

GUIDELINES For **RESEARCH**

Involving Human Subjects

ETHICS COMMITTEE FOR RESEARCH
INVOLVING HUMAN SUBJECTS

JAWATANKUASA ETIKA UNIVERSITI UNTUK
PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA

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1.0 INTRODUCTION TO JKEUPM

1.1 Overview

The Ethics Committee for Research Involving Human Subjects Universiti Putra Malaysia (Jawatankuasa Etika Universiti Penyelidikan Melibatkan Manusia) started as The Medical Research Ethics Committee. This committee included the Animal Ethics component in 1998. Recently, however, the Animal Ethics Committee has been made as an independent entity dealing only with animal care and use under the official name of IACUC (Institutional Animal Care and Use Committee).

The Ethics Committee for Research Involving Human Subjects (more commonly referred to with its Malay acronym, JKEUPM) was established under the authority of the Senate of Universiti Putra Malaysia on 8 September 2011. JKEUPM is specifically given the task of protecting research participants, and to make researchers be responsible in ensuring that the basic principles regarding the use of human subjects are observed in their research. JKEUPM is guided in its stance and decisions by the principles expressed in the Declaration of Helsinki (2008). The Declaration, which was first developed by the World Medical Association (WMA) in 1964, was intended to outline a number of ethical principles that need to be adhered to when medical research involving human subjects is carried out. There are numerous principles listed in the Declaration, but it states above all that the well-being of the human subject of the research must take precedence over all other interests and regulations, including national and international regulatory requirements.

In addition to the Declaration, a number of provisions from the Nuremberg Code of 1946 which pertain to the gathering of information in social science fields have also been utilised in the present set of guidelines, particularly the emphasis on protecting a subject's privacy, accurately representing the aims of a particular study to a subject, and the necessity of safeguarding a subject's well-being by not deliberately placing him/her in situations that can be deemed compromising.

JKEUPM is also guided by the National and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS). JKEUPM recognizes ethical clearance from other Ethics Committees, e.g. from the Ministry of Health and other universities, which are recognized by the National Pharmaceutical Control Bureau (BPFK), Ministry of Health Malaysia. Thus, a research project which has received ethical clearance from any of these other committees does not require a separate clearance from JKEUPM. However, if the research project involves either

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undergraduate or postgraduate students at any point, a JKEUPM ethical clearance is needed.

The JKEUPM seeks to fulfil the requirements for international assurances and is established and functions in accordance with Malaysian law and regulations.

1.2 Scope of Authority

The JKEUPM has the authority to:

- a. Approve, disapprove or modify studies based upon consideration of aspects related to human subject protection;
- b. Request progress reports from investigators and oversee the conduct of the study;
- c. Suspend or terminate the approval of a study; and
- d. Place restrictions on a study.

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2.0 ORGANISATIONAL STRUCTURE

Please refer to Appendix A

2.1 Overview

JKEUPM is composed of at least five (5) appointed members, including the chairperson. The members shall include at least one member whose primary area of interest is in medical science, one in non-scientific fields, and one independent of JKEUPM.

2.2 Membership

2.2.1 Appointment of members

The Deputy Vice Chancellor (Research and Innovation) (DVC) is responsible for the appointment of committee members. Members are appointed based on their research interests, ethical and/or scientific knowledge and expertise, and commitment to JKEUPM. JKEUPM members are appointed for a term period of three (3) years. The committee will co-opt members with specialized knowledge where necessary. Appointments may be renewed by the DVC with no limit to the number of renewals. JKEUPM may include new members every few years, but will, at the same time, strive to ensure continuity within the Committee.

2.2.2 Disqualification, removal and replacement of members

Members will be disqualified and removed if they are absent for three (3) consecutive meetings without a valid reason. The DVC (Research and Innovation) reserves the right to replace the disqualified member.

2.2.3 Liability coverage

The members of JKEUPM members work on behalf of the University and are indemnified by the University against all litigation that may arise from the work carried out by the Committee.

2.2.4 Conflicts of interest

The members of JKEUPM are required to sign a Confidentiality/ Conflict of Interest Agreement before the start of their term. This will help to protect the confidentiality of all information disclosed to the JKEUPM in the course of its work. Additionally, members must disclose any interest or involvement—financial, professional or otherwise—in a project or proposal being reviewed, monitored, and/or audited by the JKEUPM.

2.2.5 Use of Independent Consultants

The committee will decide whether to appoint Independent Experts to deliberate on specific ethical issues. The Independent Experts are appointed by the DVC (Research and Innovation). Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, science, law, ethics, religion, etc.

2.3 Roles and Functions

JKEUPM will review all research protocols involving human subjects, and will ensure the protection of research subjects. Additionally, the Committee will disseminate information and procedures to researchers in the university which pertain to ethical guidelines to be adhered to when undertaking research involving human subjects. The members JKEUPM shall have various backgrounds to promote a complete and adequate review of the research activities commonly conducted by the UPM researchers.

2.4 JKEUPM Secretariat**2.4.1 Functions and duties****Secretariat office**

The Research Management Centre (RMC), Office of the Deputy Vice Chancellor (Research and Innovation) will be responsible for maintaining records and other secretarial duties of JKEUPM, including:

- a. Managing the applications submitted to JKEUPM;
- b. Providing advice and information regarding rules and regulation in ethical aspects through communication with the JKEUPM members to the investigator;
- c. Preparation for Meeting and Communication Records; and
- d. Monitoring protocol implementation.

Requirements for the submission of a research project**Documents to be submitted**

- a. Documents for expedited review (2 sets)
- b. Documents for interview (16 sets)

2.4.2 Administrative checklist

The secretariat will check all applications.

3.0 APPLICATION REQUIREMENTS**3.1 Applicant Related Requirements****3.1.1 Academic staff as an investigators****Competency and qualification to conduct research**

The researcher who intends to conduct research must be competent and able to provide proof of the appropriate level of academic qualification. Additionally, the researcher must have attended appropriate training, and possess sufficient experience in conducting research projects. Researcher(s) who do not meet the criteria will be allowed to conduct research provided they are supervised by those who have the qualification and the competency.

3.1.2 Students as investigators

The research for undergraduate and postgraduate students must be supervised by qualified and competent academic staff. An undergraduate student cannot be the Chief Investigator. In special circumstances, a graduate student may be allowed. A postgraduate student is allowed to be the Chief Investigator following approval from his/her supervisory committee.

3.1.3 Vetting by supervisory/research committee

It is the responsibility of the supervisory committee (for students) or the Faculty/Department research committee (for staff) to ensure that the scientific/empirical content of the proposal is in order. However, the JKEUPM reserves the right to reject any proposal which, in the Committee's opinion, is scientifically/empirically unsound.

3.2 Subject Related Requirements**3.2.1 Research involving children (under age 18)**

Before undertaking research involving children, the investigator must ensure that:

- a. Children will not be involved in research that might equally well be carried out with adults;
- b. The purpose of the research is the acquisition of knowledge which is relevant to the health needs of children;
- c. A parent or legal guardian of each child has given proxy consent;
- d. The consent of each child has been obtained to the extent of the child's capabilities;

- e. The child's refusal to participate in research must always be respected, unless according to the research protocol the child would receive therapy for which there is no medically accepted alternative;
- f. The risk presented by interventions not intended to benefit the individual child is low and commensurate with the importance of knowledge to be gained; and
- g. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child as any other available alternative.

3.2.2 Research involving vulnerable populations

Vulnerable populations are generally defined as individuals who are not able to give informed consent or who are at risk of coercion. Vulnerable research subjects include the following: children, prisoners, pregnant women, and persons who are handicapped, mentally disabled, economically disadvantaged, or educationally disadvantaged. However, these categories are not exclusive, leaving open the interpretation of vulnerability.

Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- a. Such persons will not be subjects of research that might equally well be carried out on persons in full possession of their mental faculties;
- b. The purpose of the research is the acquisition of knowledge which is relevant to the particular health needs of persons with mental or behavioural disorders;
- c. In the case of vulnerable incompetent subjects, informed consent is obtained from the legal guardian or other duly authorized person;
- d. The degree of risk attached to interventions that are not intended to benefit the individual subject is low and commensurate with the importance of the knowledge to be gained; and
- e. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual subject as any other available alternative.

3.3 Sound Proposals

3.3.1 Study methodology

The methodology used in a particular study must adhere to the following:

- a. Sample size calculation, when appropriate, must be explicitly stated.
- b. If the study involves the use of any new medication or health supplement, proof of safety studies in animals must be submitted.
- c. Any clinical trial should be carried out in accordance with GCP/ICH Guidelines.
- d. If non-standard or new formulations are used, the manufacturing laboratories must comply with Good Manufacturing Practice (GMP) guidelines.
- e. If non-standard devices are used, proof of safety (electrical, mechanical, etc.) must be submitted.
- f. If laboratory analyses are involved, the laboratories must be certified.
- g. If a non-standard technique of collecting samples from the body is used, proof of safety of this technique must be submitted.
- h. If blood is to be taken, the volume to be taken must be stated in mls and teaspoons/ tablespoons per visit throughout the study.
- i. Assent is required for studies involving subjects aged under 18 years.
- j. The Respondent Information Sheet should state whether the investigated product contains porcine-, bovine-, or other animal-based products.

3.3.2 Scientific design and conduct of study

Studies must be designed and conducted in cognizance of:

- a. The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.
- b. The justification of predictable risks and inconveniences weighed against the anticipated benefits for research participants and the concerned communities.
- c. The justification for the use of controlled arms.
- d. Criteria for prematurely withdrawing research participants.
- e. Criteria for suspending or terminating the research as a whole.

- f. The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB).
- g. The adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
- h. The manner in which the results of the research will be reported and published.

3.3.3 Study population

The recruitment of study population must include the following:

- a. Description of selection criteria
- b. Number of subjects
- c. Gender
- d. Age range
- e. Any special characteristics: a. inclusion criteria; b. exclusion criteria
- f. Relationship between investigator and subjects
- g. Emolument or compensation for participation (to subject)

3.4 Application form and related documents

3.4.1 Application form and checklist (please refer to Appendix B) JKEUPM Application Form (Form A)

- a. Ensure that all investigators (from within and outside the institution) involved in the research project are listed.
- b. The Principle Investigator must be able to independently collect the data, and will be legally liable for any event resulting from the research process.
- c. The Principle Investigator need not be the same person as the Principle Investigator under whose name the grant was applied.
- d. Students who are working on a related project under one supervisor/Principal Investigator may apply for ethical clearance under one application. However, the names of the students and their respective roles in the project must be stated clearly.
- e. Related subprojects under one grant funding or project should be applied as one application.

3.4.2 Subject's information sheet and informed consent form

Respondent's Information Sheet

In the respondent's information sheet, the researcher should observe the following:

- a. Avoid making any unjustified claims regarding the benefits of participating in the research.

- b. State common/important adverse events under 'risks'.
- c. The Chief Investigator must sign the application form, and if necessary, present the proposal to JKEUPM.
- d. The supervisor of any research is liable for consequences arising from the project.
- e. The investigator shall safeguard the confidentiality of all information, data and samples related to the research, which will be handled in a controlled fashion. Such materials are categorized as confidential, and cannot be disclosed to another person without the express permission of relevant research authorities. The subject's name cannot be disclosed and cannot be published in any public document.

Ensure that all essential information is available to prospective research subjects. Use the UPM/TNCPI/RMC/JKEUPM/FORM B1 or UPM/TNCPI/RMC/JKEUPM/FORM B2 (please refer Appendix C and Appendix D) template as a guide. The consent form needs to be submitted in Malay, English, or any other language relevant to participants. In addition to the information listed on the template, the following must be explicitly stated if it forms part of the research protocol:

- a. The volume and frequency of blood to be taken.
- b. The use of any substance taken into, or applied onto the body, including medications and health supplements.
- c. The medical practitioner to contact if the subject feels any discomfort during the duration of the study.
- d. Duration of storage of sample (e.g., blood, DNA)

Informed Consent Form

General requirements:

- a. The JKEUPM should be appropriately informed by researchers and target populations of the impact of the research it has approved.
- b. As the Committee has been given the specific task of protecting research participants, the investigator or supervisor is responsible for ensuring that the basic principles regarding the use of human subjects are observed, as listed in the guidelines below, which are in accordance with Declaration of Helsinki/Nuremberg Code.
- c. The researcher must submit the consent form which is relevant to his/her study and field of studies.
- d. For all research involving human subjects, the

investigator must obtain the informed consent of the prospective subject; or in the case of an individual who is not capable of giving consent, the proxy consent of a properly authorized representative. Research involving human subjects includes:

- i. Studies of a physiological, biochemical or pathological process, or of the response to a specific intervention, whether physical, chemical or psychological, in healthy subjects or patients;
 - ii. Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate specific generalizable response to these measures against a background of individual biological variation;
 - iii. Studies designed to determine the consequence to individuals and communities of specific preventive or therapeutic measures; and
 - iv. Studies concerning human health-related/socio-cultural-related behavior or phenomenon in a variety of circumstances and environments.
- e. Before requesting an individual's consent to participate in research, the investigator must provide the individual with following information, in a language that he or she is capable of understanding:
- i. That each individual is invited to participate as a subject in research;
 - ii. The aims and methods of research;
 - iii. The expected duration of the subject's participation;
 - iv. The benefits that might reasonably be expected of results to the subject or to others as an outcome of the research;
 - v. Any foreseeable risks or discomfort to the subject, associated with participation in the research;
 - vi. Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
 - vii. That therapy will be provided free of charge for specific types of research related injury; and
 - viii. That the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.

- f. Obligations of investigators regarding informed consent includes the following:
 - i. Communicate to the prospective subject all the information necessary for decision making for informed consent.
 - ii. Give the prospective subject full opportunity and encouragement to ask questions.
 - iii. Exclude the possibility of unjustified deception, undue influence and intimidation.
 - iv. Seek consent only after the prospective subject has adequate knowledge of the relevant facts and of the consequences of participation, and has sufficient opportunity to consider whether to participate.
 - v. As a general rule, obtain from each prospective subject a signed form as evidence of informed consent.
 - vi. Renew the informed consent of each subject if there are material changes in the conditions of procedures of the research.
- g. Inducement to participate:
 - i. Subjects may be paid for inconvenience and time spent and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. However, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment. The Ethical Review Committee should approve all payments, reimbursements and medical services to be provided to the research subject.
- h. Ensure that all the relevant components (name of participant, IC no. etc) are in the Informed Consent Form. The consent form needs to be submitted in Malay, English or any other language relevant to the participants. The form must include:
 - i. Clinical Trial Checklist (if applicable);
 - ii. Questionnaire (if applicable);
 - iii. Full proposal;
 - iv. Curricular Vitae with Good Clinical Practice (GCP) certificate (if applicable) of Principal Investigator and members (1 set only);

- v. Letter of authorization from relevant agencies if the research is to be conducted at a site under the jurisdiction of another agency (e.g., a school, municipality, etc), ensure that a copy of the permission/approval letter from the agency is attached. The letter seeking permission is not sufficient;
- vi. Complete document submission;
- vii. A JKEUPM ID;
- viii. GCP certification for ALL investigators involved in clinical trials.

3.5 Retention of Documents

3.5.1 Archiving

Documents will be archived in secure room and will be kept for three (3) or seven (7) years after completion.

4.0 REVIEW PROCESS

4.1 Submission of Application and Procedure

- a. It is the responsibility of the UPM investigator to apply to JKEUPM for approval prior to conducting research involving human subjects. No research can commence until the investigator has obtained approval from the JKEUPM.
- b. For review procedure timelines, please refer to Appendix E.

4.2 JKEUPM Meeting Procedures

The JKEUPM secretariat will review all submissions. Study documents will be circulated to selected JKEUPM members who will review the documents and submit their recommendations and comments. Applications for JKEUPM's approval will be circulated to the members at least one week prior to the meeting.

4.3 Applications Requiring Interviews or Presentations

The Investigator will be invited for an interview at a scheduled meeting. JKEUPM members present at meeting will decide on the suitability of the study, and the decision will be communicated to the investigator at a later date. The decision provided by the Committee will indicate either that:

- a. The study is approved/rejected, or requires revision; or
- b. Changes to study documents are necessary, which is to be submitted by the investigator.

4.3.1 Quorum requirements

- a. A minimum of more than 50% of total membership must be present at a meeting in order to issue valid advice and/or come to a decision.
- b. Professional qualifications of the quorum requirement shall consist of at least one member whose primary area of expertise is in a non-scientific area (layperson).

4.3.2 Decision

- a. The decision to approve the application is by consensus. In the event that no consensus is reached, the chairperson will make the final decision.
- b. Members with conflicts of interest should not participate in the discussion nor vote on the effected application, which should be reflected in the minutes of the meeting.
- c. A letter signed by the chairperson will be sent to Chief Investigator within three weeks from the assigned date of presentation in normal circumstances.

4.4 Applications for Expedited Reviews

An expedited review is defined as an application that is not required to undergo the interview process, and which will commonly be completed in four (4) weeks. These applications will be circulated among members for comments and decision making. Expedited reviews require a quorum of at least one member. The following are the criteria of expedited reviews:

- a. Protocols involving interviews/questionnaires/surveys/group work/conversations of a non-confidential nature not likely to be detrimental to the status or interests of subjects, and not likely to offend the sensibilities and sensitivities of subjects.
- b. Those that involve collection of biological samples by non-invasive means (e.g., collection of body fluids or excreta, collection of hair or nail clippings).
- c. Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely used in clinical practice and using medical devices approved by national regulatory authorities.
- d. Research involving data, documents or specimens that have already been collected or will be collected for ongoing medical treatment or investigation.
- e. Continuing review of research previously approved with no modification to original protocol and studies that have taken place, and at no identifiable additional risk to subjects.
- f. Modification or amendment of approved protocol:
 - i. Administrative revisions, such as correction of typographical errors.
 - ii. Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
 - iii. Research activity with minimal risk.
 - vii. Minor changes to approved research activities that do not increase risk to subjects.

The JKEUPM Chairperson will examine the recommendations and comments of the reviewers, and decide on the study. If the Chairperson is unable to come to a decision, or if recommended by the reviewers, the study will be scheduled for a JKEUPM meeting. The decision will be communicated to the investigator at a later date.

4.5 Application from Overseas

All applications from overseas must obtain the approval of relevant Malaysian agencies such as Economic Planning Unit (EPU), Ministry of Health, Ministry of Education etc., and ethics approval from JKEUPM, as well as their own host institutions.

4.6 Application Approval

4.6.1 Approval

An approval is given when the committee is satisfied that the application has fulfilled all requirements.

4.6.2 Amendments to approved protocols

Any amendments and deviations from approved protocols (including Patient Information Sheet, Informed Consent Form, and other supporting documents) shall be informed in writing to the committee for review and approval; the failure to do so will result in JKEUPM's approval rendered null and void.

4.6.3 Follow-up reviews for approved protocols

Monitoring will be carried out for clinical trials, the reports of which will be sent to JKEUPM by the researcher by 31st December of each year. The researcher shall report to the committee on any Suspected Unexpected Serious Adverse Reactions (SUSARs) for review.

4.6.4 Appeal process for rejected protocols

The decision of JKEUPM to approve or reject a particular study is final. Researchers who have had their applications rejected are however encouraged to submit a new application.

5.0 SUBMISSION OF REPORTS SPECIFIC FOR CLINICAL TRIALS

5.1 Follow-up report of clinical trial for continuation of study

Please refer to 4.6.3 on follow-up review of clinical trials. All research that requires continuation of study must submit the report before approval for continuation is given.

6.0 APPENDICES

APPENDIX A

JKEUPM MEMBERS

PROF. DR. NORLIJAH OTHMAN (Chairperson)

Professor of Paediatrics & Dean, Faculty of Medicine and Health Sciences

PROF. DR. ZAMBERI SEKAWI

Professor of Medical Microbiologist & Deputy Dean (Research and Internationalization), Faculty of Medicine and Health Sciences

PROF. DATO' DR. LYE MUNN SANN

Professor of Medical Statistics, Department of Community Health, Faculty of Medicine and Health Sciences

PROF. DR. TENGKU AIZAN ABD HAMID

Professor of Gerontology & Director, Institute of Gerontology

PROF. DR. LEKHRAJ RAMPAL

Professor of Medical Statistics, Department of Community Health, Faculty of Medicine and Health Sciences

PROF. DR. ELIZABETH GEORGE

Professor of Pathology, Department of Pathology, Faculty of Medicine and Health Sciences

PROF. DR. LIM THIAM AUN

Professor of Anaesthesiology, Department of Surgery, Faculty of Medicine and Health Sciences

PROF. DR. WAN OMAR ABDULLAH

Professor of Medical Parasitology, Department of Medical Microbiology & Parasitology, Faculty of Medicine and Health Sciences

PROF. DR. PATIMAH ISMAIL

Professor of Biomedicine, Department of Biomedical Sciences, Faculty of Medicine and Health Sciences

ASSOC. PROF. DR. JOHNSON STANSLAS

Associate Professor of Pharmacology and Therapeutics, Department of Medicine, Faculty of Medicine and Health Sciences

ASSOC. PROF. DR. MANSOR ABU TALIB

Associate Professor of Guidance and Counselling, Department of Human Development and Family Studies Faculty of Human Ecology & Director, Alumni Center

ASSOC. PROF. DR. NORITAH OMAR (Lay Person)

Associate Professor of English Language, Department of English Language, Faculty of Communication and Modern Languages

Dr. ROJANAH KAHAR (Lay Person)

Senior Lecturer of Department of Human Development and Family Studies, Faculty of Human Ecology

TAN SRI DATO' NAPSIAH OMAR (Independent Member)

Chairman, National Population and Family Development Board

JKEUPM SECRETARIAT

SUZITA RAMLI

Science Officer, Research Management Centre,
Deputy Vice Chancellor (Research & Innovation) Office, UPM

5.	Potential risks of the study			
	a) Psychological risks / harm (which might make subject demeaned, embarrassed, worried or upset)			
	b) Physical risks			
	c) Social risks / harm. Loss of status, privacy and /or reputation			
6.	Competency of Investigators in carrying out research / Procedures			
	b) CVs of all research participants/supervisors			
	c) Investigators have experience conducting similar research			
7	Respondent's information sheet (language used must be appropriate to the subject's age and educational background) Information a-k available to subjects (letter of information separate from consent form): describing disease / condition to be evaluated in the research			
	The respondent's information sheet must include the following (please refer to Appendix C):			
	a) Proper translations in language understood by respondent			
	b) Disease evaluated			
	c) Drug evaluated			
	d) Others			
	e) Aim of study			
	f) Why the subject is chosen for the research			
	g) Expected outcome			
	h) Alternative treatment available			
	i) Side-effects of participating in the study			
	j) Organization and funding of research			
	k) Emolument for subjects			
8.	Study Site			
9.	Study Insurance for subjects			
10.	Informed consent form (please refer to Appendix C for sample consent form)			
	a) Appropriate language (language used must be appropriate to the subject's age and educational background)			
	b) Criteria should include reading and understanding of subject information sheet			

11.	Research funding and approval status			
	a) University			
	b) Government			
	c) Private/Company			
12.	d) Others			
	Vetting from other committees (Student's proposal must be presented to the Supervisory Committee and be endorsed by the Main Supervisor before applying for JKEUPM approval)		Investigator/Main Supervisor Signature:	
	a) Has the proposal been vetted by other committees? (e.g. supervisory committees, research committees)		Name:	
	b) If yes, please specify committee.		Date:	
			

i) First Review

Comments by JKEUPM:	
Remarks:	
Please tick (√)	
Approved	
Requires amendments	
Resubmission / Rejected	
Date:	

ii) Second Review

Comments by JKEUPM:	
Remarks:	
Please tick (√)	
Approved	
Requires amendments	
Resubmission / Rejected	
Date:	

APPENDIX C



**JAWATANKUASA ETIKA UNIVERSITI UNTUK
PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA**

FORM B1: RESPONDENT'S INFORMATION SHEET AND CONSENT

Please read the following information carefully and do not hesitate to discuss any questions you may have with the researcher.

1. **STUDY TITLE :**
2. **INTRODUCTION:**
3. **WHAT WILL YOU HAVE TO DO?**
4. **WHO SHOULD NOT PARTICIPATE IN THE STUDY?**
5. **WHAT WILL BE THE BENEFITS OF THE STUDY:**
(a) **TO YOU AS THE SUBJECT?**
(b) **TO THE INVESTIGATOR?**
6. **WHAT ARE THE POSSIBLE RISKS?**
7. **WILL THE INFORMATION THAT YOU PROVIDE AND YOUR IDENTITY REMAIN CONFIDENTIAL?**
8. **WHO SHOULD YOU CONTACT IF YOU HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?**

Please initial here if you have read and understood the contents of this page _____

9. CONSENT

I.....Identity Card No.....
address
..... hereby voluntarily agree to take part in
the research stated above *(clinical /drug trial/video recording/ focus group/
interview-based/ questionnaire-based).

I have been informed about the nature of the research in terms of methodology, possible adverse effects and complications (as written in the Respondent's Information Sheet). I understand that I have the right to withdraw from this research at any time without giving any reason whatsoever. I also understand that this study is confidential and all information provided with regard to my identity will remain private and confidential.

I* wish / do not wish to know the results related to my participation in the research

I agree/do not agree that the images/photos/video recordings/voice recordings related to me be used in any form of publication or presentation (if applicable)

* delete where necessary

Signature Signature
(Respondent) (Witness)

Date :..... Name :.....

I/C No. :.....

I confirm that I have explained to the respondent the nature and purpose of the above-mentioned research.

Date Signature
(Researcher)



**JAWATANKUASA ETIKA UNIVERSITI UNTUK
PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA**

BORANG B1: PENERANGAN DAN PERSETUJUAN RESPONDEN

Sila baca maklumat berikut dengan teliti. Sekiranya anda mempunyai sebarang pertanyaan, sila kemukakan kepada penyelidik.

1. **TAJUK KAJIAN**
2. **PENGENALAN**
3. **APAKAH YANG PERLU ANDA LAKUKAN?**
4. **SIAPA YANG TIDAK BOLEH MENYERTAI KAJIAN INI?**
5. **APAKAH FAEDAH MENYERTAI KAJIAN INI?**
 a) **KEPADA ANDA SEBAGAI PESERTA?**
 b) **KEPADA PENYELIDIK?**
6. **ADAKAH IA BERISIKO?**
7. **ADAKAH MAKLUMAT DAN IDENTITI SAYA KEKAL RAHSIA?**
8. **SIAPA YANG SAYA PERLU HUBUNGI SEKIRANYA SAYA MEMPUNYAI SOALAN TAMBAHAN SEMASA MENGIKUTI PENYELIDIKAN INI?**

Sila tandatangan di sini sekiranya anda telah membaca dan memahami kandungan halaman ini _____

9. PERSETUJUAN

Saya No Kad Pengenalan
 beralamat
 dengan ini bersetuju untuk
 mengambil bahagian secara sukarela dalam penyelidikan yang tersebut di atas
 * (kajian klinikal/percubaan ubat-ubatan/rakaman video/kumpulan sasaran/
 temuduga/ soal selidik).

Saya telah diberi penjelasan secara menyeluruh mengenai penyelidikan ini dari segi metodologi, risiko dan komplikasi (seperti tertulis pada Helaian Penerangan Responden). Saya memahami bahawa saya berhak menarik diri dari penyelidikan ini pada bila-bila masa tanpa memberi sebarang alasan. Saya juga memahami bahawa sebarang maklumat yang berkaitan identiti saya akan dirahsiakan.

Saya* berminat / tidak berminat untuk mengetahui keputusan kajian yang melibatkan saya.

Saya setuju/tidak bersetuju untuk imei/gambar/rakaman video/ rakaman suara digunakan dalam apa jua bentuk penerbitan atau pembentangan. (sekiranya berkaitan).

*potong yang tidak berkenaan

Tandatangan Tandatangan
 (Responden) (Saksi)

Tarikh : Nama :
 No. K/P:

Saya mengesahkan bahawa saya telah menerangkan kepada responden ini sifat dan tujuan penyelidikan yang tersebut di atas.

Tarikh Tandatangan
 (Penyelidik)

APPENDIX D



**JAWATANKUASA ETIKA UNIVERSITI UNTUK
PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA**

**FORM B2: RESPONDENT'S INFORMATION SHEET AND GUARDIAN'S/
PARENT'S CONSENT**

Please read the following information carefully. Do not hesitate to discuss any questions you may have with the researcher.

1. **STUDY TITLE :**
2. **INTRODUCTION:**
3. **WHAT WILL YOU HAVE TO DO?**
4. **WHO SHOULD NOT PARTICIPATE IN THE STUDY?**
5. **WHAT WILL BE THE BENEFITS OF THE STUDY:**
(a) **TO YOU AS THE SUBJECT?**
(b) **TO THE INVESTIGATOR?**
6. **WHAT ARE THE POSSIBLE RISKS?**
7. **WILL THE INFORMATION THAT YOU PROVIDE AND YOUR IDENTITY REMAIN CONFIDENTIAL?**
8. **WHO SHOULD YOU CONTACT IF YOU HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?**

Please initial here if you have read and understood the contents of this page _____

9. GUARDIAN'S/PARENT'S CONSENT

I.....Identity Card No.....
address
..... hereby voluntarily agree to allow
my *son / daughter / ward to take part in the research
stated above *(clinical/ questionnaire/drug trial/video recording/ focus group/
interview).

I have been informed about the nature of the research in terms of methodology,
possible adverse effects and complications (as written in the Respondent's
Information Sheet). I understand that my *son / daughter / ward has the right
to withdraw from this research at any time without giving any reason whatsoever.
I also understand that this study is confidential and all information provided
with regard to the identity of my* son / daughter / ward will remain private and
confidential.

I* wish / do not wish to know the results related to my my *son's / daughter's /
ward's participation in the research

I agree/do not agree that the images/photos/video recordings/voice
recordings related to my son/daughter/ward be used in any form of publication
or presentation. (if applicable).

* delete where necessary

Signature Signature
(Parent/Guardian) (Witness)

Date :..... Name :.....

I/C No. :.....

I confirm that I have explained to the respondent's parent/guardian the nature
and purpose of the above-mentioned research.

Date Signature
(Researcher)



**JAWATANKUASA ETIKA UNIVERSITI UNTUK
PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA**

BORANG B2: PENERANGAN DAN PERSETUJUAN IBUBAPA/PENJAGA

Sila baca maklumat berikut dengan teliti. Sekiranya anda mempunyai sebarang pertanyaan, sila kemukakan kepada penyelidik.

1. **TAJUK KAJIAN**
2. **PENGENALAN**
3. **APAKAH YANG PERLU ANDA LAKUKAN?**
4. **SIAPA YANG TIDAK BOLEH MENYERTAI KAJIAN INI?**
5. **APAKAH FAEDAH MENYERTAI KAJIAN INI?**
 - a) **KEPADA ANAK/JAGAAN SAYA SEBAGAI PESERTA?**
 - b) **KEPADA PENYELIDIK?**
6. **ADAKAH IA BERISIKO?**
7. **ADAKAH MAKLUMAT DAN IDENTITI ANAK/JAGAAN SAYA KEKAL RAHSIA?**
8. **SIAPA YANG SAYA PERLU HUBUNGI SEKIRANYA SAYA MEMPUNYAI SOALAN TAMBAHAN SEPANJANG PENYELIDIKAN INI?**

Sila tandatangan di sini sekiranya anda telah membaca dan memahami kandungan halaman ini _____

9. PERSETUJUAN

Saya No Kad Pengenalan
beralamat
..... dengan ini secara sukarela bersetuju
membenarkan *anak / jagaan saya menyertai
penyelidikan tersebut di atas *(klinikal/percubaan ubat-ubatan/rakaman
video/kumpulan sasaran/temuduga/ soal selidik).

Saya telah diberi penjelasan secara menyeluruh mengenai penyelidikan ini
dari segi metodologi, risiko dan komplikasi (seperti yang tercatat dalam Helaian
Penerangan). Saya memahami bahawa *anak / jagaan saya berhak menarik
diri dari penyelidikan ini pada bila-bila masa tanpa memberi sebarang alasan.
Saya juga memahami bahawa sebarang maklumat yang berkaitan identiti
*anak / jagaan saya akan dirahsiakan.

Saya* berminat / tidak berminat untuk mengetahui keputusan kajian yang
melibatkan *anak / jagaan saya.

Saya setuju/tidak bersetuju untuk imej/gambar/rakaman video/ rakaman
suara berkaitan dengan anak/ jagaan saya digunakan dalam apa jua bentuk
penerbitan atau pembentangan. (sekiranya berkaitan).

*potong yang tidak berkenaan

Tandatangan Tandatangan
(Ibubapa/Penjaga) (Saksi)

Tarikh :..... Nama :.....
No. K/P:

Saya mengesahkan bahawa saya telah menerangkan kepada ibubapa/
penjaga responden mengenai sifat dan tujuan penyelidikan tersebut di atas.

Tarikh Tandatangan
(Penyelidik)

APPENDIX E

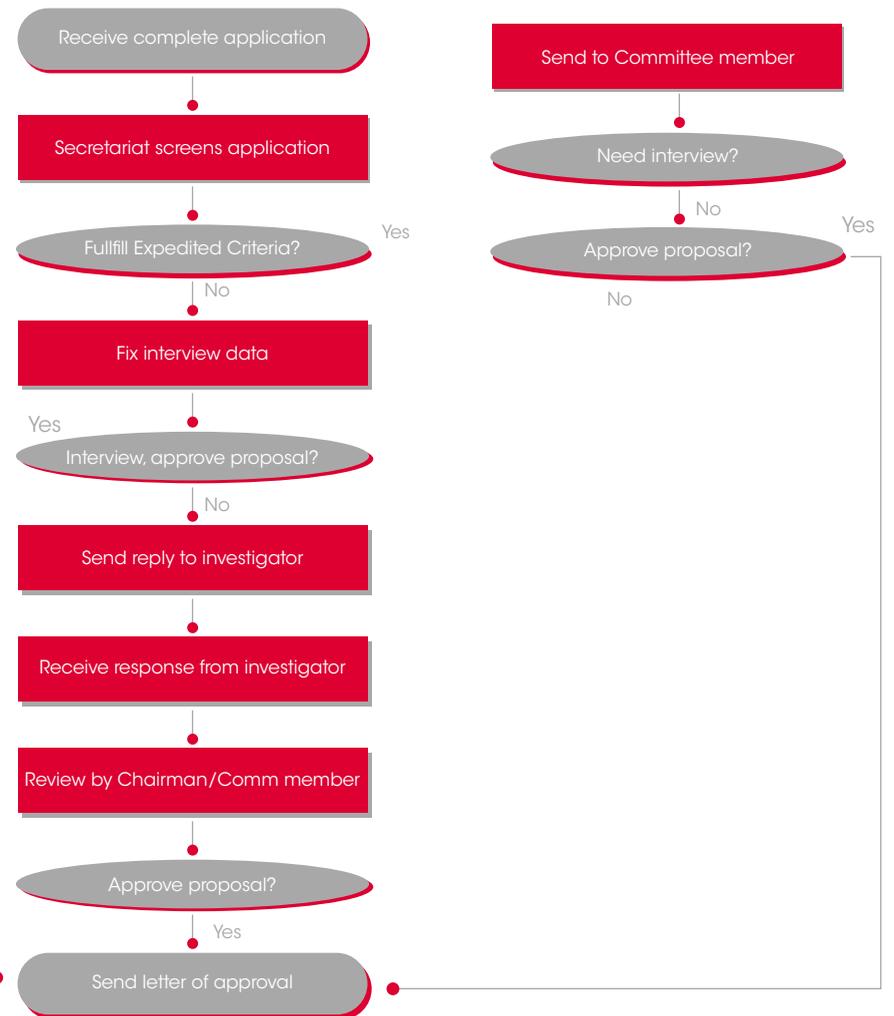
Research Ethics Committee meets according to a fixed schedule monthly

The response should include a copy of the revised manuscript with the changes marked out

Notes : The decision for re-interview is sometimes made at the first interview itself

6 - 8 weeks excluding re-interview

3 weeks



7.0 REFERENCES

Adapted from Declaration of Helsinki, ICH-GCP Guidelines and MREC Guidelines.

¹ <http://bioethics.georgetown.edu/publications/scopenotes/sn44.pdf>

For the online version of the guidelines and access to the JKEUPM guidelines and forms are available at <http://www.tncpi.upm.edu.my/>