UNIVERSITI MALAYA

Frequently Asked Questions (FAQs)

1. When should ethics clearance be obtained?

   Answer: Ethics clearance must be obtained before the research project starts. In principle, researchers should not approach or recruit participants or collect data for any purpose (including pilot study) prior to receiving ethical approval.

2. What if I have more than 2 co-investigators/supervisors?

   Answer: Please include the details of all co-investigators/co-supervisors. You can include an attachment if the space allocated is not sufficient.

3. What if the research has no funding or it is self-funded?

   Answer: Please state "no funding" or "self-funded", whichever is applicable.

4. What should be included in the explanation on recruitment of participants?

   Answer: The explanation should include information about how the researchers will go about identifying, screening, contacting and selecting potential participants.

5. What do "inclusion criteria" and "exclusion criteria" mean?

   Answer: "Inclusion criteria" are specific characteristics that participants must have if they are to be included in the study (e.g., Males who participate in less than 150 minutes of physical activity a week, aged between 21 and 30 years) whereas the "exclusion criteria" are attributes that disqualify an individual from being included in the study (e.g., Participants who have medical conditions such as hypertension, backpain, etc.).

6. In the event that participants experience distress during the interview (e.g., emotional breakdown, disorientation, distraught, agitation, etc.), how will you address such situations?

   Answer: The wellbeing of the participant must be prioritized. It is advisable to terminate the interview session and participants should be given the necessary support to ensure that he/she is not facing any immediate risk. In addition, information regarding relevant support services or helpline(s) must be provided.

7. Do I need UMREC clearance if my study involves patients?

   Answer: If the research involves government health facilities, MOH MREC ethics clearance is sufficient. If the research involves UMMC patients/staff, clearance should be obtained from UMMC Medical Research Ethics Committee.

8. What information should be provided if my study involves observation?

   Answer: The information must include i) who or what will be observed, ii) how consent will be sought from participants, iii) how observation will be done, and iv) how observation will be recorded – if the recorded materials will identify individuals as well as what are possible risks of harm, stigma or persecution and how these will be mitigated. This information must be provided in **Form 1 – item 15.i**

9. What information should be provided regarding how confidentiality and anonymity will be preserved during data collection and analysis as well as when reporting results?

   Answer: Please explain in detail how you will protect the confidentiality or anonymity of participants. For example, if you know the identity of each participant you may take steps to protect their confidentiality by assigning a pseudonym or unique code that will not be disclosed at any time. If photographs are used, the participant's face must be masked. If the researcher wishes to disclose or state the identity of participants in any reports or publications, this must be clearly stated in **Form 2 – Participant Information Sheet**

10. Who will have access to the data?

    Answer: Only researchers and supervisors should have access to the data. Justification should be given if other individuals or parties will have access to the data

11. Who owns the data?

    Answer: The data belongs to the Universiti Malaya. If you are collaborating with a third party (e.g., the Ministry of Education, other universities, etc.), a Memorandum of Understanding (MoU) has to be signed for co- ownership of the data.

12. How long should the data be kept?

    Answer: The data should be kept for at least 5 years from the publication date (thesis, journal article, etc.) for audit purposes. After that period, the data should be destroyed. Paper-based data should be shredded. Data in digital form should be completely deleted. This has to be stated in **Form 1 – item 15.ii**.

13. What is the appropriate method for data storage? How will the data be kept secure?

    Answer: Provide details on where data will be kept and how data will be kept secure. The hardcopy version of the data (e.g., questionnaires, written notes) should be stored in locked cabinets within a secured room in the university. Digital versions of the data should be stored in secure, password-protected computers. If the data are stored in an online platform, additional measures must be put in place to ensure the safety and security of data (e.g., access will only be made via personal laptop using a private network). This has to be stated in **Form 1 – item 15.ii**.

14. What is the participant information sheet (PIS)?

    Answer: The participant information sheet (PIS) provides pertinent information about your research that is given to research participants for the purpose of obtaining informed consent. A participant information sheet should be succinct, clear, written in lay language, and easily understandable by the intended audience. Avoid using technical terms or jargon that might confuse the potential participants.

15. What is an assent form?

    Answer: This is the simplified version of PIS that is designed to provide information about the study to minors or individuals who may not have the legal capacity to provide informed consent on their own. While the ultimate decision-making authority lies with the legally authorized representative (e.g., parent or guardian), the assent form allows the minor to express their willingness to participate to the best of their understanding. The language used must be suitable for the age of the intended participants.

16. What is the consent form?

    Answer: A consent form is a one-page sheet containing the title of the study together with the consent statements. Consent from participants is required before data collection is conducted. You are required to submit a template of your consent form (available from the UMREC website) with your ethics application.

17. I am doing an online survey. How do I obtain informed consent from the participants?

    Answer: All studies, including online studies, must include informed consent. The page should include the participant information sheet and the consent form for online surveys. At the bottom of the page, include a "checkbox" which states *"By clicking the checkbox, I have given full consent and have agreed to participate in this study".*

18. Is it necessary to translate all research materials that will be given to participants?

    Answer: If the study population are not proficient in the language used in the research materials (e.g. English), translating the materials into a language they are familiar with becomes essential to ensure their understanding and meaningful participation in the study. This is particularly important when collecting informed consent, surveys, questionnaires, instructions, or any other crucial information that participants need to comprehend accurately.

19. When is a Non-Disclosure Agreement necessary?

    Answer: When hiring a third party or individuals to assist with specific research activities (e.g., enumerators, moderators, transcribers, etc.), it is necessary to establish a Non-Disclosure Agreement (NDA) to protect the confidentiality of sensitive information of study participants shared between the researcher and the third party.

20. Should the application forms be handwritten or computer typed?

    Answer: The application forms should be computer typed. Handwritten forms will be rejected.

21. How long will it take for UMREC to process my application for ethical clearance?

    Answer: After the submission deadline, UMREC will take about 30 days to process your application. However, the processing time might take up to 60 days, depending on the research complexity. Please keep in mind that the required amendments will require additional processing time. Applicants are advised to submit their ethics clearance application as **EARLY** as possible prior to their data collection. The complete and correctly filled-in applications must reach us before the closing dates. Any late submission will be processed in the next following cycle of review.

22. When will the ethics review meeting take place?

Answer: The ethics meeting will be held on the fourth week of every month.

23. What is a research ethics audit?

Answer: Starting in January 2023, all approved applications may be subject to research ethics audit conducted by UMREC. This audit aims to ensure that all research is being conducted in keeping with the reviewing committee's approval conditions. Therefore, UMREC may require researchers to provide all information and documents pertaining to the study.