staff and researchers.

These guidelines will be continuously updated and improved from time to time to ensure the quality and research ethics at the NDUM is always at its best. It is hoped that through this guide, NDUM researchers will maintain the quality of their research such that research conducted in NDUM is at par with international standards and recognized as such.

These guidelines were approved by the Senate at its 46th Meeting, No. 2/2015, held on 31 March 2015.

CHAPTER I

RESEARCH ETHICS

1. Background

1.1 All academic staff at public universities (UA) in Malaysia are required to conduct research and scholarly activities as well as publish their research findings or to patent them. As such researchers have to apply for research grants to finance the research that they want to conduct. In fact, conducting research is one of the requirements of UA academic staff career development.

1.2 The research conducted may involve human subjects, animals, plants, other forms of life, the environment, machinery and structures, political and social issues. Generally, any research undertaken by staff (academic and support) and / or students shall comply with research discipline and ethics as prescribed by the University whether in the country or abroad, by any applicable government and by any third party that provides sponsorship to the research.

1.3 The importance of human rights has been emphasised at the international level with the Universal Declaration of Human Rights being adopted by the General Assembly of the United Nations in 1948. In 1966, in order to give legal and moral force to this Declaration, the UN General Assembly adopted the International Covenant on Civil and Political Rights. Part 7 of this Covenant states that "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." Through this statement the public at large requires that the basic values of humanity should be used to govern all research involving human subjects in particular to ensure the protection of the rights and welfare of all human subjects involved in scientific experimentation.

2. Values and Principles of Ethical Research

2.1. There are four principles that underpin the ethical conduct of research, namely: respect for each human being (respect for persons); of benefit and not detrimental (beneficence); justice; and, research merit and integrity. Each of these principles are outlined below:

a. **Respect for Persons.**

The principle of respect for every human is based on the realisation that every human being has their own self worth. Researchers need to accept this fact and must respect the dignity of those who are involved in their research. The moral aspect arising from the involvement of research subjects emphasises the need for researchers to accept that respect for every human being is based on the acceptance that every research participant is a person who has a right to their own autonomy and researchers must always protect people who have their autonomy curtailed or controlled. It is the responsibility of researchers to obtain informed consent of each research participant and to maintain confidentiality on their behalf. Researchers need to give them the

opportunity to make their own decisions voluntarily throughout the investigation process. If participants are unable to make their own decisions or have a limited capacity to do so then, in order to maintain respect for them, there should be a process to authorise consent where possible and to provide means for their protection according to their situation. Researchers should always respect the privacy, confidentiality, sensitivity and culture of the research participants and, if applicable, their communities. If there are any agreements made with research participants or their community, such agreement should be discharged completely.

b. **Beneficial and Not Detrimental**.

This principle is the balance between the benefits and dangers associated with participation in the research. The benefits of research must justify the risk, danger or discomfort that may occur as a result of the investigation. The risks and dangers involve not only the individuals participating in the investigation but also extend to communities from which they come. Researchers have an obligation to maximise the possible benefits while minimising the risk of injury. In particular, the researchers are responsible for:

- designing the research methodology to reduce the risk of injury and discomfort to the participants;
- explain clearly to the research participants of the benefits and risks that may arise as a result of the research conducted, and
- looking after the wefare of the research participants throughout the research.

In situations where there is no direct benefit that may be received by the participant, the ethical principle is the risk faced by the participant is less than the benefit that has been obtained from other similar research.

c. **Justice**.

The principle of justice is based on the regard for human sameness that each person shares with others, that equals should be treated equally. This principle means that the burdens and benefits of research shall be distributed fairly, and include fair treatment in the recruitment of research participants and research implementation. Researchers need to ensure that the vulnerable are not exploited and that prospective research participants who are eligible and could benefit from the participation are not exempted without sound reason. This principle requires that research conducted complies to the following:

- The criteria for selection, exclusion and subsequent inclusion of any research participants in a research project is fair and the information about these criteria is accurately described in the research report.
- The process of recruiting / selection of participants is done fairly.
- The selection of research participants is not unfairly burdened on particular groups of potential participants.
- The distribution of benefits of participation in the research is done fairly.

- There is no exploitation of research participants during implementation of research work.
- There is fair access to the benefits from the research work.
- The research outcome should be accessible to the research participants.

d. **Research Merit and Integrity**.

The involvement of participants in any research is unethical unless the research work proposed has merit and the researchers have integrity. Research that has merit:

- shall have reasonable potential benefits, either in terms of it's contribution to knowledge, understanding, skill or expertise of researchers and / or an improvement in welfare and social benefits and / or the welfare of individuals;
- shall be designed using suitable methods for achieving the research objectives;
- shall be based on literature review covering current and past knowledge relevant to the research question. But this does not rule out novel research proposals where there may be limited information or the lack of information, or if the research is needed to provide a quick response to address an unforeseen situation;
- shall be designed such that respect for participants is not compromised by the research, the way the research is conducted, or by the results;
- shall be conducted or supervised by persons or an experienced, qualified and competent team appropriate for the research; and
- shall be conducted using facilities and resources that are appropriate to the research.

2.2. There are specific requirements for compliance to the international code of ethics for research using human subjects or animals. For research using human subjects, the Helsinki Declaration document, published by the World Medical Association (WMA) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects, published by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health organization (WHO) is referred to. Whilst for animals, the standard published by the World Animal Health Organisation (Organisation Mondiale de la Santé Animale) (OIE) is used.

2.3. Any research using human subjects must comply with the ethics and discipline of research as listed below:

a. Compliance with ethical principles and standard procedures for research related to humans as defined by the WHO or other recognised bodies;

b. Providing respect for human dignity;

c. Obtains written consent or the agreement of research participants;

d. Minimises the harm and maximises the benefits to humans; ande. Has obtained approval from the Research Ethics Committee of the University (JKEP) or any other committee recognized by the University.

2.4. Whereas research involving animals must also comply with the ethics and discipline of research as listed below:

a. Complies with the ethical standards set by the World Animal Health Organization (OiE) or any other recognised body;

b. Be performed or supervised by academic staff, students or other personnel who are competent and trained;

c. Shall ensure animal welfare, which includes:

- minimising hunger and extreme thirst;
- minimising pain and injury;
- minimising fear and distress; and
- allowing animals to express their natural behavior.

d. Shall have obtain written permission from the relevant agencies of animals protected under national law and international;

e. Reduces the number of animals used for research and replaces the use of animals, where possible, with other alternatives;

f. Uses research methods that are appropriate to the animals used in the research; and

g. Has the approval of the Research Ethics Committee of the University or any other agency that is recognised by the University.

2.5. Any research involving the use of genetically modified organisms must comply with the ethics and discipline of research as listed below:

a. Complies with the Bio-safety Act (2007) or any other act and rules related to genetically modified organisms; and

b. Has the approval of the Research Ethics Committee of the University or any other agency that is recognised by the University.

3. Scope of Research Ethics

3.1. Research on human subjects includes any method of research conducted by or about people, data or biological specimens, including:

a. surveys or interviews;

b. testing or psychological, physiological and medical methods;

c. observations by researchers;

d. access to their personal documents or other forms of information;

e. the collection and use of organs, tissues or body fluids (example: skin, blood, urine, saliva, hair, bone, tumours, and another biopsy specimens); or

f. access to their personal information (whether individually identifiable, re-identifiable or nonidentifiable), which is a component of sources of information previously published or a part of a database.

3.2. Research using animal subjects, includes any research conducted with or on animals, data or biological specimens. This includes studying animal subjects through:

a. testing or psychological, physiological and medical methods;

b. observations by researchers;

c. access to records and documents related to the animals or other relevant information; or

d. the collection and use of organs, tissues or body fluids of animals (example: skin, blood, urine, saliva, hair, bone, tumours, and another biopsy specimens).

CHAPTER II

RESEARCH ETHICS COMMITTEE

4. Roles, Members and Management of the Institutional Research Ethics Committee (EC)

4.1. The role, membership and management of an institutional research ethics committee (EC) is described in the Guidelines for the Review of the Operation of the Ethics Committee of Biomedical Research (published by the WHO). The following are extracted from these guidelines:

a. The establishment of an EC is to examine biomedical research applications to ensure that the dignity, rights, safety, and welfare of all study participants either actual participants or those with the potential to participate are maintained. The basic principle in research involving human participants is the 'respect for human dignity'. The goals of research, while important, should not be allowed to ignore the health, welfare, and well being of the research participants. The EC should also take into account the principle of justice. This principle requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnicity.

b. The committee is to make an ethical assessment that does not favour any particular interest, is competent, and without any undue delay. The EC is to be free from interference from any political, institutional, and professional entities, and also from market influences in all aspects of its functions including it's membership, procedures, and the decisions made. The committee must be competent and efficient in performing its functions.

c. The EC is responsible for evaluating research proposals before the research is initiated. Regular monitoring should also be conducted with respect to research ethics in approved research proposals.

d. It is responsible in the execution of its functions to provide due consideration towards the interests of the research participants and the communities involved, and take into account the interests and needs of the researchers, as well as ensuring compliance with the laws and regulations of any regulatory agencies concerned.

5. Establishment of an EC

5.1 An EC should be established to ensure that each research proposal received is evaluated in accordance with research ethics and to ensure that the EC can execute its tasks free of any influence and bias that could impact the independence of the EC.

5.2 The EC should be established to include experts from various disciplines and sectors, including those with scientific expertise, and with its members also being balanced in terms of both age and gender distribution, and with appropriate members representing the interests and concerns of the community.

5.3 The EC shall be established in accordance with the laws and regulations of the country concerned and in line with the values and principles of the communities it serves.

5.4 The EC should establish standard operating procedures that can be accessed by the public which discloses the authority of the EC, it's functions and duties, the conditions and terms of reference of its members, its office address, its organisational structure, procedures, and the quorum for assessment. The EC should publish an annual report that lists its activities.

6. Members of the EC

6.1. Clear procedures should be established for the shortlisting or recruitment of potential EC members. A description must be provided regarding nomination needs of a candidate as well as a list of tasks and responsibilities of an EC member.

6.2. The following terms of membership shall be provided:

a. The responsible authority appointing the EC member;

b. The procedure for the appointment of members, including the method of appointment;

c. The procedures governing conflict of interest should also be created, including the importance of transparency.

d. An EC membership rotation system should be considered in order to maintain continuity and to support the development and maintenance of expertise within the EC while allowing for continuous influx of new ideas and approaches.

e. The terms of appointment shall specify the period of appointment, the procedures for the renewal of the appointment, disqualification, resignation and replacement.

6.3. Members who are appointed shall be required to fulfill the following terms of appointment:

a. Members shall allow the disclosure of their full name, profession and professional affiliations without restriction;

b. All reimbursements for work done and expenditures, if any, whether because of or related to the EC shall be recorded and may be provided to the public upon request, and

c. Members shall be required to sign a non-disclosure agreement with regards to the discussions during meetings, applications received and research proposals, information about research participants and other related matters.

d. These confidentiality requirements are also applicable to all the administrative staff of the EC. They will be required to sign a non-disclosure agreement as well.

7. The National Defence University of Malaysia (NDUM) Research Ethics Committee (JKEP)

7.1. To facilitate and catalyse research involving the use of human and animal subjects, The NDUM Senate at its 46th Meeting, No. 2/2015 which was held on 31 March 2015 agreed with and approved the creation of the **NDUM Research Ethics Committee (JKEP)**.

7.2. The JKEP shall pay particular attention to research proposals that may exploit specific groups such as, but are not limited to, the following:

a. children, prisoners / detainees, members of the security forces and adults who are not competent to give consent;

b. involve the use of animal subjects;

c. involve the use of genetic material; and

d. may expose the participants to unwarranted risk.

8. JKEP Terms of Reference

8.1. The JKEP Terms of Reference are as follows:

a. Approve, reject or modify research based on considerations relating to the protection of human subjects and animals.

b. Ensure that the conduct of the investigation carried out is in accordance with the research proposal that has been approved.

c. Ensure that the Laws of Malaysia and NDUM regulations that are related and relevant to the research are identified and complied with at all material times.

d. To monitor research progress reports for proposals approved.

e. To suspend or terminate the ethical approval given to researchers if they contravene any of the conditions of approval from the JKEP and / or Malaysian laws and NDUM regulations applicable.

8.2. The JKEP shall adopt the approvals which have been obtained from other Ethics Committees, such as the Medical Review and Ethics Committee, Ministry of Health, the Research Ethics Committee of local universities and the ethics committee of research agencies that are accredited by the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia. Therefore, in general, research proposals that have received approval from the research ethics committees as named above do not require the approval of the JKEP. However, if the research project involves undergraduates or postgraduates, facilities and / or funds of the NDUM, the JKEP has the right to examine and re-evaluate the approval given and may set additional conditions if necessary.

8.3. Any violation of the JKEP conditions of approval which contain elements of academic misconduct will be referred to the NDUM University Research and Innovation Committee (JPIU) for further action.

8.4. The JKEP may develop processes and procedures to help researchers to apply for JKEP approval. These processes and procedures shall be submitted to the JPIU for scrutiny and recommendation before being submitted to the Senate for approval.

8.5. The evaluation of research proposals is to be done without delay and should be expedited so that researchers do not face delays in commencing their research. The

JKEP shall act to provide advice to researchers with regards research proposals that do not meet the standards of research ethics. An explanation of the breach of research ethics in the research proposals which are not approved must be provided to researchers and advice given on how the proposal can be improved

9. Membership of the JKEP

9.1. The JKEP shall be composed of at least 16 members and shall contain at least five members who are not from the disciplines of medical sciences. The membership of the JKEP also be balanced in gender and age.

9.2. In general, the JKEP have the following members:

a. For members from the disciplines of medical science, at least one shall have experience with clinical trials and the involvement of experts from the disciplines of surgery, medicine, pre-clinical sciences, public health, molecular biology, genetics, and obstetrics and gynecology shall be necessary when their expertise is needed in a research proposal.

b. At least one member shall be a scientist, who is not from the fields of medical sciences.

c. At least one member shall be a scientist who has experience with research using animal subjects.

d. At least one member shall be a veterinary doctor with experience in the handling of laboratory animals.

e. At least one member shall represent public interest and shall not be involved in any medical, scientific, legal, academic or animal care work.

f. At least one member shall have qualifications in law (but not shall not be NDUM lawyers appointed to represent NDUM in legal matters).

g. At least one member shall have experience and knowledge in the field of health care and / or counseling.

h. At least one member shall be a person who has religious qualifications.

9.3. In particular, the membership of the JKEP shall be as follows:

a. Chairman.

b. Representative of the disciplines of Surgery.

c. Representative of the disciplines of Medicine.

d. Representative of the discipline of Obstetrics & Gynecology.

e. Representative of the disciplines of Community Health.

f. Representative of the pre-clinical disciplines of medicine (including molecular biology and genetics).

g. Representative of the disciplines of Engineering Sciences.

h. Representative of the disciplines of Pure Sciences.

i. Representative of the disciplines of Applied Sciences.

j. Representative of the discipline of Veterinary Medicine (experienced in the conduct of research using animal subjects).

k. Representative of the discipline of Social Sciences.

l. Public representative (a member who is not involved in any medical, scientific, legal, academic or animal care work).

m. Legal representative (a member with legal qualifications, but is not a lawyer appointed by NDUM to represent it in legal matters).

n. Representative of the healthcare disciplines and/or counseling.

o. Religious representative (a person who has religious qualifications).

p. Other members deemed appropriate (no number predetermined but the JKEP shall contain not less than 16 members)

10. JKEP Chairman and Members

10.1. The JKEP Chairman shall be appointed from among NDUM academic staff and shall have Good Clinical Practice certification

10.2. The appointment of the Chairman and all members is for a period of two years and all members are eligible to be appointed again after the expiry of the period of the original appointment.

10.3. Members who fail to be present for three consecutive meetings without valid reasons will have their appointment in the JKEP terminated.

10.4. Members may resign by submitting a valid reason to the appointing authority and a copy is to be provided to the JKEP Chairman.

10.5. All JKEP members and the administrative staff involved with the JKEP shall sign a confidentiality agreement / undertaking and a declaration of non-conflict of interest related to their duties and responsibilities in this committee.

CHAPTER III

RESEARCH REQUIRING RESEARCH ETHICS APPROVAL

11. Types of Research Requiring Research Ethics Approval

11.1. In general, all research (including clinical trials) involving human subjects, whether patients or healthy volunteers (including biological materials and / or patient data) and animal subjects require review and approval by the JKEP before the research is started.

11.2. This research includes:

a. All clinical trials and biomedical research aimed at:

i. discovering or verifying the clinical effects, pharmacology, and / or pharmacodynamic investigation of a research product.

ii. identifying the adverse reactions of a research product.

iii. studying the absorption, distribution, metabolism and excretion of a research product with the intent to:

(a) determining its safety and / or efficacy.

(b) assess the utility of any drug or procedure not yet accepted in routine medical practice.

b. All research that requires procedures to be performed upon human subjects. This refers to research that requires additional investigation, or invasive procedures, or additional drugs that exceed standard (common) medical practice, even if those tests or procedures or drugs used are not new.

c. All questionnaire surveys involving patients or their relatives. This is to protect patients from unnecessary distress and discomfort.

d. All studies that use data from patients not under the professional care of the researchers involved. It is understood that every practitioner is bound by the Code of Professional Ethics of the Medical Council of Malaysia to protect the integrity and confidentiality of the records of patients that they treat, and this Code remains applicable if the data about these patients are included in the research. Thus, research based solely on routine data from patients treated by a medical practitioner does not require the approval of the JKEP. However, if researchers wish to access information from patient records of patients other than their own, then the proposal must be approved by the JKEP.

e. Research that has been approved but subsequently requires significant changes from the original protocol or in the collection, storage, analysis, and reporting of data; or if it involves research where ethical issues have arisen.

f. Research conducted by non-NDUM researchers and students, either undergraduate or postgraduate students who want access to students, staff or patients of NDUM (including biological materials and / or patient data) as

subjects of study where those research proposals have been approved in other institutions.

g. All research that involves healthcare emergencies, whether involving physical or psychological characteristics, must comply with the guidelines set by the JKEP.

CHAPTER IV

RESEARCH THAT DOES NOT REQUIRE JKEP APPROVAL

12. Types of Research Not Requiring JKEP Approval

12.1. Types of research that do not require review and approval by JKEP are listed below:

a. Research about a living individual who is in the public arena, or an artiste, based exclusively on information obtained from the public domain.

b. Research methods, interview procedures and collection of data in the public domain.

c. Research involving only the use of educational tests (cognitive, diagnostic, aptitude, achievement).

d. Tests that are related to ordinary educational and training needs.

e. Quality assurance studies.

f. Performance evaluations conducted as part of routine activities.

g. Diagnostic and therapeutic procedures that are accepted as current practice in the care of patients and generally recognised by the medical profession.

h. Activities involving the training in professional practice (eg, teacher-in-training; doctor-in-training).

i. Consultations with colleagues who are not a part of the research project.

CHAPTER V

REQUESTING JKEP ASSESSMENT AND APPROVAL

13. Procedure for Research Ethics Application and Approval

13.1. Applications for the assessment of research proposals or for the use of animals in teaching activities shall be submitted to the JKEP using the prescribed forms (the forms are shown in Appendices G, H and I).

13.2. Applications for research ethics evaluation of each research proposal that is to be submitted to the JKEP shall be reviewed in advance by the Faculty Research Committee and the views and recommendations of that committee is to be submitted to the JKEP together with the research proposal.

13.3 The applicant is to submit the following documents to the JKEP:

a. The research proposal with a description of the study design and methodology, for data acquisition.

b. The Ethics Approval Application Form (Borang JKEP 01/2015 or the latest edition) must be attached.

c. The Informed Consent Form (either for Clinical Research and Qualitative Research).

d. The Patient / Human Subject Information Sheet (if separate from the informed consent form).

e. If the study involves the use of children as subjects, an Informed Consent Form for Child Subjects and a Parents Informed Consent Form is to be included.

f. If the study involves the use of questionnaires, these instruments are to be submitted.

g. If the study uses animal subjects, then the Research Using Animals Ethics Approval Application (Borang JKEP 02/2015) should be submitted.

13.4 A sample or template for the Informed Consent Form is displayed in Appendix A. This template is in English and is a template that has been provided by the Ethical Research Committee (ERC) of the WHO. Each of these templates gives a detailed explanation on the contents needed in a Informed Consent Form and Information Sheet for the subject of a study.

13.5 The JKEP will request the applicant to provide additional information, if required, to enable their proposal to be given suitable consideration.

14. Procedure for Ethics Approval for the Use of Animals in Teaching

14.1. For ethics approval applications for the use of animals in teaching, the lecturers concerned are to submit their applications using the Animal Ethics Approval Application Form for the Use of Animals in Teaching (Borang JKEP 03/2015).

15. JKEP Assessment Process

15.1. Once an application is received, the JKEP Secretariat will check the documents submitted and if complete, the application will be listed on the JKEP meeting agenda.

15.2. Normally the JKEP shall convene once a month, but if there are numerous applications, these meetings can be held more frequently. Generally, the JKEP meeting is to convene not later than 30 days after a complete research proposal application is received.

15.3. In the case of an incomplete application, the applicant will be notified and the application will be brought to the next JKEP meeting after all the necessary information has been provided.

15.4. When the JKEP meeting is convened, if the application is complete and meets the requirements of research ethics, the JKEP will approve the proposal. The JKEP Chairman will issue a Research Ethics Approval Certificate using Borang JKEP 04/2015 as evidence of approval. The JKEP will use the format of assessment shown in Appendix G for each JKEP approval application.

15.5. However, if it is found that there are matters that are contrary to the requirements of research ethics, the JKEP will submit a written response to the applicant explaining the observed discrepancies and propose improvements necessary to enable the application to comply with the principles of research ethics. Applicants are to make the necessary corrections and improvements and return the corrected documents to JKEP for approval.

15.6. The JKEP may provide conditional approval with improvements to be made or may require an application to be resubmitted for reconsideration at the monthly JKEP meeting at the discretion of the JKEP Chairman. If improvements are made in accordance with the recommendations of the JKEP, the Chairman will issue the JKEP Research Ethics Approval Certificate using Borang JKEP 04/2015.

15.7. The JKEP may reject an application that does not comply with the requirements of research ethics, in these cases the applicant is to be informed in writing of the reasons for rejection and an explanation of where the application conflicts with the requirements of research ethics.

15.8. To strengthen ethical research practices, particularly the use of human and animal subjects, the JKEP also plays an advisory role to NDUM researchers and should provide advice on research design and methodology for collecting information in addition to assessing the ethical approval of research proposals.

16. JKEP Meetings and Quorum

16.1 The attendance and frequency of JKEP meetings shall be determined by the JKEP Chairman in accordance to the type of research proposal assessment application received.

16.2 The quorum of the meeting shall be at least 5 members, with at least the following members:

a. Chairman (either the JKEP Chairman or another member designated by the JKEP Chairman to chair the meeting).

b. A member who with a legal background (but not a lawyer appointed by NDUM to represent it in legal matters).

c. A member who has experience with the type of research proposed.

d. If it involves animal subjects, a veterinary doctor.

e. A scientist who is not from the discipline of the proposed research.

f. Any other member deemed appropriate by the JKEP Chairman with regards experience, skills or knowledge.

17. Appeals by Applicants

17.1. If an application is not approved by the JKEP, the applicant may appeal to the Director, Centre for Research and Innovation NDUM (PPPI) in writing stating the reasons why the appeal is made. The Director PPPI shall discuss the appeal with the JKEP Chairman and prepare the feedback to the applicant. This prepared feedback will be submitted to the Deputy Vice-Chancellor Research & Innovation NDUM (TNC P & I) before being presented to the applicant. The decision of TNC P & I in this matter is final.

Chart 1. APPLICATION FOR RESEARCH ETHICS APPROVAL PROCESS FLOW CHART

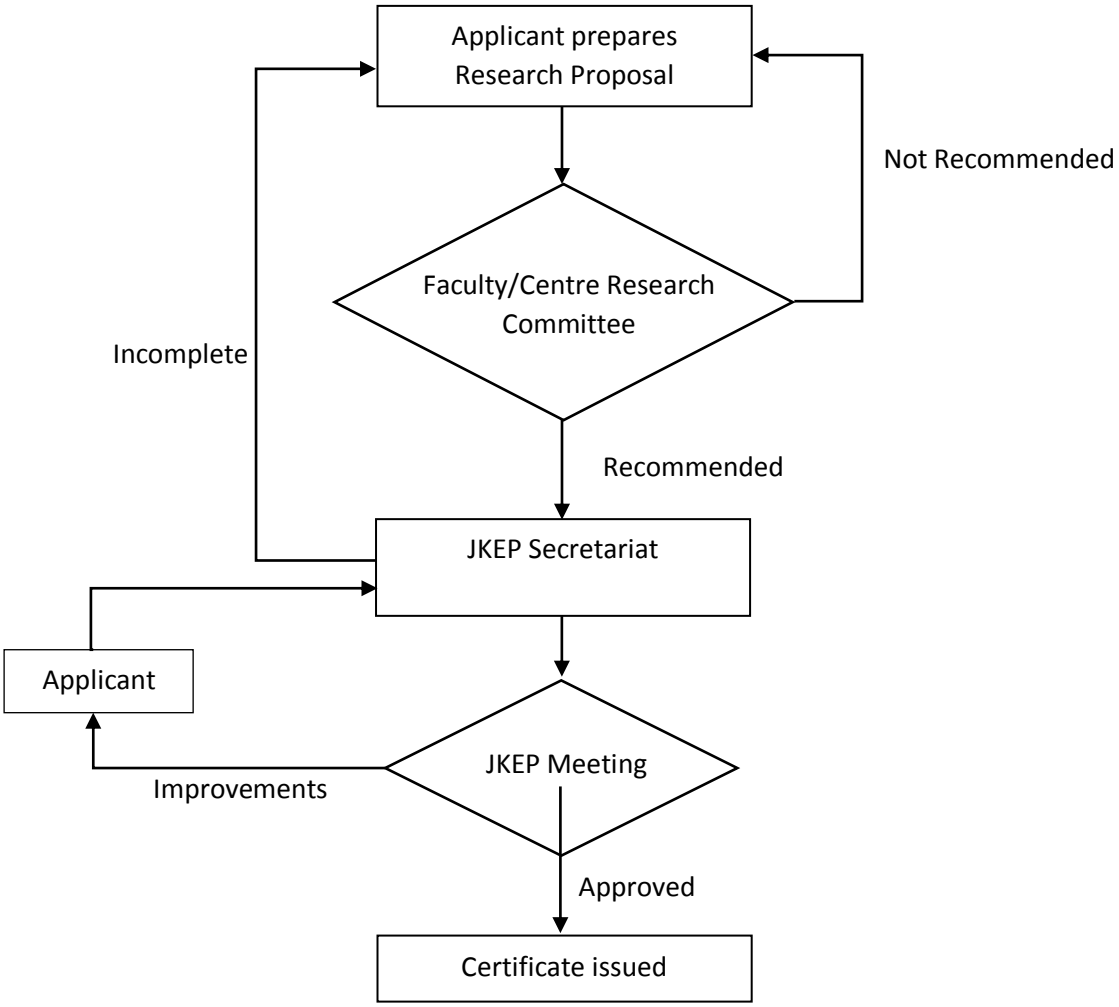
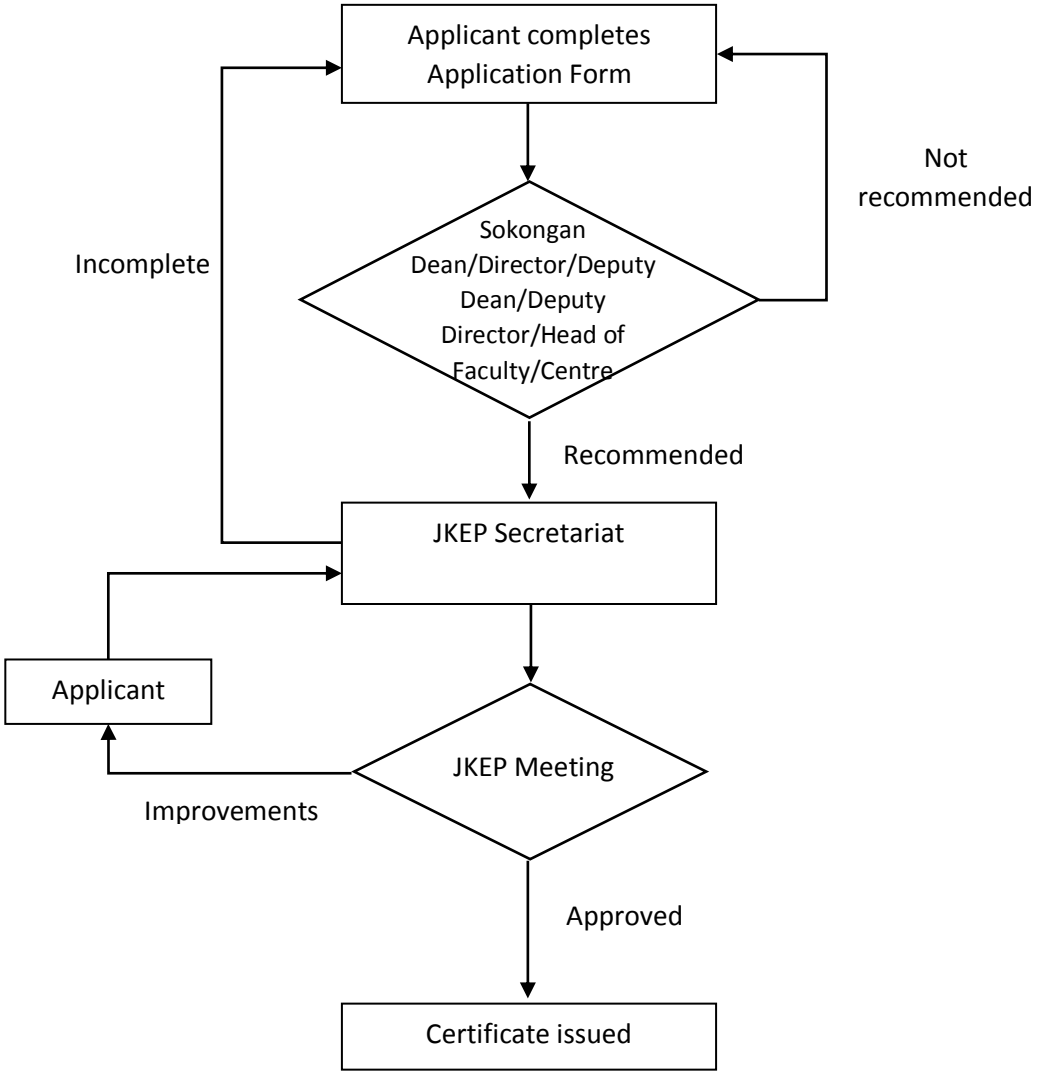


Chart 2. APPLICATION FOR ETHICS APPROVAL FOR THE USE OF ANIMALS IN TEACHING PROCESS FLOW CHART



CHAPTER VI

ANIMAL RESEARCH ETHICS

18. Ethical Protection for Research Involving the Use of Animals

18.1. The meaning of "animal" in this chapter includes any living being which is a member of the animal kingdom; i.e. mammals; birds; reptiles; amphibians; fish (bony or cartilaginous); invertebrates and any other member of the animal kingdom that may be announced from time to time, including any mammalian foetus. It does not include any human or animal at the prenatal stage, prelarval, larvae, or other similar stages of development except as otherwise stated.

18.2. In any research on animals or using research animals, all involved are responsible for the welfare of these animals, including all researchers and all those connected to a research project (academic / research staff, graduate research assistants [GRA] / research assistants [RA] or students). They need to receive suitable training on techniques and handling of laboratory animals before conducting any studies or experiments on animals.

18.3. The care of animals used in research includes housing, feeding and watering and be conducted in healthy conditions specific to the special needs of the animal species. This is very important to prevent the spread of infection between animals through materials and fomites that can transfer bacteria, parasites and other organisms. The physical environment where animals are kept and sleep or breed should be regularly checked and timely appropriate action be taken to ensure that animal welfare is a priority.

19. Ethics in the Use of Animals in Teaching

19.1. Generally, animals that would be used in teaching are subject to the same ethical considerations as used in research (see section 8 below). The need to use animals in teaching should be made with the same considerations as for the use of animals in research and an application to use animals in teaching must also be submitted to the JKEP. Until determined otherwise, the JKEP shall act as the Institutional Animal Care and Use Committee [IACUC] for NDUM.

19.2. Applications to use animals for teaching purposes requires the lecturer to fill out a specific application form (Borang JKEP 04/2015 or the latest version available) and the applicant shall seek approval from the faculty / centre Research Committee before being submitted to the JKEP Secretariat. The JKEP will examine the application and if the application fulfills the ethical considerations for the use of animal subjects in teaching, the JKEP will approve the request in writing.

20. Experiment/Test Design

20.1. Any study or experiment that uses animal subjects requires the researcher to give consideration to a number of factors. These factors include the:

a. The number of animals needed.

b. The type and suitability of research animal used.

c. The procurement of the research animal/s

d. The health status of the animal.

e. The transportation of the animal.

f. Physiological and physical distress/injury to the animal.

g. The humane termination of life/disposal of the animal.

21. The Number of Animals Needed

21.1. The experiment/study that is to be done shall be based on a suitable research design and be conducted on the least number of animals.

21.2. However, in complying to the principle of reducing the number animals needed, this should not be at the expense of increased suffering/hardship to the individual animals.

21.3. Ideally the techniques and procedures used must encompass an in vitro biological system that uses the least number of animals.

22. The Type and Suitability of Research Animal Used

22.1. The animal chosen for the experiment/test should of a quality and suitable species. The research proposal shall specifically name the type (species) of animal to be used in the research and state the references used to determine the species of animal selected.

22.2. The study design shall be described clearly in the research proposal and include the proposed study parameters that involve the use of animals.

22.3. The method used to verify data and the statistics to be used need to be elaborated clearly. Specifically the research proposal needs to show the method used to calculate or determine the sample size or the number of animals that are to be used in the study. Generally only the minimum number of animals needed to obtain a scientifically valid result will be approved by the JKEP.

23. The Procurement of Research Animals

23.1. The procurement of research animals shall be, as far as is possible, from specific research breeding programs. Other animals not from specific research breeding programs may be used if the animal meets the needs of the research and is procured using lawful methods.

23.2. The capture of wild animals is to be avoided and wild life should not be taken from their natural habitats unless domestically reared animals are difficult to obtain or unsuitable for the specific needs of the research. All the necessary permits from the local authorities responsible (wild life, forestry reserve, etc) must be obtained before the animal is captured. The capture methods used must be humane and take into account the health, welfare and safety of both humans and animals.

23.3. If the research animal is a threatened or endangered species, then the use of animal is dependent on the Animal Act 1953 and its relevant subsidiary laws as well subject to review by the relevant authorities. The research proposal is to include the

authorisation documents from the relevant authorities allowing the use of the animal for the research proposed. Endangered species may only be used in extraordinary circumstances based on concrete scientific evidence that the expected research findings cannot be obtained through the use of other animals.

24. The Health of the Animal

24.1. The health status of the animal is to be determined before the study begins. Where necessary, routine observation of the health of the animals, the microbial and parasitological status of the research animal colony should be recorded as well as the establishment of a disease prevention program to ensure the reproducibility of the results from the experiment.

24.2. The researcher and any others involved must ensure that a complete record monitoring animal use for scientific purposes is kept from the date the animal is procured throughout the duration of the research project. A copy of the report is to be submitted with the Final Report of the research project to PPPI NDUMThis record shall be kept for at least 5 years.

24.3. The record is to contain accurate and detailed information about the research animal, resources, use, disposal, capture technique and other related information. The researcher is to maintain this record ready for inspection when required by the JKEP or by the NDUM Officer who is responsible for the health and safety of research animals.

25. The Transportation of the Animal

25.1. The research animals are to be transported in a humane, clean manner appropriate to the physiological and behavioural needs of the animal. The duration needed to transport the animal shall be as short as possible.

25.2. The process of transportation is to take into consideration the route and travel plan, the enclosure design, type of vehicle used, the skill and attitude of the driver and the others involved in the transportation, duration of travel, type and methods of food and drink preparation as well as the adaptation/acclimatiosation plan after arrival.

25.3. Both the supplier as well as the recipient of the animal are to ensure that the delivery rocedures will result in the responsible recepient receiving the animal in a safe and healthy condition.

25.4. The researchers are to be prepared to provide the JKEP with information with regards this matter when requested.

26. Physiological and physical distress/injury to the animal

26.1. The research proposal should provide sufficient information regarding the effects that might result from any physiological distress/injury to the animal and explain why the distress/injury may occur.

26.2. In the research proposal, the researcher is to inform of any potential side effects, disorders and the impact on the animal’s health and welfare that may result from a physiological disorder or injury.

26.3. Researchers must also provide details of the monitoring to be done to identify any adverse effects, whether expected or unexpected, that may arise due to disorders/injury to the animals.

26.4. If the animal is to be used for toxicological tests or studies involving the administration of a therapeutic substance / test by any means (e.g. injection, food, drinks, ointments, etc.), then the test procedures and materials to be used must be described in the research proposal. Specific reasons must be given for the use of animals in toxicological procedures that may have worse than expected impact on these animals, and these reasons acceptable to the JKEP.

26.5. Where possible, when there is non-animal based study method, these methods must be preferred. In particular, in vitro methods should be used for the initial or pilot studies when and where needed.

26.6. End-point toxicological studies must be completed as soon as possible using suitable reliable toxicological analytical methods that minimises the amount of pain and distress. Researchers are to prevent causing pain, suffering and the delayed death of the animals unless there is no other suitable method of completing the study and the objective of the study is the prevention, reduction/relief or cure of diseases or life-threatening situations of humans and animals.

26.7. If the death of the animal is inevitable at the end of the study, the study must be designed to minimise the number of animal deaths.

26.8. At the end of the experiment or study, researchers are to state the method of disposal of the animals used. If there is no need to euthanise the animals after completing studies conducted, the disposal of the animals must be described. process will be conducted. The researcher remains responsible for the care of the animal until animal disposal is completed.

27. The humane termination of life of the animal

27.1. All animals that are to be sacrificed shall use appropriate methods. The research proposal is to state the method of sacrifice that is to be used.

28. Research Involving Surgery On Animals

28.1. In studies that involve the use of surgical procedures on animals there are a number of issues that require attention. The research proposal is to provide sufficient information in the methodology of the study that describes the following issues:

28.2. **Anaesthesia & Analgesia.** Where required, procedures conducted on animals should be done using a suitable means of anaesthesia and/or analgesics and/or other suitable methods of providing anaesthesia/analgesia to minimise the pain, suffering, distress or harm caused to the animals concerned. All animals undergoing anaesthesia must be continuously monitored by trained personnel.

28.3. **Surgery.** The surgical procedure must be performed using appropriate anaesthesia, either local or general. The surgical procedure must be performed by personnel who have undergone training and have the appropriate experience.

28.4. **Post-operative care.**

a. The comfort of the animals must be given priority during the post-operative period. Attention must be given to recovery of the animals from the effects of surgery. Researchers must ensure cleanliness, adequate fluid intake and feed in addition to ensuring infection control procedures are carried out.

b. Animals that are recovering from the effects of anaesthesia should be cared for so that the animals do not hurt themselves through involuntary movement. The animal should also not be placed in an enclosure with other animals as this may provoke the other animals to attack or kill the recovering animal.

29. The Reuse of Animals

29.1. To reduce suffering, research animals are not allowed to undergo procedures that exceed that needed to achieve the objectives of the research, testing and teaching. If it is required that the animal undergoes several procedures, this must be brought to the attention of the JKEP in the application for ethical approval of the research.

29.2. In considering the re-use of animals, the following factors will be taken into account by the JKEP:

a. The pain or suffering from the procedures and the possibility of long-term cumulative effects resulting from the procedurea undertaken earlier.

b. The overall period of use of the animal, the pain and suffering that may be caused by the subsequant procedures.

c. Whether the animal has fully recovered from a previous procedure before it undergoes the next procedure.

30. Disposal of Live Animals

30.1. **Return of the animals to their place of origin**: animals obtained from farms, hatcheries, homes, etc. are not to be returned to their place of origin due to the high risk of triggering infectious disease in the place of origin.

30.2. **Release of the animals into wild habitats/jungle**: animals obtained from the wild should be only be returned to their natural environment only on the advice of the wildlife authorities concerned. Animals that are not the original residents/non-native, any kind of domesticated vertebrate species and those reared in cages are not be released into the wild/jungle.

30.3. **Release of the animals to students**: The practice of allowing students to take home animals used in experiment / studies (live or dead) as pets or for other purposes is not recommended. This should not be allowed to prevent the possibility of the spread of zoonotic diseases.

31. Euthanasia and Termination of Experiment

31.1. Death of the animal must be confirmed before disposal of the carcass. The killing/culling and disposal of the animal must be carried out using appropriate methods or by other methods approved by the JKEP.

31.2. Euthanasia is to be performed by a trained person. The euthanasia method chosen shall depend on the species of animal and the projects in which the animal is used.

Euthanasia must be executed humanely, in accordance with the species, and in a way that will ensure instant death.

31.3. The disposal of euthanised animals must be completed in a manner consistent with the applicable laws and regulations, and consistant with the interests of health, environment and aesthetics, and must be approved by the JKEP.

32. Keeping Animals for Observation

32.1. All the animals used for research purposes should be kept for the shortest period of time (minimum) consistent with the scientific or educational objectives. Researchers, students and animal care staff must be trained to handle animals humanely. Training should include information about the normal / common behavior of the species concerned and their possible reactions to captivity.

32.2. The compound or enclosures used for storing the animal must be safe, clean and not noisy in line with current international standards. For enclosures such as bags and boxes, it must:

a. Allow the animal to rest comfortably.

b. Reduce the risk of escape or injury.

c. Have adequate ventilation.

d. Keep the animal in suitable lighting and temperature conditions.

e. Provide a suitable environmental humidity appropriate for the species.

f. Reduce the risk of disease transmission.

32.3. The animals need to be given good food that is uncontaminated and nutritionally balanced, and also be given uncontaminated drinking water in sufficient quantities for the daily needs of the animal. Any change from this circumstance is to be stated in the research proposal and should be compatible with the objectives of the study and in line with the research goals.

32.4. Particular attention should be given to the provision of the right number of containers for food and water appropriate for the animal enclosure/facility. The animal storage facilities are to include suitable methods and equipment for filling, refilling, cleaning and arrangement of food and water containers while taking into account the eating habits of the animal.

33. Ethical Issues in Genetics and Biotechnological Experiments Using DNA Material Recombination

33.1. All proposals involving the use of genetic material must contain enough information about the possible effects of the introduction of new genes, or the modification of existing genes including if breeding program is proposed. In the research proposal, researchers must inform of any potential side effects of the genetic manipulation that may have a negative impact on animal welfare of the mother or her young, as well as describe the method to be used to deal with these possibilities.

33.2. Researchers should provide complete information about the adverse effects that might arise from the genetic modification that is done in the proposed study. Records must be maintained, including biocontainment conditions, genetic and

phenotypic information, and individual identification of the genetic material in the study.

34. Inspections by the JKEP

34.1. The JKEP may conduct inspections on the facilities available for housing and conducting studies involving the use of research animals when necessary. If the facilities provided are incomplete or inappropriate such that the welfare and care of research animals is affected, JKEP approval of the proposal will not be granted until the deficiency or discrepancy is addressed.

RUJUKAN

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PANDUAN BAGI PENYELIDIK DAN TEMPLAT BORANG KEIZINAN BERMAKLUMAT

Dalam kembaran ini terdapat beberapa templet Borang Keizinan Bermaklumat yang boleh digunakan oleh para penyelidik bagi menyediakan Borang Keizinan Bermaklumat bagi projek penyelidikan mereka. Umumnya maklumat yang terkandung dalam templet ini adalah yang disyorkan oleh *Ethics Review Committee, World Health Organization* (WHO ERC). Templet ini (hanya dalam Bahasa Inggeris) memberi panduan dan penjelasan ke atas maklumat yang diperlukan bagi menyediakan Borang Keizinan Bermaklumat yang menepati keperluan etika penyelidikan.

Templat-templat ini didahulukan dengan penerangan *Guide for Principal Investigators* (**Kembaran A1**). Garis panduan ini menyediakan panduan yang mudah yang membantu para penyelidik membangunkan protokol penyelidikan yang lengkap dan mengikut prinsip-prinsip penyelidikan beretika.

Penyelidik yang memerlukan maklumat tambahan boleh merujuk kepada laman sesawang WHO ERC di http://www.who.int/rpc/research_ethics/erc/en/.

Templat yang dipaparkan adalah:

- Templat Borang Keizinan Bermaklumat bagi Kajian Klinikal (Lihat **Kembaran A2**)
- Templat Borang Keizinan Bermaklumat bagi Kajian Kualitatif (Lihat **Kembaran A3**)
- Templat Borang Keizinan Bermaklumat bagi Keizinan bagi Penyimpanan dan Penggunaan di Masa Akan Datang bagi Sampel Yang Belum Terpakai (Lihat **Kembaran A4**)
- Templat Borang Persetujuan Bermaklumat bagi Kajian Melibatkan Kanak-Kanak/Remaja (Lihat **Kembaran A5***)*
- Templat Borang Keizinan Bermaklumat Ibubapa bagi Kajian Melibatkan Kanak-kanak (Kajian Klinikal) (Lihat **Kembaran A6***)*
- Templat Borang Keizinan Bermaklumat Ibubapa bagi Kajian Melibatkan Kanak-kanak (Kajian Kualitatif) ***(*Lihat Kembaran A7***)**

GUIDANCE FOR RESEARCHERS AND TEMPLATES FOR INFORMED CONSENT FORMS

In this appendix there are a number of templates of Informed Consent Forms provided that can be used by researchers to develop their own Informed Consent Form for their research projects. The information contained within these templates are as recommended by the Ethics Review Committee, the World Health Organization (WHO ERC). These templates (in English) provide guidance and clarification on the necessary information needed in a Informed Consent Form that meet the requirements of ethical research.

These templates are preceded by a document entitled 'Guide for Principal Investigators' (see ***Appendix A1****). This guide gives a simple description that will help researchers to develop a complete research protocol which is in accordance with the principles of ethical research.*

Researchers who require additional information can refer to the WHO website at http://www.who.int/rpc/research_ethics/erc/en/ ERC*.*

The templates displayed include:

- *Informed Consent Form (ICF) Template for Clinical Studies* (See **Appendix A2**).
- *Informed Consent Form Template for Qualitative Studies* (See **Appendix A3**)
- *Informed Consent Form Template for Consent for Storage and Future Use of Unused Samples* (See **Appendix A4**)
- *Informed Assent Form Template for Children/Minors* (See **Appendix A5***)*
- *Informed Parental Consent Form Template for Research Involving Children (Clinical Studies* (See **Appendix A6***)*
- *Informed Parental Consent Template for Research Involving Children (Qualitative Studies) (*See **Appendix A7***)*

WHO ERC
Guide for Principal Investigators

Introduction- conducting ethical research

WHO follows the World Medical Association Declaration of Helsinki (1964), amended in 2000, and further revised in 2008 as well as the CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* published in 2002. During the ethical review of a protocol, the WHO ERC evaluates the risks and benefits to the research participants and research communities in the following domains:

Respect for persons
Justice
Autonomy

The table below lists examples of the potential risks/harms and benefits that may accrue to research participants as a result of taking part in research.

Risks/Harms	***Benefits***
Physical harm	*Access to treatment/ Free treatment*
Social harm/social risk	*Emotional support*
Emotional harm/risk	*Psycho-social support*
Stigmatisation	*Humanitarian*
Loss of privacy	*Contribution to society*
Insensitivity to vulnerabilities, exposing individuals to various types of harms/risks	*Others*
Sharing of confidential information resulting in tangible or intangible losses	
Perpetuation of gender and other biases	
Others	

Purpose of the ERC Guide

This guide has been designed by the WHO ERC to help to ensure that all the elements necessary for the development of a complete and ethically sensitive protocol are covered. The guide consists of a series of questions that address key considerations in the design of research protocols, development of informed consent forms and recruitment/information material. It is divided into 2 sections. Section 1 raises key questions related to scientific and technical issues of the protocol. Section 2 consists of questions around key ethical issues that should be addressed in the protocol (including in a section on ethics), as well as informed consent forms and recruitment/information material for participants.

As this guide functions as a 'self checklist', check boxes have been included to help researcher's flag areas that require more attention. Researchers are **not required to fill in these boxes or to submit this document to the ERC**. Please note that not all the elements described here are relevant to all protocols. Please ensure that those items which correspond with the research you are conducting are included in your submission to WHO because they will be assessed by WHO Ethics Review Committee reviewers.

SECTION 1
PROTOCOL (SCIENTIFIC AND TECHNICAL ISSUES)

The ethical integrity of research depends substantially on its design and methodology. Consequently, the following section includes key questions on scientific and technical issues that should be included in the research protocol. This section does not provide guidance on how to design a study, but rather raises key technical and scientific issues that need to be well explained in study protocols. For guidance on how to design a research study, please consult the following link: http://www.emro.who.int/publications/pdf/healthresearchers_guide.pdf

The ERC website also has additional guidance documents on writing research protocols and informed consent forms, available at the following link: http://www.who.int/rpc/research_ethics/format_rp/en/index.html

Background information

1. Is the rationale for the study clearly stated in the context of present knowledge? ☐

2. Have you included a review of literature with references? ☐

3. Have you described the study setting? ☐

Goals and objectives

4. Are the objectives and/or hypothesis to be tested clearly stated? ☐

Study Design

5. Have you provided a clear description of the study design (e.g. whether it is basic science research, social science research, or epidemiological - observational or intervention - research) and the study participants, outcomes and intervention and control groups (if relevant)? ☐

Methodology

6. Is an estimate of sample size provided, along with the assumptions on which it is based? ☐

7. Are the inclusion and exclusion criteria clearly stated? ☐

8. Are the procedures for participant recruitment, admission, follow up and completion fully described? ☐

9. Are the laboratory tests and other diagnostic procedures fully described? ☐

10. Does the protocol include information on procedures that are experimental and part of the research, as opposed to those that are part of routine care? ☐

11. Does the protocol describe how the specimens and/or data will be coded/anonymised? ☐

12. If the study is an intervention study, including placebo controlled trials, is justification for the control group provided? ☐

13. If the study is an intervention study, are the types and methods for subject allocation to intervention and control group clearly explained? ☐

Participant safety

14. Have any risks to participating in the research been identified and does the protocol state how these will be minimized? ☐

15. If the research involves new drugs or vaccines, is clearance from the national drug regulatory authority attached? ☐

16. If the research involves new drugs or vaccines, is the Investigator's Brochure (including safety information) attached? ☐

17. If the study is an intervention study, is a Data Safety Monitoring Board (DSMB) envisaged? If yes, has information about the DSMB been included, such as terms of reference and list of members? ☐

18. If the study is an intervention study, is a plan for adverse event reporting included in the protocol? ☐

Data Management and Statistical Analysis

19. Does the protocol include a discussion on the quality assurance mechanisms for data collection, storage and analysis? ☐

20. Is the plan for statistical analysis provided? ☐

Expected outcomes and dissemination of results

21. Does the protocol indicate how the study will contribute to advancement of knowledge and how the results will be utilized? ☐

22. Does the protocol include a plan for the dissemination of results, not only to the research community (through open access online publication, and other journal publications) but also to policy makers (through meetings, reports etc) and back to the research participants and research communities (through community meetings, flyers, leaflets etc)? ☐

Gender issues

23. Does the protocol discuss how the research contributes to identifying and/or reducing inequities between women and men in health and health care or does not perpetuate gender imbalances? ☐

Project Management

24. Does the protocol state the expected duration of the project? ☐

25. Does the protocol describe the role and responsibility of each member of the team? ☐

Study instruments

26. Where questionnaires, diary cards and other materials are used, are these relevant to answer the research questions? ☐

27. Are they provided in English? (translations should be submitted after an English version has been approved by the WHO ERC) ☐

28. Are they written in lay language, worded sensitively and easily understood? ☐

29. Where applicable, have Case Report Forms, Adverse Event forms etc been prepared and are they included? ☐

Ethical issues (see section 2 for detailed guidance on addressing ethical issues in the study protocol)

30. Does the protocol include a discussion of ethical issues? (See section 2) ☐

31. Have consent forms been prepared? Are these included? (See Section 3) ☐

32. Have assent forms been prepared for children aged between 12 and 18 years? Are these included? ☐

SECTION 2- Protocol (Ethical Issues)

Please ensure that your protocol minimizes harms and maximizes benefits to the research participants, and discuss under ethical issues how this has been achieved. The sections below outline key ethical considerations and are included to assist you in identifying and addressing the ethical issues that may be posed by your research.

Process for gaining informed consent

1. Have you described the process through which informed consent will be obtained? Where written consent from participants is not possible, have you explained the reasons for this and how the agreement of participants will be recorded? ☐

2. Is this a cluster randomized controlled trial? If so, has the process of taking consent for the clusters to be included in the trial described? If this is not possible, is information provided to all communities participating in the trial? Is the process of taking consent from individuals in the clusters before they participate in any study procedures or data collection described? * ☐

***** Community leaders cannot give 'consent' on behalf of individuals in communities to participate in randomized controlled trials, but rather permission to approach individuals in communities to invite their participation.

Vulnerable populations

3. Is a vulnerable population being studied (i.e. any of the following)?

- pregnant women, children, adolescents, elderly people, people with mental or behavioural disorders, prisoners, refugees, those who cannot give consent (unconscious), others? ☐

4. If a vulnerable population is being studied, is the justification adequate? Have adequate provisions been made to ensure that the vulnerable population is not being exploited? ☐

Risks vs. benefits of the study

5. Has the individual risk vs. the benefits from research been adequately addressed? ☐

6. Does the protocol describe whether and how communities from which the participants are to be drawn are likely to benefit from the research? ☐

7. Is the research outcome also likely to benefit communities beyond the research population? ☐

Autonomy/Incentives/Coercion

8. Is the design of the study free of inducements to participate in the research? ☐

9. Are the research participants free not to participate or to leave the research at any time without penalty? ☐

Privacy/Confidentiality

10. Does the study outline the procedures for the protection of the privacy and psycho-social needs of the participants? ☐

11. Are there mechanisms to ensure the confidentiality of the data? ☐

Monitoring safety/protection

12. Do provisions exist in the proposals to deal with adverse reactions associated with the research (medical/physical/emotional/psychological) as well as coincidental findings during the course of the research (e.g. through blood tests etc)? ☐

13. When appropriate, do provisions exist for counselling research participants prior to, during and after the research? ☐

14. Are there issues that may affect the safety of the researchers involved in the study? How are these being addressed? ☐

SECTION 3 - Informed consent forms (ICFs)

Informed consent forms must be submitted to the ERC along with the study protocol. The ERC has developed templates of informed consent forms in order to assist the Principal Investigator in designing ICFs. However, it is important that the Principal Investigators adapt their own ICFs to their particular study and include the relevant information for participants. In addition, the logo of the collaborating institution must be used on the ICF and not the WHO logo. ICF templates are available at the following link:

http://www.who.int/rpc/research_ethics/informed_consent/en/

Some additional questions are included below to provide guidance on addressing key issues in the content and format of information sheets and consent forms.

General format and content

1. Does the informed consent form make it clear that the participant is being asked to participate in research? ☐

2. Is the information sheet free of technical terms and written in lay-person's language that is easily understandable and appropriate to the educational level of the community concerned? ☐

3. Does it describe why the study is being done and why the individual is being asked to participate? ☐

4. Does it provide participants with a full description of the nature, sequence and frequency of the procedures to be carried out, including the duration of the study? ☐

5. Does it explain the nature and likelihood of anticipated discomfort or adverse effects (including psychological and social risks) if any, and what has been done to minimize these? Does it state the action to be taken should these occur? ☐

6. Does it outline the procedures to protect the confidentiality of data, and if confidentiality is not possible due to the research design, has this been conveyed to all relevant persons? ☐

7. Does it inform the research participants that their participation is voluntary and they are free to decide whether or not to participate, or to withdraw at any time and for any reason without further penalty either personal or professional or affecting their future medical care? ☐

8. Does it describe the nature of any compensation or reimbursement to be provided (in terms of time, travel, man-days lost from work, etc)? ☐

9. Does it outline how participants will be informed of the progress and outcome of the research? ☐

10. Does it provide the name and contact information of a person who can provide more information about the research project at any time? ☐

11. Has a provision been made for subjects incapable of reading and signing the written consent form (e.g. illiterate patients)? ☐

12. Does a provision exist for participants incapable of giving personal consent (e.g. because of cultural factors, children or adolescents less than the legal age for consent in the country in which the research is taking place, participants with mental illness, etc) to express their decision? ☐

Questionnaires

13. If questionnaires will be used for the research, does the information sheet and consent form describe the nature and purpose of the questions to be asked, and if applicable, state if some questions may prove embarrassing for the participant? ☐

14. State that the participant is free to not answer any question? ☐

15. Where applicable, make it clear that the interviews (in-depth or focus group discussions) are likely to be audio or video taped? ☐

16. Where applicable, mention how and for how long are the tapes going to be stored? ☐

Human biologic materials (tissues, cells fluids, genetic material or genetic information)

17. If human biologic materials are to be collected, does the information sheet and consent form describe in simple language the nature, number and volume of the samples to be obtained and the procedures to be used to obtain them? ☐

18. Indicate if the procedures for obtaining these samples are routine or experimental and if routine, are more invasive than usual? ☐

19. Describe the use to which these samples will be put both in the study and in the longer term? ☐

20. Does it include a provision for the subject to decide on the use of left over specimens in future research of a restricted, specified or unspecified nature? ☐

21. State for how long the specimens can be kept and how they will finally be destroyed? ☐

22. Mention that genetic testing/genomic analysis will be carried out on the human biologic materials, where applicable? ☐

Participant Recruitment Material

If you plan to use participant recruitment material (e.g. advertisements, notices, media articles, transcripts of radio messages) please review the material in light of the following questions.

1. Is the information provided in both English and in the local language? ☐

2. Can you support the claims made? ☐

3. Does the material make promises that may be inappropriate in the research setting (e.g. provide undue incentives, emphasize remuneration)? ☐

This guidance is complementary to information and advice provided by the WHO technical unit or available on the department specific website. For additional guidance materials on preparing a research proposal that satisfies ERC requirements, as well as the process of ethics review please see the link

http://www.who.int/rpc/research_ethics/guide_rp/en/index.html

WHO ERC
Informed Consent Form (ICF) Template for Clinical Studies

(This template is for either clinical trials or clinical research)

(Language used throughout form should be at the level of a secondary school leaver)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist Principal Investigator's in the design of their own informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the ICFs that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, which could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions in accordance with their study.

5. In this template:

   - square brackets indicate where specific information IS to be inserted
   - bold lettering indicates sections or wording which SHOULD be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in italics. Suggested questions to elucidate understanding are given in italics as well.

THE TEMPLATE IS ON THE FOLLOWING PAGES

[Informed Consent form for _____]

Name the group of individuals for whom this informed consent form is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "……")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the research

Explain in lay person's terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. Please find substitutes for words which are overly scientific or are professional jargon.

(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic.)

Participant selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research.Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example: Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not

look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers)

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Example: If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

<u>If the protocol is for clinical research:</u>

Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

<u>For any clinical study (if relevant):</u>

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide

information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. In total, we will take about ……..this much blood in x number of weeks/months. At the end of the research, in 1 year, any left over blood sample will be destroyed.)

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

(Example: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- *After one week, you will come back to the clinic for a blood test. This will involve….)*

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____ (number of) days, for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use

of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Example: By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

Examples of question to elucidate understanding: *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. The WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

(Example: We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)

Examples of question to elucidate understanding: *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

Example of question to elucidate understanding: *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)
OR
(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by UPNM Research Ethics Committee (JKEP), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the JKEP, contact [name, address, and telephone number.]).

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

WHO ERC
Informed Consent Form Template for Qualitative Studies

(This template is for research interventions that use questionnaires, in-depth interviews or focus group discussions)

(Language used throughout form should be at the level of a local secondary school leaver)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. This template includes examples of key questions that may be asked at the end of each section that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
5. In this template:
    - square brackets indicate where specific information is to be inserted
    - bold lettering indicates sections or wording which should be included
    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided, and examples are provided in italics. Suggested questions to elucidate understanding are given in black in italics.

THE TEMPLATE IS ON THE FOLLOWING PAGES

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example counselors, community members, clients of services - it is important that you identify which group this particular consent is for.

(Example: This informed consent form is for social service providers in the community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".)

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

(Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose of the research

Explain the research question in lay terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general. We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).

Participant Selection

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

(Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change. OR

The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Procedures

A. Provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to….:)

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

(Example 1 (for focus group discussions)
We are asking you to take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.

The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who are the people to go to for help and what happens when people become sick with it.

We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask……. ***We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.***

The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)
We are asking you to participate in an interview with [name of interviewer] or myself.

During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (for questionnaire surveys)
We are asking you to fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. OR

You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.

If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

- ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

Risks

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview" OR
If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).

Reimbursements

State clearly what you will provide the participants with as a result of their participation. The WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc])

The following applies to focus groups:

Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that we cannot guarantee complete confidentiality of information that you share with us in a group discussion? Do you have any more questions?*

Sharing the Results

Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

(Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible - **a** local person who can actually be contacted. State also the name (and contact details) of the local EC that has approved the proposal.

(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____ .)

This proposal has been reviewed and approved by the UPNM Research Ethics Committee (JKEP), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the JKEP, contact [name, address, and telephone number.]).

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Part II: Certificate of Consent

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

> *Example: I have been invited to participate in research about malaria and local health practices.*

(This section is mandatory)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate [1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ ***Thumb print of participant*** | |

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

[1] *A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.*

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

WHO ERC
Informed Consent Form Template for Consent for Storage and Future Use of Unused Samples

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. In this template:

- square brackets indicate where specific information is to be inserted
- bold lettering indicates sections or wording which should be included
- standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided, and examples are provided italics. Suggested questions to elucidate understanding are given in black in italics.

THE TEMPLATE IS ON THE FOLLOWING PAGES

Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

Example: You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

- ☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
- ☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

- ☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]
- ☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

- ☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.
- ☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

WHO ERC
Informed Assent Form Template for Children/Minors

(Language should be at a level appropriate to the child's age and development)

This template is written for a pre-adolescent or young adolescent.

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed assent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed assent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your assent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

THE TEMPLATE IS ON THE FOLLOWING PAGES

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

[Informed Assent Form for _____]

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

(This informed assent form is for children between the ages of 12 - 16 who attend clinic X and who we are inviting to participate in research Y.)

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

Introduction

This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you do and clearly state that you are doing research. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

(Example: My name is ____and my job is to research and test vaccines to see which work best to stop malaria before it makes someone sick .We want to know if this new vaccine will stop children from getting sick and we think this research could help tell us that.

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your

parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at anytime and I will take time to explain).

Purpose: Why are you doing this research?

Explain the purpose of the research in clear simple terms.

(Example: We want to find better ways to prevent malaria before it makes children sick. We have a new vaccine to prevent malaria which we are hoping might be better than the one that is currently being used. In order to find out if it is better we have to test it.)

Choice of participants: Why are you asking me?

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

(Example: We are testing this vaccine on children who are your age - between 12 and 16 years old - who live in a place where there is malaria. We are only testing the vaccine on children who do not have malaria.)

Participation is voluntary: Do I have to do this?

State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

(Example: You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, its okay and nothing changes. This is still your clinic, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it's still okay.

If applicable: If anything changes and we want you to stay in the research study even if you want to stop, we will talk to you first .)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

I have checked with the child and they understand that participation is voluntary __(initial)

Information on the Trial Drug [Name of Drug]: What is this drug and what do you know about it?

Include the following section only if the protocol is for a clinical trial:

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The vaccine we are testing in this research is called ABX. It has been tested twice before with adults who do not have malaria but who live in areas where malaria is common. We now want to test the vaccine on teenagers who do not have malaria. This second research is called a "phase 2" trial.

The vaccine ABX is made by Company C. It has very few side effects. It can make you feel tired for the first 24 hours after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no greater risk or other side effects. Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known side effects.)

Procedures: What is going to happen to me?

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

(Example: We are going to test the vaccine by giving some of the children in the research study the new vaccine and the others are going to get the vaccine that is already being used to prevent malaria. Neither you nor the researchers will know which vaccine you were given until after the study is over. By doing the research like this, we can compare which of the vaccines is better without being influenced by what we think or hope the research will show.

If you decide that you want to do this, there will be three things that happen.

1. In about ten days, you will come to the clinic with your parents and you will get an injection/shot in your arm. This is either the vaccine that we are testing or the vaccine that is usually used to prevent malaria.

2. At the clinic we will also give you a mosquito net to take home and sleep under. Maybe you have seen these before. They stop mosquitoes from biting you during the night when you sleep.

3. Once a month for six months after that, you will come to the clinic and the nurse will take your temperature. She will also take a little bit of your blood, about three or four drops, from your finger with a finger prick. This might hurt a little but the hurt will go away before very long.

Altogether you will come to the clinic 7 times over 7 months. At the end of seven months, the research will be finished.

I have a picture here to show you what will happen. You can ask me to stop and explain again at any time and I will explain more about the process).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? How many times extra will you have to come if you decide to take part in the research study? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

I have checked with the child and they understand the procedures _____(initial))

Risks: Is this bad or dangerous for me?

Explain any risks using simple, clear language.

(Example: The vaccine is considered safe. It has already been tested on adults and on other children. There has been nothing that has worried us at all. If anything unusual happens to you, however, we need to know and you should feel free you to call us anytime with your concerns or questions. Another way of us knowing how you are is by having you come to the clinic every month for a check-up. If you get sick or have concerns or questions in-between the scheduled visits to clinic, you should let me or the staff nurse know. You don't have to wait for a scheduled visit.)

Discomforts: Will it hurt?

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

(Example: There are a few other things that I want you to know.

The injection might hurt for just a second when it goes into your arm. It might get a little bit red and hard around the place where the injection/needle goes in. That should go away in a day. If it hurts longer than that, or if it stays hard for longer or swells up, tell your parents or me. If you feel bad or strange, tell us.

Sleeping under a mosquito net can be uncomfortable because it can be hot and stuffy.

Sometimes you may not want to come to the clinic to get your blood checked or have your temperature taken. It's important that you try to come. It won't take very long. You will miss a little bit of school - about an hour every month - and we will tell your teacher about that so that she knows its okay.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

I have checked with the child and they understand the risks and discomforts ____(initial)

Benefits: Is there anything good that happens to me?

Describe any benefits to the child.

(Example: Nothing really good might happen to you. The vaccine may not stop you from getting malaria. But this research might help us to find a vaccine now or later that could help other children. There are a couple of good things if you do decide that you want to do this. You do get regular check-ups with the nurse so that if you are sick, we will know very soon and this can be important. And you will keep the mosquito net which will help keep mosquitoes away from you. Because mosquitoes cause malaria, this is important.)

I have checked with the child and they understand the benefits_____ (initial)

Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country contex

(Example: Because you live quite far from the clinic, we will give your parents enough money to pay for the trip here and (whatever other expense is reasonable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality: Is everybody going to know about this?

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

(Example: We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. After the research is over, you and your parents will be told which of the two injections you received and the results.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Compensation: What happens if I get hurt?

Describe to the ability of the child to understand and explain that parents have been given more information.

(Example: If you become sick during the research, we will look after you. We have given your parents information about what to do if you are hurt or get sick during the research.)

Sharing the Findings: Will you tell me the results?

Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan

and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

(Example: When we are finished the research, I will sit down with you and your parent and I will tell you about what we learnt. I will also give you a paper with the results written down. Afterwards, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.)

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You may want to re-emphasize that participation is voluntary and any limits to this.

(Example: You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.)

Who to Contact: Who can I talk to or ask questions to?

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

(Example: You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.)

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

(Example: I understand the research is about testing a new vaccine for malaria and that I might get either the new vaccine which is being tested or the vaccine which is currently being used. I understand that I will get an injection and that I will come for regular monthly check-ups at the clinic where I will give a blood sample with a finger prick.)

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>not</u> signed the assent below._____(initialled by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____

Date:_____
day/month/year

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

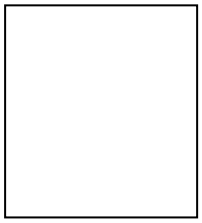
I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent)_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year



I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher_____

Signature of researcher_____

Date_____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

1.

2.

3.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____
Day/month/year

Copy provided to the participant _____(initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)

WHO ERC
Informed Parental Consent Form Template for Research Involving Children (Clinical Studies)

(This template is for either clinical trials or clinical research)

(Language used throughout form should be at the level of a local secondary school student)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section which could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

    - square brackets indicate where specific information is to be inserted
    - bold lettering indicates sections or wording which should be included
    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in italics. Suggested questions to elucidate understanding are given in black in italics.

THE TEMPLATE IS ON THE FOLLOWING PAGES

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X)

[Name of Principal Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form.

PART I: Information Sheet

Introduction

Briefly state who you are. Explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country.

I am going to give you information and invite you to have your child participate in this research. You do not have to decide today whether or not you agree that your child may participate in the research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose

Explain the problem/research question in lay terms which will clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Recognize that parents' feelings about involving their children in research can be complicated. The desire and feeling of responsibility to protect their child from risk or discomfort may exist alongside the hope that the study drug will help either their child or others. It is, therefore, important to provide clear and understandable explanations, and to give parents time to reflect on whether they will consent to have their child participate.

(Malaria is one of the most common and dangerous diseases in this region. The vaccine that is currently being used is not as good as we would like it to be but there is a new vaccine which may work better. The purpose of this research to test the new vaccine to see if it protects young children better than the current vaccine).

Type of Research Intervention

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

(An injection OR a series of three injections OR taking a vaccine orally, a biopsy).

Participant selection

State clearly why you have chosen their child to participate in this study. Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

(The vaccine has been found to be effective with adults and older children. Because of how young children grow and develop, we can't assume that the vaccine will be as effective on young children unless we test it on children

We are inviting you to take part in this research because it is important that we test a new vaccine on children who do not have malaria but who live in an area where malaria is a serious problem. Because you and your child live in this area and your child does not have malaria, we are asking if you would allow your child to participate.)

- ***Example of question to elucidate understanding:*** *Do you know why your child has been identified as a potential research participant? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose

to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue.)

- ***Examples of question to elucidate understanding:*** *If you decide that you do not want your child to take part in this research study, do you know what your options for him/her are? Do you know that you do not have to accept that your child takes part in this research study? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(The ABX vaccine has been tested twice before but only with older children and adults. In both studies, the vaccine worked better than the vaccine that currently exist. While the current vaccine protects only 60% of people who take the vaccine, the new one protected more than 80% of the people. The new vaccine also protected for a longer time period. We want to compare those two vaccines - the current one and the new one - in a younger age group, and that is why we are doing this research.

The drug is made by Company AB, who is working with a local hospital to have it tested. It's called a _____type of drug because it helps part of the blood to_____. The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects.)

Procedures and Protocol

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this should be stated.

Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

(Because we do not know if the new vaccine is better than the currently available vaccine for treating this disease, we need to make comparisons. Children taking part in this research will be put into groups which are selected by chance, as if by tossing a coin.

One group will get the vaccine we are testing, and the other group will get the malaria vaccine which is currently used in this region. It is important that neither you nor we know which of the two vaccines your child was given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing vaccines without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the medicines or treatment is doing, we will find out which vaccine your child is getting and make changes.)

2) involving a placebo it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

(A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you and your child do not know whether the real medicine or the pretend or dummy medicine was given. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine.".)

B. Description of the Process

Describe the process on a step-by-step basis.

(You may stay with your child during each of the visits and during the procedures. In the first visit, a small amount of blood, equal to about a teaspoon will be taken from your child's arm. This will be tested for the presence of substances that help your child's body to fight infections. Your child will feel some discomfort when the needle stick goes into her/his arm but this will go away very quickly. There may be slight bruising but this will disappear in a few days.

In the next visit, your child will be given either the test vaccine or the vaccine that is currently being used for malaria in this region. Neither you nor we will know, until later in the study, which vaccine your child was given. The vaccine will be given by a trained healthcare worker. After the vaccine, we ask that you and your child stay at the clinic for 30 minutes so that the healthcare worker can observe any immediate changes in the child's mood, and if swelling occurs around the injection site. We will give you and your child juice and something small to eat.

We will ask your child's physician to give us the details of your child's health and illness related information. If you do not wish us to do that, please let us know. However, because your child's health records are very important for the study, if we cannot look at the health records, we will not be able to include your child in the study.

At the end of the study, we will contact you by letter to tell you which of the two vaccines your child was given….)

In case of a clinical research:

Explain that there are standards/guidelines that must be followed. If a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Your child will receive the treatment for his/her condition according to national guidelines, etc. The sample will be taken using a local anesthesia which means that only the part of your child that we are taking the sample from, and a small surrounding area, will lose feeling for a short time. Your child shouldn't feel pain, etc.)

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a table-spoon full will be taken.

If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

If not, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ___ years, when the research is completed.

Duration

Include a statement about the time commitments of the research for the participant and for the parent including both the duration of the research and follow-up, if relevant.

(The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days, for ____ (number of) hours each day. We would like to meet with you six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year).

> ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at anytime and ask to see

[name of nurse, doctor, researcher].

We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

(By participating in this research it is possible that your child will be at greater risk than he/she would otherwise be. There is a possibility that _____may happen as a result of taking this drug. While the possibility of this happening is very low, you should still be aware of the possibility. If something unexpected happens and harm does occur, we will provide your child with_____. [Explain the level of care that will be available, who will provide it, and who will pay for it. Inform the parent if there is a particular insurance in place.])

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

(By participating in this research it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.)

> ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine your child is receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that your child may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not your child is in the research study? Etc. Do you have any questions?*

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(If your child participates in this research, he/she will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any other benefit for your child but his/her participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(You will not be provided any incentive to take part in this research. However, you will be reimbursed with - provide a figure if money is involved - for your lost time and travel expense.)

> ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your and your child's travel costs and your time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. Because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

> ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you and/or your child will remain confidential? Do you have any questions about them?*

Sharing of the results

Your plan for sharing the information with the participants and their parents should be provided.

If you have a plan and a timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.

(The knowledge that we get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our research).

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

(You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child's treatment at this Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child's treatment at this Centre will be affected in any way.)

Alternatives to participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.

(If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]

This proposal has been reviewed and approved by UPNM Research Ethics Committee (JKEP), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the JKEP, contact [name, address, and telephone number.])

PART II: Certificate of Consent

Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

(I have been invited to have my child participate in research of a new malaria vaccine).

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Participant _____

Print Name of Parent or Guardian _____

Signature of Parent or Guardian _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of parent

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1.

2.

3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

An Informed Assent Form will_____ OR will not _____ be completed.

WHO ERC

Informed Parental Consent Template for Research Involving Children (Qualitative Studies)

(For use with Participant Observation, Focus Group Discussions, Interviews, and Surveys)

(Language used throughout form should be at the level of a local secondary school student)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, which could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:

    - square brackets indicate where specific information is to be inserted
    - bold lettering indicates sections or wording which should be included
    - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in italics. Suggested questions to elucidate understanding are given in black in italics.

THE TEMPLATE IS ON THE FOLLOWING PAGES

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(e.g. This informed consent form is for parents of adolescent girls and boys participating in the research titled. "What do we want: Adolescents and health systems ")

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

(Example: I am X, and I work at Y organization in _____. I am doing some research which might help your clinic/hospital do more to help teenagers become and stay healthier. In our research we will talk to many teenagers, both girls and boys, and ask them a number of questions. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose

Explain in lay terms why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

(Example: It is possible that the clinics and the hospital in this region are not providing some of the services that are important for teenagers. In this study we will talk to teenage girls and boys about what they know about caring for their bodies in a healthy way including sexual and reproductive health. We will invite them to share their knowledge and understanding with us so that we can find ways of meeting their needs at the local clinics and hospital.)

Type of Research Intervention

Briefly state the intervention. This will be expanded upon in the procedures section.

(Example: A questionnaire OR a focus group OR an interview)

Selection of Participants

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

(Example: We want to talk to many teenagers about their health and what information or services they want for themselves. One part of health that we want to talk to them about is sexuality. We would like to ask your daughter/son to participate because she/he is a teenager and lives in this region.)

> ***Example of question to elucidate understanding:*** *Do you know why we are asking your child to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

(Example: You do not have to agree that your daughter/son can talk to us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your children. And it can be especially hard when the research includes sensitive topics like sexuality. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.)

> ***Examples of question to elucidate understanding:*** *If you decide not to allow your child to take part in this research study, do you know what the optionsfor him are? Do you know that your child does not have to take part in this research study, if you do not wish so? Do you have any questions?*

Procedure

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

(Examples:

1) the following applies only to focus group discussions*:*

Your daughter/son will take *part in a discussion with 7-8 other teenagers, or a mix of teenagers and social service workers from the community. The girls and boys will be in separate groups. This discussion will be guided by [give name of moderator] or me.*

2) the following applies only to interviews*:*

Your daughter/son will participate in an interview with [name of interviewer] or myself.

3) the following applies only to questionnaire surveys*:*

*Your daughter/son will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires].**OR** The questionnaire can be read aloud and she/he can give me the answer which she/he wants me to write.)*

Explain the type of questions that the participants are likely to be asked in the focus group discussion, interview or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these. Parents may be concerned that if researchers talk to their children about sexuality it may encourage them to explore sexual activities with their peers. Other concerns may include disbelief that their child is ready to talk about sexuality, or parents may be personally embarrassed.

(Examples:

1) The following applies only to focus group discussions:

The group discussion will start with me, or the focus group guide (use the local word for group discussion leader), making sure that the participants are comfortable. We will also answer questions about the research that they might have. Then we will ask questions about the health system in this community. We will talk about where they go for information about health, and whether they get the information and services they need and want. We will encourage them to talk about sexual and reproductive health as well as other important health topics such as food and nutrition. These are the types of questions we will ask. We will not ask them to share personal stories or anything that they are not comfortable sharing.

The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after ____period of time.]

2) The following applies only to interviews:

If your daughter does not wish to answer any of the questions during the interview, she may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present unless your child asks for someone else to be there. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to the

information documented during your interview.) [The tapes will be destroyed after _____period of time.]

3) The following applies only to questionnaires and surveys:

If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after _____period of time.])

Duration

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

*(Example: We are asking your child to participate in an interview which will take about 1 hour of her/his time. We can do this outside of school/work hours. There is also a questionnaire that we will either provide to your child or which we will do together with her/him. This also takes about an hour. Altogether, we are asking for about 2 hours of your child's time.***)**

> ***Examples of question to elucidate understanding:*** *If you decide that your child can take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending a transport to pick up your child from your home? Do you know how much time will the discussion with other people take? If you agree that your child can take part, do you know if he/she can stop participating? Do you know that your child may not respond to the questions that he/she does not wish to respond to? Etc. Do you have any more questions?*

Risks and Discomforts

Explain any risks or discomforts including any limits to confidentiality.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking your son/daughter to share with us some very personal and confidential information, and he/she may feel uncomfortable talking about some of the topics. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she doesn't wish to do so, and that is also fine. He/she does not have to give us any reason for not responding to any question, or for refusing to take part in the interview"

OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that your son/daughter may share some personal or confidential information by chance, or that he/she may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she feels the question(s) are too personal or if talking about them makes him/her uncomfortable.)

Your daughter/son may choose to tell you about the interview and the questionnaire but she/he does not have to do this. We will not be sharing with you either the questions we ask or the responses given to us by your child.)

Benefits

Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

(Example: There will be no immediate and direct benefit to your child or to you, but your child's participation is likely to help us find out more about the health needs of teenage girls and boys and we hope that these will help the local clinics and hospitals to meet those needs better in the future.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(Example: Your daughter/son will not be provided with any payment to take part in the research. However, she/he will be given with [provide a figure, if money is involved] for her/his time, and travel expense (if applicable).)

> ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality:

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

(Examples:

Because something out of the ordinary is being done through research in your community, it will draw attention. If your daughter/son participates, she and you may be asked questions by other people in the community.

We will not be sharing information about your son or daughter outside of the research team. The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].

The following applies to focus groups*:*

We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

> ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as*

researchers collect about your child will remain confidential? Do you understand that that we cannot guarantee complete confidentiality of information that your child shares with us in a group discussion Do you have any more questions?

Sharing of Research Findings

Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

(Example: At the end of the study, we will be sharing what we have learnt with the participants and with the community. We will do this by meeting first with the participants and then with the larger community. Nothing that your child will tell us today will be shared with anybody outside the research team, and nothing will be attributed to him/her by name. A written report will also be given to the participants which they can share with their families. We will also publish the results in order that other interested people may learn from our research.)

Right to refuse or withdraw

Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

(Example: You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Choosing to participate or not will not affect either your own or your child's future treatment at the Centre here in any way. You and your child will still have all the benefits that would otherwise be available at this Centre. Your child may stop participating in the discussion/interview at any time that you or she/he wish without either of you losing any of your rights here.)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted). State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]

This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.])

Example of question to elucidate understanding: *Do you know that you do not have to allow your child take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

PART II: Certificate of Consent

Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over

the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

I have been asked to give consent for my daughter/son to participate in this research study which will involve her completing one interview and one questionnaire

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1.

2.

3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant ____

Print Name of Researcher/person taking the consent_____

An Informed Assent Form will ____ OR will not ____ be completed.

KEMBARAN B
APPENDIX B

Borang JKEP 01 / 2015

Pusat Pengurusan Penyelidikan dan Inovasi
Center For Research And Innovation Management
Universiti Pertahanan Nasional Malaysia
Kem Sg Besi
57000 KUALA LUMPUR

Tel: 03 – 9051-3400 samb 3085/3099/1054/1055/4620/3594
Faks: 03 – 9051 3084

Borang Permohonan Kelulusan Etika

Application Form for Ethics Approval

Jawatankuasa Etika Penyelidikan UPNM
NDUM Research Ethics Committee

Permohonan ini dikemukakan untuk tujuan kelulusan isu-isu Etika sahaja. Sila lampirkan salinan kertas cadangan penyelidikan yang telah diluluskan di peringkat Fakulti/Pusat.
This application is for the purpose of obtaining approval for ethical issues only.Please attach a copy of Research Proposal that has been approved by Faculty/Centre

BAHAGIAN A: Maklumat Ringkas Projek *Part A : Brief Details of Project*

Tajuk Projek :
Title of Project :

.....

Nama Ketua Projek:
Name of Project Leader :

.....

No.Staf/No.Pelajar:
Staff ID/Student ID:

.....

Bidang Pengkhususan :
Area of Specialisation :

.....

Alamat Jabatan dan
Hospital/ Institut:
Affiliation:

.....

No.Telefon/ E-mail :
Contact No/ E-mail :

.....

Kelulusan Peringkat Fakulti/Pusat *Approval at Faculty/Centre level*

Ulasan *Comments*

.....		
Tandatangan *Signature* Pengerusi Jawatankuasa Penyelidikan Fakulti *Chairman of Faculty Research Committee*	Cop rasmi *Official stamp*	Tarikh *Date*

BAHAGIAN B: Protokol Projek *Part B : Project Protocol*

1.	**Latar Belakang:** *Background* (Keterangan ringkas tentang masalah penyelidikan dan kajian kepustakaan yang relevan. Sila lampirkan lembaran lain sekiranya ruang tidak mencukupi) *(A brief explanation of the research problem and relevant literature review. Please append additional pages if more space is required.)*
2.	**Objektif dan Justifikasi Ringkas Projek Penyelidikan:** *Objectives and Justification of the Research Project:*
3.	**Faedah yang Dijangka:** *Expected Benefits :*

4.	**Jangkamasa Projek:** *Timeframe of the Project :*
5.	**Lokasi Projek Penyelidikan dijalankan:** *Location where the Project will be carried out :*
6.	**Keterangan bagaimana hasil kajian akan digunakan:** *Explain how the results will be used :*
7.	**Kaedah Penyelidikan: (Sila terangkan perkara-perkara berikut)** *Experimental : (Please explain the following)*
7.1	**Rekabentuk kajian, metodologi yang diguna:** *Experimental design and methodology :*
7.2	**Saiz sampel, kriteria pemilihan:** *Sample size and selection criteria :*

7.3	**Pembahagian kumpulan ujian dan kontrol; dan ciri-ciri kohort atau sampel dan jenis kontrol:** *Division of test and control groups, cohort properties or samples, and type of control :*
7.4	**Pemprosesan data dan penganalisaan statistik:** *Data processing and statistical analysis :*

Sila lampirkan **Borang Keizinan Bermaklumat** ataupun **Lembaran Maklumat Subjek** dan **Borang Persetujuan Subjek**. Permohonan yang tidak menyertakan dokumen ini tidak akan dipertimbangkan

*Please attach examples of **Informed Consent Form** OR **Subject Information Sheet** and **Subject Consent Form**. Applications without these documents will not be considered*

Bahagian C: Peruntukan *Part C : Research grant*

Geran projek: Ada/ Tiada

Project Grant : Already obtained/ Not obtained yet

Jika ada, nyatakan yang berikut: .....
If obtained, please state :

Jumlah peruntukan: …….....
Total allocation :

Jangkamasa peruntukan : .....
Duration of grant :

Bahagian D: Persetujuan Menjalankan Projek Penyelidikan

Part D : Agreement on the Conduct of the Research Project

Mesti dilengkapkan dan ditandatangani oleh semua ahli kumpulan penyelidikan
Must be completed and signed by all members of the research group

Ketua Projek *Project Leader*

Nama: *Name*		
No.Staf/No.Pelajar: *Staff ID/Student ID*		
Jawatan/ kepakaran: *Position/ Specialisation*		
Jabatan: *Affiliation*		
No. Tel.: *Tel no.*		Handphone: Email:
Tandatangan: *Signature*		Tarikh: *Date*

Penyelidik bersama *Co-researcher*

Nama: *Name*		
No.Staf/No.Pelajar: *Staff ID/Student ID*		
Jawatan/ kepakaran: *Position/ Specialisation*		
Jabatan: *Affiliation*		
No. Tel: *Tel no.*		Handphone: Email:
Tandatangan: *Signature*		Tarikh: *Date*

Penyelidik bersama *Co-researcher*

Nama: *Name*		
No.Staf/No.Pelajar: *Staff ID/Student ID*		
Jawatan/ kepakaran: *Position/ Specialisation*		
Jabatan: *Affiliation*		
No. Tel: *Tel no.*		Handphone: Email:
Tandatangan: *Signature*		Tarikh: *Date*

Penyelidik bersama *Co-researcher*

Nama: *Name*		
No.Staf/No.Pelajar: *Staff ID/Student ID*		
Jawatan/ kepakaran: *Position/ Specialisation*		
Jabatan: *Affiliation*		
No. Tel: *Tel no.*		Handphone: Email:
Tandatangan: *Signature*		Tarikh: *Date*

(Tambah sekiranya perlu. *Add if necessary*)

Pusat Pengurusan Penyelidikan dan Inovasi
Center For Research And Innovation Management
Universiti Pertahanan Nasional Malaysia
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57000 KUALA LUMPUR

Tel: 03 – 9051-3400 samb 3085/3099/1054/1055/4620/3594
Faks: 03 – 9051 3084

Borang Permohonan Kelulusan Etika Penyelidikan Menggunakan Haiwan

Application Form for Ethics Approval For Research Involving Animals

Jawatankuasa Etika Penyelidikan UPNM
NDUM Research Ethics Committee

Permohonan ini hendaklah dikemukakan bersama-sama Borang JKEP 01/2015
This application is to be submitted together with Borang JKEP 01/2015

BAHAGIAN A: Maklumat Ringkas Projek *Part A : Brief Details of Project*

Tajuk Projek : *Title of Project*	
Nama Ketua Projek: *Name of Project Leader*	

BAHAGIAN B: Maklumat Am Projek *Part B : General Details of Project*

Nama, alamat dan no. pendaftaran pembekal/pembiak haiwan yang akan diperoleh untuk cadangan ini: *Name, address and registration number of supplier/breeder from which animals acquired (or to be acquired) for this proposal*	
Tempat di mana haiwan ini di simpan (atau dicadang disimpan): *Place where the animals are presently kept (or proposed to be kept).*	
Tempat di mana kajian/eksperimen akan dilakukan: *Place where the experiment is to be performed*	

Tarikh cadangan untuk pelaksanaan eksperimen dan tempohnya: *Date on which the experiment is to commence and duration*	
Jenis penyelidikan terlibat (Asas/Pengajaran/Pengawasan/Penyelidkan Berkontrak): *Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)*	

Tandatangan: .....
Signature

Nama dan Designasi Ketua Projek: .....
Name and Designation of Project Leader

Tarikh: .....
Date:

BAHAGIAN C: Maklumat Pengalaman Penyelidik Dengan Penyelidikan Menggunakan Haiwan
Part C : Details of Researcher Experience in Research Using Animals

Nama Ketua Projek: *Project Leader Name*	
Pengalaman dengan penyelidikan menggunakan haiwan: *Experience in research using animals*	
1. Nama Ahli Projek: *Name of Project Member*	
Butiran pengalaman penyelidikan menggunakan haiwan: *Details of research experience using animals*	
2. Nama Ahli Projek: *Name of Project Member*	
Butiran pengalaman penyelidikan menggunakan haiwan: *Details of research experience using animals*	
3. Nama Ahli Projek: *Name of Project Member*	
Butiran pengalaman penyelidikan menggunakan haiwan: *Details of research experience using animals*	
4. Nama Ahli Projek: *Name of Project Member*	
Butiran pengalaman penyelidikan menggunakan haiwan: *Details of research experience using animals*	

(Tambah sekiranya perlu. *Add if necessary*)

1. Senarai nama semua individu yang dibenarkan melakukan prosedur yang terkandung dalam cadangan penyelidikan ini:
   List of names of all individuals authorised to conduct procedures under this proposal

Name/*Nama*	Tempat Kerja/ *Place of Work*	Pengalaman /*Experience*	Prosedur yang akan dilakukan/*Procedure to be conducted*

(Tambah sekiranya perlu. *Add if necessary*)

2. Jenis haiwan di perlukan/*Animals required:*

Spesis/Nama lazim: *Species / Common name*	
Umur / Berat / Saiz: *Age/ weight/ size*	
Jantina: *Gender*	
Bilangan digunakan (Bilangan mengikut tahun kajian dan jumlah keseluruhan *Number to be used (Year-wise breakups and total figures needed to be given)*	
Bilangan hari haiwan akan di simpan *Number of days each animal will be housed*	
Sumber haiwan (jika berlainan dari Bahagian B di atas) *Proposed source of animals (if different from Part B above)*	
Kemudahan yang disediakan untuk penjagaan dan perumahan haiwan (e.g. keperluan tempat tidur, makanan, minuman, pembuangan sisa, jenis sangkar haiwan yang akan digunakan): *Facilities provided for the animals care and housing (e.g. bedding, feeding, drinking, waste disposal, type of animal housing to be used)*	

3. Kenapa haiwan diperlukan untuk penyelidikan ini
Rationale for animal usage

Kenapa haiwan diperlukan untuk cadangan kajian ini? *Why are the animals use necessary for this study?*	
Kenapa spesis haiwan ini diperlukan? *Why is this particular species required?*	
Kenapa bilangan haiwan yang dicadangkan perlu? *Why is the estimated number of animals essential?*	
Pernahkan kajian seumpama di lakukan sebelum ini? Jika ada, nyatakan bilangan haiwan digunakan dan hasil penyelidikan yang diperolehi dengan ringkas. *Have similar experiments been conducted in the past? If so, the number of animals used and results obtained in brief.*	
Jika ya, kenapa kajian baru ini diperlukan? *If yes, why is this new experiment required?*	
Pernahkah penyelidikan seumpama ini di lakukan oleh organisasi/agensi lain? Jika ada, senaraikan hasil penyelidikan mereka secara ringkas. *Have similar experiments been made by any other organization/agency? If yes, list their results briefly.*	

4. Huraian Prosedur yang Dicadangkan
Description of the procedures proposed.

<table>
<tr><td rowspan="5">Senaraikan dan huraikan semua prosedur invasif dan prosedur bukan invasif yang menyebabkan stres kepada haiwan semasa kajian dilakukan: List and describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments.</td><td colspan="4">1.</td></tr>
<tr><td colspan="4">2.</td></tr>
<tr><td colspan="4">3.</td></tr>
<tr><td colspan="4">4.</td></tr>
<tr><td colspan="4">5.</td></tr>
<tr><td colspan="5">Sediakan butiran penjadualan suntikan Furnish details of injections schedule:</td></tr>
<tr><td>Bahan: Substance:</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Dos Dose:</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Tempat Site :</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Isipadu Volume:</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Pengambilan sampel darah Blood withdrawal</td></tr>
<tr><td>Isipadu Volumes:</td><td colspan="4"></td></tr>
<tr><td>Tempat Sites:</td><td colspan="4"></td></tr>
<tr><td colspan="5">Sinaran Mengion Radiation:</td></tr>
<tr><td>Dos Dosage</td><td colspan="4"></td></tr>
<tr><td>Jadual Schedules</td><td colspan="4"></td></tr>
</table>

5. Sila berikan huraian ringkas mengenai kajian lain yang seumpama samada *in vitro/in vivo* (dari model haiwan yang lain) terhadap penyelidikan dalam tujahan ataupun mengenai komponen yang seumpama. Jika ada maklumat sila berikan justifikasi terhadap penyelidikan yang seumpama.
Please provide brief descriptions of similar studies, either in vitro / in vivo (from other animal models) on same / similar test component or line of research. If, enough information is available, justify the proposed reasons.

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6. Adakah kaedah penyelidikan **TIDAK** membenarkan penggunaan bius ataupun analgesik sebelum melakukan prosedur/teknik yang menyebabkan kesakitan (yakni prosedur/kaedah yang menyebabkan kesakitan yang lebih dari prosedur suntikan ataupun pengambilan sampel darah)? Jika Ya, sila beri penjelasan dan justifikasi.
*Does the research protocol **PROHIBIT** the use of anaesthesia or analgesic use before for the conduct of painful procedures (any procedures which cause more pain than that associated with routine injection or blood withdrawal)? If Yes, explanation and justification.*

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7. Adakah prosedur pembedahan dilakukan ke atas haiwan dalam penyelidikan?
Will surgical procedures be done on the animals used in the research?

Ya / Tidak

Yes / No

8. Jika Ya, maklumat berikut hendaklah disediakan:
If Yes, the following to be described.

a. Senarai dan penjelasan semua prosedur pembedahan yang akan dilakukan (termasuk kaedah mengawal jangkitan).
List and description of all such surgical procedures (including methods of asepsis).

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b. Nama, kelayakan, afiliasi dan pengalaman semua ahli yang terlibat dalam penyelidikan dan penjagaan terhadap haiwan dalam kajian.
Names, qualifications, affiliations and experience levels of persons involved in the research and care of the animals used in the research.

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c. Penjelasan mengenai penjagaan pasca-pembedahan.
Description of post-operative care.

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d. Justifikasi jika pembedahan berulang perlu dilakukan pada haiwan yang sama dalam penyelidikan.
Justification if surgery is to be performed more than once on the same animal in the research.

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9. Kaedah pelupusan haiwan selepas penyelidikan.
Methods of disposal post-experimentation.

a. Eutanasia (Kaedah khusus):
Euthanasia (Specific method)

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b. Kaedah pelupusan bangkai haiwan:
Method of carcass disposal

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c. Pemulihan haiwan (jika perlu):
Animal rehabilitation (if needed)

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10. Kaedah pengangkutan haiwan, jika pihak pengangkutan luar dari UPNM digunakan.
Animal transportation methods if extra-institutional transport (UPNM) is to be used

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11. Penggunaan agen berbahaya (e.g. penggunaan agen rekombinan berasaskan DNA atau patogen yang berpotensi mengancam manusia. Untuk setiap kategori di bawah, nyatakan agen terlibat dan tahap bio-keselamatan yang diperlukan, langkah-langkah terapeutik yang perlu disediakan, dan kaedah pelupusan makanan, hasil kumuhan dan bangkai haiwan yang diperlukan).
Use of hazardous agents (e.g. use of recombinant DNA-based agents or potential human pathogens. For each category below, state the agents and the biosafety level required, appropriate therapeutic measures needed and the mode of disposal of contaminated food, animal wastes and carcasses).

a. Radionuklid:
Radionuclides

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b. Mikroorganisma/Agen Biologi Berjangkit:
Microorganisms / Biological infectious Agents

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c. Bahan kimia / ubat yang berbahaya:
Hazardous chemicals or drugs

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d. DNA Rekombinan:
Recombinant DNA

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……

e. Lain-lain (nyatakan):
Any other (give name)

……

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Pengisytiharan Ketua Projek
Project Leader's Declaration

1. Saya mengesahkan bahawa saya telah menentukan bahawa cadangan penyelidikan ini bukan menduplikasi penyelidikan lain yang pernah dilaporkan sebelum ini tanpa sebab yang kukuh.
   I certify that I have determined that the research proposal herein is not unnecessarily duplicative of previously reported research.

2. Saya mengesahkan bahawa saya berkelayakan dan mempunyai pengalaman dengan penyelidikan yang menggunakan haiwan.
   I certify that I am qualified and have experience in experimentation on animals for research.

3. Bagi prosedur yang dinyatakan dalam cadangan penyelidikan yang dikemukakan, saya mengesahkan bahawa saya telah meneliti literature saintifik yang berkaitan dan tidak menemui alternative lain yang sesuai bagi mana-mana prosedur yang dinyatakan dalam permohonan ini yang boleh mengurangkan kesakitan ataupun penderitaan kepada haiwan penyelidikan.
   For procedures listed in the research proposal submitted, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress to the reaserch animals.

4. Saya akan mendapatkan kelulusan JKEP sebelum membuat sebarang perubahan yang signifikan dalam projek penyelidikan ini.
   I will obtain approval from the JKEP before initiating any significant changes in this study.

5. Saya akan menyimpan semua rekod yang dikehendaki.
   I shall maintain all the records required.

6. Saya mengesahkan bahawa saya tidak akan memulakan cadangan penyelidikan ini sehinggalah kelulusan JKEP diperolehi secara bertulis. Seterusnya, saya mengesahkan bahawa saya akan mematuhi syor yang dibuat oleh JKEP terhadap permohonan ini.
   I certify that I will not initiate the study unless approval from JKEP has been received in writing. Further, I certify that I will follow the recommendations of JKEP for this proposal.

Tandatangan/*Signature* : ……..

Nama Ketua Project: …….
Name of Project Leader

Tarikh/*Date*: ……

KEMBARAN D
APPENDIX D

Borang JKEP 03 / 2015

Pusat Pengurusan Penyelidikan dan Inovasi
Center For Research And Innovation Management
Universiti Pertahanan Nasional Malaysia
Kem Sg Besi
57000 KUALA LUMPUR

Tel: 03 – 9051-3400 samb 3085/3099/1054/1055/4620/3594
Faks: 03 – 9051 3084

Borang Permohonan Kelulusan Etika Haiwan Bagi Penggunaan Haiwan Dalam Pengajaran

Application Form for Animal Ethics Approval For Using Animals in Teaching

Jawatankuasa Etika Penyelidikan UPNM
NDUM Research Ethics Committee

BAHAGIAN A: Maklumat Ringkas Pengajaran ***Part A : Brief Details of Teaching Activity***

Tajuk Kursus dan Aktiviti Pengajaran: *Course Title and Teaching Activity*	
Nama Pensyarah Terlibat: *Name of Lecturer Concerned*	

BAHAGIAN B: Maklumat Am Projek ***Part B : General Details of Project***

Nama, alamat dan no. pendaftaran pembekal/pembiak haiwan yang akan diperoleh untuk cadangan ini: *Name, address and registration number of supplier/breeder from which animals acquired (or to be acquired) for this proposal*	
Tempat di mana haiwan ini di simpan (atau dicadang disimpan): *Place where the animals are presently kept (or proposed to be kept).*	
Tarikh dan tempat di mana aktiviti pengajaran akan dilakukan: *Date and place where the teaching activity is to be performed*	Tarikh/*Date*: Tempat/*Place*:

Kemudahan yang disediakan untuk penjagaan dan perumahan haiwan (e.g. keperluan tempat tidur, makanan, minuman, pembuangan sisa, jenis sangkar haiwan yang akan digunakan): *Facilities provided for the animals care and housing (e.g. bedding, feeding, drinking, waste disposal, type of animal housing to be used)*	

BAHAGIAN C: Maklumat Pengalaman Pensyarah Dengan Pengajaran Menggunakan Haiwan
Part C : Details of Lecturer's Experience in Using Animals for Teaching

Nama Pensyarah: *Lecturer's Name*	
Pengalaman dengan pengajaran menggunakan haiwan: *Experience in teaching using animals*	
Nama Pensyarah: *Lecturer's Name*	
Pengalaman dengan pengajaran menggunakan haiwan: *Experience in teaching using animals*	

(Tambah sekiranya perlu. *Add if necessary*)

1. Senarai nama semua individu yang dibenarkan melakukan prosedur yang terkandung dalam cadangan ini:
   List of names of all individuals authorized to conduct procedures under this proposal

Name/*Nama*	Tempat Kerja/ *Place of Work*	Pengalaman /*Experience*	Prosedur yang akan dilakukan/*Procedure to be conducted*

2. Jenis haiwan di perlukan/*Animals required:*

Spesis/Nama lazim: *Species / Common name*				
Umur / Berat / Saiz: *Age/ weight/ size*				
Jantina: *Gender*			Bilangan digunakan *Number to be used*	
Bilangan hari haiwan akan di simpan *Number of days each animal will be housed*				

3. Kenapa haiwan diperlukan untuk pengajaran ini?
Rationale for animal usage in teaching?

Kenapa haiwan diperlukan untuk pengajaran ini? *Why are the animals necessary for this teaching?*	
Kenapa spesis haiwan ini diperlukan? *Why is this particular species required?*	
Kenapa bilangan haiwan yang dicadangkan perlu? *Why is the estimated number of animals essential?*	

4. Huraian Prosedur yang Dicadangkan
Description of the procedures proposed.

Senaraikan dan huraikan semua prosedur invasif dan prosedur bukan invasif yang menyebabkan stres kepada haiwan semasa kajian dilakukan: *List and describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments.*	1.			
	2.			
	3.			
	4.			
	5.			
Sediakan butiran penjadualan suntikan *Furnish details of injections schedule:*				
Bahan: *Substance:*				
Dos *Dose:*				
Tempat *Site :*				
Isipadu *Volume:*				
Pengambilan sampel darah *Blood withdrawal*				
Isipadu *Volumes:*				
Tempat *Sites:*				

5. Adakah kaedah pengajaran **TIDAK** membenarkan penggunaan bius ataupun analgesik sebelum melakukan prosedur/teknik yang menyebabkan kesakitan (yakni prosedur/kaedah yang menyebabkan kesakitan yang lebih dari prosedur suntikan ataupun pengambilan sampel darah)? Jika Ya, sila beri penjelasan dan justifikasi.
*Does the teaching activity **PROHIBIT** the use of anaesthesia or analgesic use before for the conduct of painful procedures (any procedures which cause more pain than that associated with routine injection or blood withdrawal)? If Yes, explanation and justification.*

……

……

6. Adakah prosedur pembedahan dilakukan ke atas haiwan ini? (Bulatkan jawapan)
Will surgical procedures be done on these animals? (Encircle your answer)

Ya / Tidak
Yes / No

Jika Ya, maklumat berikut hendaklah disediakan:
If Yes, the following information is to be described.

a. Senarai dan penjelasan semua prosedur pembedahan yang akan dilakukan (termasuk kaedah mengawal jangkitan).
List and description of all such surgical procedures (including methods of asepsis).

……

……

b. Nama, kelayakan, afiliasi dan pengalaman semua ahli yang terlibat dalam penjagaan terhadap haiwan dalam kajian.
Names, qualifications, affiliations and experience levels of persons involved in the care of the animals used in the research.

……

……

c. Penjelasan mengenai penjagaan pasca-pembedahan.
Description of post-operative care.

……

……

7. Kaedah pelupusan haiwan selepas pengajaran *Methods of disposal post-teaching:*

a. Eutanasia (Kaedah khusus) *Euthanasia (Specific method):*

……

……

b. Kaedah pelupusan bangkai haiwan *Method of carcass disposal:*

……

……

c. Pemulihan haiwan (jika perlu):
Animal rehabilitation (if needed)

……

……

8. Penggunaan agen berbahaya (e.g. penggunaan agen rekombinan berasaskan DNA atau patogen yang berpotensi mengancam manusia. Untuk setiap kategori di bawah, nyatakan agen terlibat dan tahap bio-keselamatan yang diperlukan, langkah-langkah terapeutik yang perlu disediakan, dan kaedah pelupusan makanan, hasil kumuhan dan bangkai haiwan yang diperlukan).
Use of hazardous agents (e.g. use of recombinant DNA-based agents or potential human pathogens. For each category below, state the agents and the biosafety level required, appropriate therapeutic measures needed and the mode of disposal of contaminated food, animal wastes and carcasses).

a. Radionuklid:
Radionuclides

……

b. Mikroorganisma/Agen Biologi Berjangkit:
Microorganisms / Biological infectious Agents

……

c. Bahan kimia / ubat yang berbahaya:
Hazardous chemicals or drugs

……

d. DNA Rekombinan:
Recombinant DNA

……

e. Lain-lain (nyatakan):
Any other (give name)

……

Pemohon/*Applicant*:

Tandatangan/*Signature* : ……..

Nama Pensyarah: ……
Name of Lecturer

Unit/Jabatan: ……
Unit/Department:

Tarikh/*Date*: ……

Dekan/Pengarah/Timbalan Dekan/Timbalan Pengarah/Ketua:
Dean/Director/Deputy Dean/Deputy Director/Head:

Fakulti/Pusat: ……
Faculty/Centre

Ulasan/*Comments:*

……

……

……

Tandatangan/*Signature* : ……..

Nama: …….
Name
Tarikh/Date: ……

KEMBARAN E
APPENDIX E

Borang JKEP 04 / 2015

Pusat Pengurusan Penyelidikan dan Inovasi
Center For Research And Innovation Management
Universiti Pertahanan Nasional Malaysia
Kem Sg Besi
57000 KUALA LUMPUR

Tel: 03 – 9051-3400 samb 3085/3099/1054/1055/4620/3594
Faks: 03 – 9051 3084

Sijil Kelulusan Etika Penyelidikan
Certificate of Ethical Research Approval

Jawatankuasa Etika Penyelidikan UPNM
NDUM Research Ethics Committee

Adalah disahkan bahawa projek bertajuk:
This is certify that the project entitled

……

……

telah diluluskan oleh Jawatankuasa Etika Penyelidikan
Universiti Pertahanan Nasional Malaysia
has been approved by the National Defence University of Malaysia
Research Ethics Committee

Tandatangan:
Signature

Nama Pengerusi
Name of Chairman:

No. Kawalan JKEP:
JKEP Control Number

Tarikh:
Date

KEMBARAN F
APPENDIX F

Borang JKEP 05 / 2015

Pusat Pengurusan Penyelidikan dan Inovasi
Center For Research And Innovation Management
Universiti Pertahanan Nasional Malaysia
Kem Sg Besi
57000 KUALA LUMPUR

Tel: 03 – 9051-3400 samb 3085/3099/1054/1055/4620/3594
Faks: 03 – 9051 3084

Sijil Kelulusan Etika Penggunaan Haiwan dalam Pengajaran

Certificate of Approval For the Ethical Use of Animals in Teaching

Jawatankuasa Etika Penyelidikan UPNM
NDUM Research Ethics Committee

Adalah disahkan bahawa penggunaan haiwan jenis
This is certify that the use of the following animal

……

bagi pengajaran Kursus
for the teaching of the following course

……

telah diluluskan oleh Jawatankuasa Etika Penyelidikan
Universiti Pertahanan Nasional Malaysia
has been approved by the National Defence University of Malaysia
Research Ethics Committee

Tandatangan:
Signature

Nama Pengerusi
Name of Chairman:

No. Kawalan JKEP:
JKEP Control Number

Tarikh:
Date

FORMAT PENAKSIRAN PERMOHONAN KELULUSAN ETIKA PENYELIDIKAN/PENGAJARAN
ASSESSMENT FORMAT FOR RESEARCH/TEACHING ETHICS APPROVAL APPLICATIONS

BAHAGIAN 1
SECTION 1

PROTOKOL (ISU SAINTIFIK DAN TEKNIKAL)
PROTOCOL (SCIENTIFIC AND TECHNICAL ISSUES)

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
	Maklumat Latar Belakang ***Background Information***		
1.	Apakah rasional untuk kajian dinyatakan dengan jelas dalam konteks pengetahuan masa kini? *Is the rationale for the study clearly stated in the context of present knowledge?*		
2.	Adakah kajian kepustakaan bersama rujukan berkaitan dimasukkan dalam kertas cadangan? *Has a review of literature with references been included in the proposal?*		
3.	Adakah susunatur kajian digambarkan secukupnya? *Has the study setting been described adequately?*		
	Objektif ***Objectives***		
4.	Adakah objektif dan / atau hipotesis yang akan diuji dinyatakan dengan jelas? *Are the objectives and/or hypothesis to be tested clearly stated?*		
	Reka Bentuk Kajian ***Study Design***		
5.	Adalah penerangan yang jelas tentang reka bentuk kajian diberikan (e.g. penyelidikan sains asas, penyelidikan sains sosial, atau epidemiologi – penyelidikan berintervensi atau pemerhatian)? *Is a clear description of the study design provided (e.g. basic science research, social science research, or epidemiological research - observational or intervention)*		
6.	Adakah penerangan yang jelas mengenai peserta kajian, hasil kajian, intervensi yang dirancang dan kumpulan kawalan disediakan (jika berkenaan)? *Is there a clear description of the study participants, outcomes, intervention planned and control groups provided (if relevant)?*		
	Metodologi ***Methodology***		
7.	Adakah anggaran saiz sampel disediakan, termasuk andaian yang digunakan? *Is an estimate of sample size provided, along with the assumptions on which it is based?*		
8.	Adakah kriteria kemasukan dan pengecualian dinyatakan dengan jelas? *Are the inclusion and exclusion criteria clearly stated?*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
9.	Adakah prosedur bagi pengambilan peserta, kemasukan, susulan dan penyelesaian dalam kajian dinyatakan sepenuhnya? *Are the procedures for participant recruitment, admission, follow up and completion in the study fully described?*		
10.	Adakah ujian makmal dan prosedur diagnostik dinyatakan sepenuhnya? *Are the laboratory tests and diagnostic procedures fully described?*		
11.	Adakah protokol mengandungi maklumat mengenai prosedur yang eksperimental dan sebahagian daripada penyelidikan yang dijalankan, berbanding dengan prosedur yang merupakan sebahagian daripada rutin penjagaan lazim? *Does the protocol include information on procedures that are experimental and part of the research, as opposed to those that are part of routine care?*		
12.	Adakah protokol menyatakan bagaimana spesimen dan / atau data yang dikumpulkan akan dikodkan / dinyah pengenalan diri? *Does the protocol describe how the specimens and/or data collected will be coded/anonymised?*		
13.	Jika kajian ini adalah kajian intervensi, termasuklah ujian plasebo terkawal, adakah justifikasi untuk kumpulan kawalan disediakan? *If the study is an intervention study, including placebo controlled trials, is justification for the control group provided?*		
14.	Jika kajian ini adalah kajian intervensi, adakah jenis dan kaedah memperuntukkan subjek kepada kumpulan intervensi dan kumpulan kawalan diterangkan dengan jelas? *If the study is an intervention study, are the types and methods for subject allocation to intervention and control groups clearly explained?*		
	Keselamatan Peserta Kajian *Participant safety*		
15.	Adakah risiko kepada peserta kajian telah dikenal pasti dan adakah protokol kajian menerangkan bagaimana ia akan dikurangkan? *Have any risks to participating in the research been identified and does the protocol state how these will be minimized?*		
16.	Jika penyelidikan melibatkan dadah baru atau vaksin, adalah pelepasan daripada Biro Pengawalan Farmaseutikal Kebangsaan dilampirkan? *If the research involves new drugs or vaccines, is clearance from the National Pharmaceutical Control Bureau attached?*		
17	Jika penyelidikan melibatkan dadah baru atau vaksin, adalah Risalah Penyiasat (termasuk maklumat keselamatan) dilampirkan? *If the research involves new drugs or vaccines, is the Investigator's Brochure (including safety information) attached?*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
18.	Jika kajian ini adalah kajian intervensi, adakah prosedur laporan peristiwa buruk termasuk dalam protokol? *If the study is an intervention study, is a adverse event reporting procedure included in the protocol?*		
	Pengurusan Data dan Analisis Statistik ***Data Management and Statistical Analysis***		
19.	Adakah protokol mengandungi perbincangan mengenai mekanisme jaminan kualiti bagi pengumpulan, penyimpanan dan analisis data? *Does the protocol include a discussion on the quality assurance mechanisms for data collection, storage and analysis?*		
20.	*Adakah rancangan analisis statistik disediakan?* *Is the plan for statistical analysis provided?*		
	Hasil Kajian yang Diharapkan dan Penyebaran Hasil Kajian ***Expected Outcomes and Dissemination of Results***		
21.	Adakah protokol menunjukkan bagaimana kajian ini akan menyumbang kepada kemajuan pengetahuan dan bagaimana keputusan akan digunakan? *Does the protocol indicate how the study will contribute to advancement of knowledge and how the results will be utilized?*		
22.	Adakah protokol mengandungi rancangan bagi penyebaran hasil kajian? (Komuniti penyelidikan - melalui penerbitan dalam talian akses terbuka, dan penerbitan jurnal yang lain; kepada pembuat dasar - melalui mesyuarat, laporan dan lain-lain; dan kepada peserta kajian (melalui mesyuarat, risalah dan lain-lain)? *Does the protocol include a plan for the dissemination of results? (Research community - through open access online publication, and other journal publications; policy makers - through meetings, reports etc; and to the research participants (through meetings, leaflets, etc)?*		
	Isu Jantina *Gender issues*		
23.	Adakah protokol membincangkan bagaimana penyelidikan ini menyumbang kepada mengenal pasti dan / atau mengurangkan ketidaksamaan antara wanita dan lelaki dalam kesihatan dan penjagaan kesihatan atau tidak mengekalkan ketidakseimbangan jantina? *Does the protocol discuss how the research contributes to identifying and/or reducing inequities between women and men in health and health care or does not perpetuate gender imbalances?*		
	Pengurusan Projek *Project Management*		
24.	Adakah protokol menyatakan tempoh yang dijangkakan bagi projek ini? *Does the protocol state the expected duration of the project?*		
25.	Adakah protokol menerangkan peranan dan tanggungjawab setiap ahli pasukan? *Does the protocol describe the role and responsibility of each member of the team?*		
	Instrumen Kajian *Study instruments*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
26.	Jika kertas soal selidik, kad diari dan bahan-bahan lain yang digunakan, adalah ini relevan untuk menjawab soalan penyelidikan? *Where questionnaires, diary cards and other materials are used, are these relevant to answer the research questions?*		
27.	Adakah bahasa yang digunakan sesuai dengan penyerta kajian? *Is the language used appropriate to the study participants?*		
28.	Adakah mereka ditulis dalam bahasa biasa dan mudah difahami? *Are they written in lay language and easily understood?*		
29.	Di mana berkenaan, adakah Borang Laporan Kes, Borang Peristiwa Buruk dan lain-lain telah disediakan dan adakah disertakan? *Where applicable, have Case Report Forms, Adverse Event forms etc been prepared and are they included?*		
	Isu Etika *Ethical issues*		
30.	Adakah protokol termasuk perbincangan mengenai isu-isu etika? (Lihat Bahagian 2) *Does the protocol include a discussion of ethical issues? (See Section 2)*		
31.	Ada borang keizinan disediakan? Adakah borang ini disertakan? (Lihat Bahagian 3) *Have consent forms been prepared? Are these included? (See Section 3)*		
32.	Ada borang persetujuan disediakan untuk kanak-kanak berusia antara 12 dan 18 tahun? Adakah borang ini disertakan? *Have assent forms been prepared for children aged between 12 and 18 years? Are these included?*		

BAHAGIAN 2
SECTION 2

PROTOKOL (ISU ETIKA)
PROTOCOL (ETHICAL ISSUES)

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
	Proses Memperoleh Keizinan Bermaklumat ***Process For Gaining Informed Consent***		
1.	Adakah penyelidik menerangkan proses di mana keizinan bermaklumat akan diperolehi? *Does the researcher describe the process through which informed consent is to be obtained?*		
2.	Jika keizinan bertulis peserta tidak dapat diperolehi, adakah cadangan menerangkan sebab-sebabnya dan bagaimana persetujuan peserta akan direkodkan? *Where written consent from participants is not possible, does the proposal describe the reasons for this and how the agreement of participants will be recorded?*		
3.	Adakah kajian ini kajian percubaan terkawal berkelompok rawak? *Is this a cluster randomized controlled trial?*		
	• Jika ya *If it is:*		
	— Adakah proses mengambil keizinan bagi kelompok peserta dimasukkan ke dalam kajian diterangkan? *Has the process of taking consent for the clusters to be included in the trial described?*		
	— Jika ini tidak dapat dilakukan, adalah maklumat yang diberikan kepada semua kumpulan masyarakat yang mengambil bahagian di dalam kajian mencukupi? *If this is not possible, is the information provided to all communities participating in the trial sufficient?*		
	— Apakah proses mengambil keizinan daripada individu dalam kelompok sebelum mereka menjalani mana-mana prosedur kajian atau pengumpulan data dinyatakan? *Is the process of taking consent from individuals in the clusters before they participate in any study procedures or data collection described?*		
	Nota: Pemimpin masyarakat tidak boleh memberi 'kebenaran' bagi pihak individu dalam masyarakat mereka bagi tujuan mengambil bahagian dalam kajian rawak terkawal, tetapi kebenaran untuk mendekati individu dalam masyarakat untuk menjemput penyertaan mereka harus diperolehi. ***Note:*** *Community leaders cannot give 'consent' on behalf of individuals in communities to participate in randomized controlled trials, but rather permission to approach individuals in communities to invite their participation.*		
	Populasi Subjek Terancam ***Vulnerable Populations***		
4.	Apakah populasi subjek terancam yang dikaji? (bulatkan populasi terlibat dalam senarai di bawah - lebih dari satu populasi boleh ditandakan) *Is a vulnerable population being studied? (circle the population involved as listed below – more than one population can be marked)*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
	• wanita hamil *pregnant women*		
	• kanak-kanak *children*		
	• remaja *adolescents*		
	• warga emas *elderly persons*		
	• orang dengan masalah mental ataupun masalah tingkah laku *people with mental or behavioural disorders*		
	• banduan *prisoners*		
	• pelarian *refugees*		
	• anggota tentera *military personnel*		
	• mereka yang tidak boleh memberi keizinan (tidak sedar diri) *those who cannot give consent (unconscious)*		
	• Lain-lain *Others* *(*Nyatakan *Specify:* *……)*		
5.	Jika populasi subjek terancam dikaji, adakah justifikasi pemilihan mereka mencukupi? *If a vulnerable population is being studied, is the justification adequate?*		
6.	Ada peruntukan yang mencukupi telah dibuat untuk memastikan bahawa populasi subjek terancam tidak dieksploitasi? *Have adequate provisions been made to ensure that the vulnerable population is not being exploited?*		
	Risiko vs Faedah Dari Kajian ***Risks vs. Benefits Of The Study***		
7.	Adakah risiko vs manfaat terhadap individu dalam kajian ditangani sewajarnya? *Has the individual risk vs. the benefits from research been adequately addressed?*		
8.	Adakah protokol menerangkan sama ada dan bagaimana masyarakat dari mana peserta datang mungkin mendapat manfaat daripada penyelidikan? *Does the protocol describe whether and how communities from which the participants are to be drawn are likely to benefit from the research?*		
9.	Adakah hasil penyelidikan itu mungkin memberi manfaat kepada masyarakat di luar populasi penyelidikan? *Is the research outcome likely to benefit communities beyond the research population?*		
	Autonomi/Insentif/Paksaan ***Autonomy/Incentives/Coercion***		
10.	Apakah reka bentuk kajian bebas dari dorongan peserta mengambil bahagian dalam kajian? *Is the design of the study free of inducements to participate in the research?*		
11.	Adakah peserta penyelidikan bebas untuk tidak menyertai atau meninggalkan penyelidikan itu pada bila-bila tanpa penalti? *Are the research participants free not to participate or to leave the research at any time without penalty?*		
	Privasi / Kerahsiaan *Privacy/Confidentiality*		
12.	Adakah kajian ini menggariskan prosedur bagi melindungi maklumat sulit dan keperluan psiko-sosial peserta? *Does the study outline the procedures for the protection of the privacy and psycho-social needs of the participants?*		
13.	Adakah terdapat mekanisme untuk memastikan kerahsiaan data?		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
	Are there mechanisms to ensure the confidentiality of the data?		
	Pemantauan Keselamatan/Perlindungan ***Monitoring safety/protection***		
14.	Adakah peruntukan wujud dalam cadangan untuk menangani kesan sampingan yang berkaitan dengan penemuan penyelidikan (e.g. perubatan / fizikal / emosi / psikologi) dan penemuan secara kebetulan semasa penyelidikan (e.g. melalui ujian darah dan lain-lain)? *Do provisions exist in the proposal to deal with adverse reactions associated with the research (e.g. medical / physica l/ emotional / psychological) as well as coincidental findings during the course of the research (e.g. through blood tests etc)?*		
15.	Di mana sesuai, adakah peruntukan wujud untuk peserta penyelidikan diberi kaunseling sebelum, semasa dan selepas penyelidikan? *When appropriate, do provisions exist for counselling research participants prior to, during and after the research?*		
16.	Adakah terdapat isu-isu yang boleh menjejaskan keselamatan para penyelidik yang terlibat dalam kajian ini? Adakah permohonan ini menggambarkan bagaimana ia ditangani? *Are there issues that may affect the safety of the researchers involved in the study? Does the application describe how these are addressed?*		
	Jika haiwan digunakan dalam kajian; *If animals are used in the study;*		
	— Adakah penyelidik berpengalaman dalam eksperimen menggunakan spesies haiwan yang dicadangkan? *Are the investigators experienced in experiments using this animal species?*		
	— Adakah penerangan mengenai penggunaan haiwan sesuai dengan kajian / pengajaran yang dicadangkan? *Is the description of animal use appropriate to the study/teaching being proposed?*		
	— Adakah kemudahan bagi jagaan dan perumahan haiwan kajian mencukupi? *Are the facilities for the care and housing of the study animals adequate?*		
	— Adakah prosedur yang dilakukan kepada haiwan diterangkan dengan mencukupi? *Are the procedures to be done to the animals described adequately?*		
	— Adakah terdapat apa-apa prosedur / teknik yang tidak sesuai digunakan? *Are there any inappropriate procedures/techniques being used?*		
	— Apakah kaedah euthanasia sesuai? *Is the method of euthanasia appropriate?*		
	— Adakah pelupusan bangkai haiwan diperuntukkan? *Is the disposal of animal carcasses provided for?*		
	— Adakah terdapat penggunaan apa-apa ejen berbahaya? *Is there the use of any hazardous agents?*		

BAHAGIAN 3
SECTION 3

Borang Keizinan Bermaklumat
INFORMED CONSENT FORMS (ICFs)

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
1.	Adakah ICF disertakan dengan permohonan? *Have the ICFs been submitted with the application?*		
	Format Am dan Kandungan ***General format and content***		
2.	Adakah ICF menjelaskan bahawa peserta adalah diminta untuk mengambil bahagian dalam penyelidikan? *Does the ICF make it clear that the participant is being asked to participate in research?*		
3.	Adakah lembaran maklumat yang digunakan bebas daripada bahasa teknikal dan ditulis dalam bahasa yang mudah difahami serta sesuai dengan tahap pendidikan masyarakat yang berkenaan? *Is the information sheet free of technical terms and written in lay-person's language that is easily understandable and appropriate to the educational level of the community concerned?*		
4.	Adakah ia menerangkan mengapa kajian dilakukan dan mengapa individu itu diminta untuk mengambil bahagian? *Does it describe why the study is being done and why the individual is being asked to participate?*		
5.	Adakah ia menyediakan penerangan sepenuhnya kepada peserta mengenai tujuan, turutan dan kekerapan prosedur yang perlu dijalankan, termasuklah tempoh kajian? *Does it provide participants with a full description of the nature, sequence and frequency of the procedures to be carried out, including the duration of the study?*		
6.	Adakah ia menerangkan sifat dan kemungkinan ketidakselesaan dijangka atau kesan buruk (termasuk risiko psikologi dan sosial) jika ada, dan apa yang telah dilakukan untuk meminimumkan? Adakah ia menyatakan tindakan yang akan diambil sekiranya perkara di atas berlaku? *Does it explain the nature and likelihood of anticipated discomfort or adverse effects (including psychological and social risks) if any, and what has been done to minimize these? Does it state the action to be taken should these occur?*		
7.	Adakah ia menggariskan prosedur untuk melindungi kerahsiaan data, dan jika kerahsiaan tidak mungkin dipelihara disebabkan oleh reka bentuk kajian, adakah hal ini disampaikan kepada semua orang yang berkaitan? *Does it outline the procedures to protect the confidentiality of data, and if confidentiality is not possible due to the research design, has this been conveyed to all relevant persons?*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
8.	Adakah ia memberitahu para peserta penyelidikan yang penyertaan mereka adalah secara sukarela dan mereka bebas untuk memutuskan sama ada menerima atau tidak untuk menyertai, atau menarik diri dari penyelidikan ini pada bila-bila masa dan untuk apa-apa sebab tanpa penalti selanjutnya, sama ada peribadi atau profesional, terhadap penjagaan perubatan mereka di masa depan? *Does it inform the research participants that their participation is voluntary and they are free to decide whether or not to participate, or to withdraw at any time and for any reason without further penalty either personal or professional affecting their future medical care?*		
9.	Adakah ia menggambarkan sifat apa-apa pampasan atau pembayaran balik akan disediakan (dari segi masa, perjalanan, manusia kehilangan hari kerja, dan lain-lain)? *Does it describe the nature of any compensation or reimbursement to be provided (in terms of time, travel, man-days lost from work, etc)?*		
10.	Adakah ia menggariskan bagaimana peserta akan dimaklumkan mengenai kemajuan dan hasil penyelidikan? *Does it outline how participants will be informed of the progress and outcome of the research?*		
11.	Adakah ia memberikan nama dan maklumat perhubungan bagi seseorang yang boleh memberikan maklumat lanjut mengenai projek penyelidikan pada bila-bila masa? *Does it provide the name and contact information of a person who can provide more information about the research project at any time?*		
12.	Adakah peruntukan telah dibuat bagi subjek kajian yang tidak mampu membaca dan menandatangani borang keizinan bertulis (seperti pesakit yang buta huruf)? *Has a provision been made for subjects incapable of reading and signing the written consent form (e.g. illiterate patients)?*		
13.	Adakah peruntukan wujud untuk peserta yang tidak berupaya untuk memberikan persetujuan peribadi (e.g. seperti disebabkan faktor budaya, usia kanak-kanak atau remaja yang mengikut undang-undang negara di mana penyelidikan yang sedang berlaku tidak mencukupi untuk memberi keizinan bermaklumat, peserta yang mempunyai penyakit mental, dan lain-lain) untuk menyatakan keputusan mereka? *Does a provision exist for participants incapable of giving personal consent (e.g. because of cultural factors, children or adolescents less than the legal age for consent in the country in which the research is taking place, participants with mental illness, etc) to express their decision?*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
	Kertas Soal Selidik *Questionnaires*		
14.	Jika kertas soal selidik digunakan dalam kajian ini, adakah lembaran maklumat dan borang keizinan menggambarkan jenis dan tujuan soalan-soalan yang ditanya, dan jika berkenaan, menyatakan jika terdapat soalan yang boleh memalukan peserta? *If questionnaires are used in this research, does the information sheet and consent form describe the nature and purpose of the questions to be asked, and if applicable, state if some questions may prove embarrassing for the participant?*		
15.	Nyatakan sekiranya peserta adalah bebas untuk tidak menjawab apa-apa soalan? *State if the participant is free to not answer any question?*		
16.	Di mana berkenaan, adakah ia dimaklumkan bahawa temu bual (samada yang mendalam atau perbincangan kumpulan fokus) berkemungkinan untuk dirakam audio atau video? *Where applicable, has it been made known that the interviews (in-depth or focus group discussions) are likely to be audio or video taped?*		
	Jika berkenaan, adakah dinyatakan bagaimana dan untuk berapa lama rakaman akan disimpan? *Where applicable, is it mentioned how and for how long are the recordings are going to be stored?*		
17.	**Bahan Biologi Manusia (tisu, sel-sel, cecair, bahan genetik atau maklumat genetik)** ***Human Biologic Materials (tissues, cells, fluids, genetic material or genetic information)***		
18.	Jika bahan biologi manusia dikumpulkan, adakah lembaran maklumat dan borang keizinan menerangkan dalam bahasa yang mudah difahami, jenis, bilangan dan isipadu sampel yang akan diambil dan prosedur yang digunakan untuk mendapatkannya? *If human biologic materials are collected, does the information sheet and consent form describe in simple language the nature, number and volume of the samples to be obtained and the procedures to be used to obtain them?*		
19.	Adakah prosedur untuk mendapatkan sampel ini adalah rutin atau eksperimental dan jika rutin, adakah ia lebih invasif daripada biasa? *Are the procedures for obtaining these samples are routine or experimental and if routine, are they more invasive than usual?*		
20.	Apakah penggunaan sampel dalam kajian ini diterangkan dan adakah penggunaan jangka panjang yang dirancang (selepas selesai kajian ini)? *Is the use of these samples described in the study and is there longer term usage planned (after the completion of this study)?*		

Bil *No*	**Perkara** *Item*	**Keputusan** *Decision*	**Catatan** *Remarks*
21.	Adakah ia mengandungi peruntukan bagi peserta kajian untuk membuat keputusan mengenai penggunaan spesimen yang tertinggal (tidak dihabiskan) dalam penyelidikan pada masa depan yang berbentuk kajian terhad, kajian nyata atau kajian lain yang belum dapat dinyatakan pada masa sekarang? *Does it include a provision for the subject to decide on the use of left over specimens in future research of a restricted, specified or unspecified nature?*		
22.	Adakah dinyatakan untuk berapa lama spesimen boleh disimpan dan bagaimana mereka akan dimusnahkan akhirnya? *Is it mentioned for how long the specimens can be kept and how they will finally be destroyed?*		
23.	Adakah dinyatakan bahawa ujian genetik / analisis genomik akan dijalankan ke atas bahan-bahan biologi manusia, di mana berkenaan? *Is it mentioned that genetic testing/genomic analysis will be carried out on the human biologic materials, where applicable?*		
	Maklumat Pengambilan Peserta ***Participant Recruitment Material***		
24.	Jika dirancang untuk menggunakan bahan maklumat pengambilan peserta (e.g. iklan, notis, artikel media, transkrip mesej radio), adakah bahan tersebut: *If it is planned to use participant recruitment material (e.g. advertisements, notices, media articles, transcripts of radio messages), is the material:*		
	— disediakan dalam bahasa Melayu, Inggeris dan/atau dalam bahasa tempatan yang lain? *provided in both Malay, English and in the other local languages?*		
	— bolehkah saranan yang dibuat dipenuhi? *can the claims made be supported?*		
	— adakah bahan yang disediakan mengandungi janji-janji yang tidak sesuai dalam persekitaran penyelidikan (e.g. menyediakan insentif yang tidak wajar, menekankan pemberian imbuhan)? *do the materials make promises that may be inappropriate in the research setting (e.g. provide undue incentives, emphasize remuneration)?*		

Keputusan Jawatankuasa Etika Penyelidikan UPNM
NDUM Research Ethics Committee Decision

Tiada / Ada isu etika penyelidikan/pengajaran dalam permohonan
There are / There are no *research/teaching ethical issues in the application*

Jika ada isu etika, pemohon di minta meneliti permohonan yang dikemukakan dan membuat penambah baikan serta mengemukakan kembali cadangan bersama ICF serta lain-lain borang yang diperlukan kepada JKEP dengan seberapa segara untuk ditelitikan semula oleh JKEP

If there are any ethical issues, applicants are requested to review the application submitted and make improvements then resubmit the application with the ICF and other forms required to the JKEP as soon as possible so the application can be reviewed by the JKEP

Pengerusi: …….. ……..
Chairman *(Nama Name)* *Tandatangan Signature*

Ahli:
Members

1. ……... ……...
(Nama Name) *Tandatangan Signature*

2. ……... ……...
(Nama Name) *Tandatangan Signature*

3. ……... ……...
(Nama Name) *Tandatangan Signature*

4. ……... ……...
(Nama Name) *Tandatangan Signature*

5. ……... ……...
(Nama Name) *Tandatangan Signature*