Important Note

- Ethics clearance is to be obtained before the research project starts. Researchers **should not** approach or recruit participants or collect data for any purpose (including pilot study) prior to receiving ethical approval.
- Applications for research where data collection has already started or been completed will not be accepted.
- Submit their ethics clearance application as EARLY as possible prior to their data collection.
- **We DO NOT provide urgent reviews.** Therefore, please plan your research accordingly as any request for an expedited review will not be entertained.
- Please make sure that your submission is complete prior to the checklist. The secretariat will strictly reject and will not entertain any incomplete submissions.

Important Note

- The Human research ethics committee:
  - conducts an ethics review prior to the beginning of any research involving human participants.
  - examines the ethics components of the research such as, sound methodology, possible risks and benefits to the subjects, recruitment of subjects, consent from the subjects, confidentiality or anonymity for the subjects, the way in which the data is handled, and how feedback can be provided for the subjects.

Please note that any data collection and participants recruitments for any purposes are strictly prohibited **before obtaining ethical clearance**.

FAQ Human Research Ethics

Q: Where can I find information about human research ethics workshop?

A: Information about courses is available on the Staff and student's email and MyUPSI portal.

FAQ Human Research Ethics

Q: When should ethics clearance be obtained?

A: 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.

FAQ Human Research Ethics

Q: Can I get the ethical clearance to use data that I have already collected?

A: Retrospective approval of research protocols cannot be given. Any data collected before approval has been gain cannot be used.

FAQ Human Research Ethics

Q: Who is the principal investigator?

- A: In the case of a staff conducting research, that staff is the Principal Investigator. In the case of students, whilst the student may be the principal researcher, for the purposes of the institution the supervisor must act as the Principal Investigator and as such must sign off the application form (Section 3). This is because the supervisor is a UPSI staff member and must sign the application to undertake responsibility for the conduct of the research.

FAQ Human Research Ethics

Q: What should be included in the explanation on recruitment of participants?

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

FAQ Human Research Ethics

Q: What if I have more than 2 co investigators/ supervisors?

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

FAQ Human Research Ethics

Q: What if the research has no funding or it is self-funded?

A: Please state “no funding” or “self-funded”, whichever is applicable

FAQ Human Research Ethics

Q: Do I still need to apply for UPSIHREC ethics approval if I already have approval from another Human Research Ethics Committee?

A: The UPSIHREC seeks to avoid the unnecessary duplication of ethical review. Please note that the approval from the other HREC must be current (i.e., not expired), and must cover the entire period of the project. If you need to extend the approval period you must do that with the original approving HREC.

FAQ Human Research Ethics

Q: What do “inclusion criteria” and “exclusion criteria” mean?

A: “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.).

FAQ Human Research Ethics

Q: How do I know the level of risk to my participants?

A: Feel free to scan, download and read this article.

FAQ Human Research Ethics

Q: What are the potential benefits to the participants if they involved in my study?

Recipients of benefits	Potential benefits
Participants	• Access to information • Knowledge about diagnosis, interventions or procedures • Opportunities to share experience and greater solidarity with others (Rennie et al. 2019) • Acknowledgement in publications • Feelings of doing good and making a contribution • Copies of reports

FAQ Human Research Ethics

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

A: 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 Participant Information Sheet.

FAQ Human Research Ethics

Q: What is an assent form?

A: This is the simplified version of Participant Information Sheet 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.

FAQ Human Research Ethics

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

A: 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.

FAQ Human Research Ethics

Q: What is the consent form?

A: 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 with your ethics application.

FAQ Human Research Ethics

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

A: 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”.

FAQ Human Research Ethics

Q: Is it necessary to translate all research materials that will be given to participants?

A: 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.

FAQ Human Research Ethics

Q: When is a Non-Disclosure Agreement necessary?

A: 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.

FAQ Human Research Ethics

Q: How long will it take for UPSI Human Research Ethic Committee (UPSIHREC) to process my application for ethical clearance?

A: After the submission deadline, UPSIHREC 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.

FAQ Human Research Ethics

Q: When will the ethics review meeting take place?

A: Please check the calendar in RMIC website. The ethics meeting will be held on the fourth week of every month.

FAQ Human Research Ethics

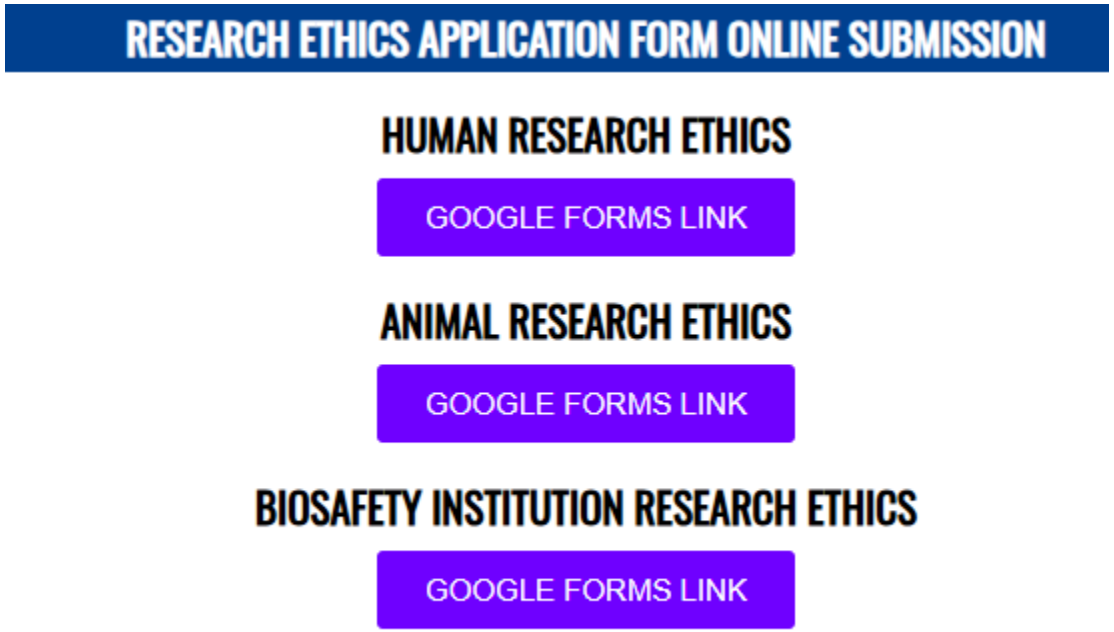
Q: What is a research ethics audit/monitoring?

A: Starting in January 2025, all approved applications may be subject to research ethics audit/monitoring conducted by UPSIHREC. This audit aims to ensure that all research is being conducted in keeping with the reviewing committee's approval conditions. Therefore, UPSIHREC may require researchers to provide all information and documents pertaining to the study.

FAQ Human Research Ethics

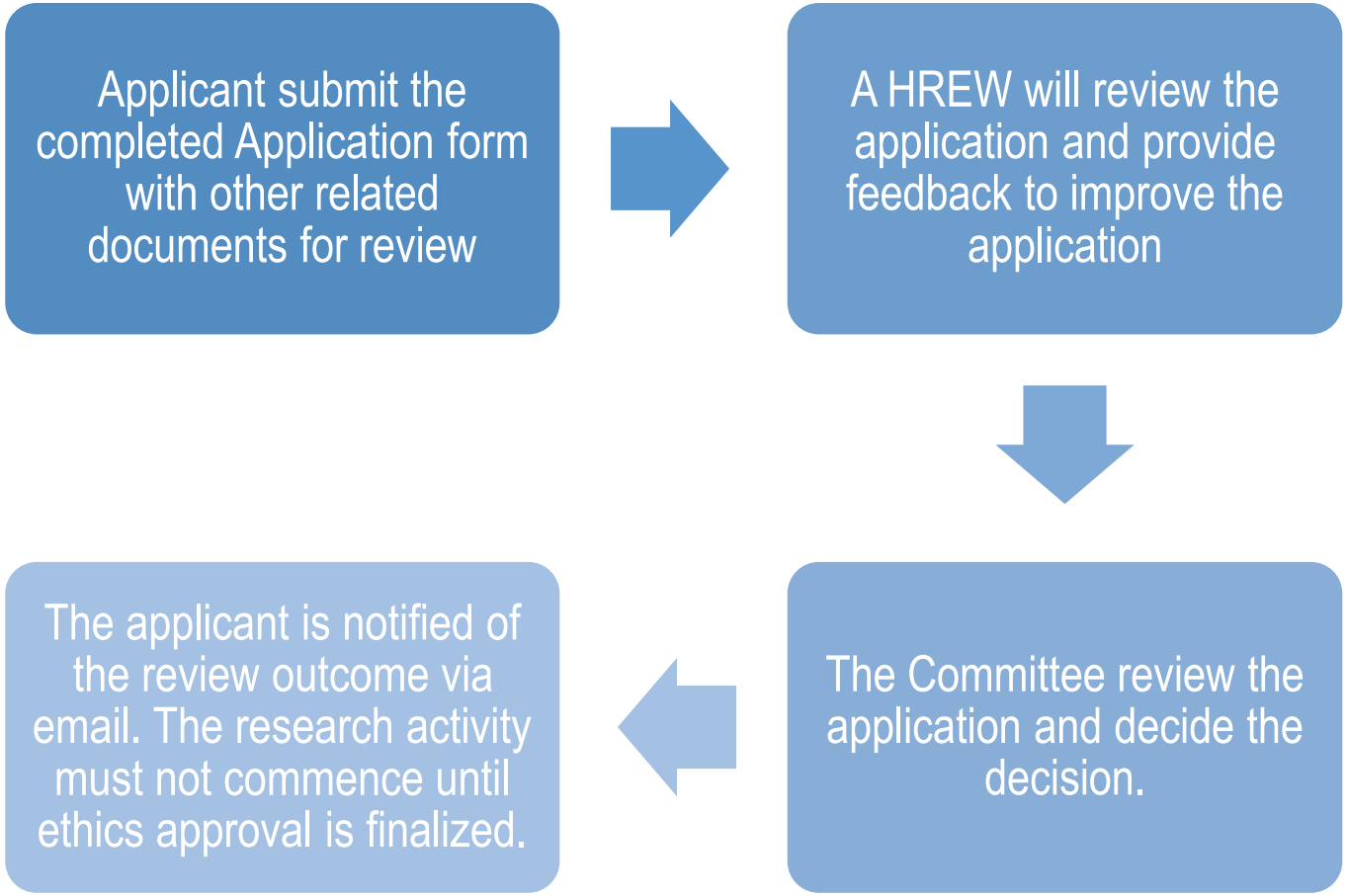
Q: How do I submit an ethics application?

A: UPSI has implemented an online system, through a Google Form, for submitting and reviewing Human Research Ethics applications.



FAQ Human Research Ethics

Q: How does the human ethics review process work?



FAQ Human Research Ethics

Q: I'm using data about people who aren't identifiable: do I need to get ethics approval?

A: In general, if the data has been previously collected, and cannot be traced back to identifiable individuals, you need not obtain ethics approval.

FAQ Human Research Ethics

Q: Is ethics approval needed when observing individuals or groups?

A: Yes. Observation may seem more intrusive to the people being observed than to the observer and does still count as research involving human participants.

FAQ Human Research Ethics

Q: Do I need ethics approval if I plan to access publicly available data on the internet?

A: Your project may be exempt from requiring ethics approval if:

- you are accessing publicly available data; and
- you will only publish or present these data in a non-identifiable way; and
- your research does not pose any risks to those from whom the data are sourced.

FAQ Human Research Ethics

Q: Can I modify or add to my proposal research protocol, documents/instruments or procedure, after getting approval?

A: Yes, you can. Download amendment form in the RMIC website. However, the proposed modifications must be approved by the ethics committee or delegate before the changes are implemented. Please do not proceed with implementing any changes before such approval is obtained.

FAQ Human Research Ethics

Q: How long do I need to keep research data or materials?

A: Basically, research data should be retained for as long as there is a need for referral to the data, such as to justify or defend the research, or to satisfy legislative or some other standard.

For most research, the minimum recommended standard is five years from the date of any outcome based on the data.

FAQ Human Research Ethics

Q: Do I need special consent to take photographs of participants?

A: If you plan to take photographs during the course of your research, your ethics application should include details of what will be captured in these images and how they will be used. For example, will the photographs be used for the purposes of analysis only, or will they be published in the reporting of results?

FAQ Human Research Ethics

Q: Do I need to provide participants with a summary of my findings?

A: HREC generally considers that it is the researcher's responsibility to proactively offer to provide participants with a summary of their findings wherever possible. To enable this, the following statement can be included in the Participant Information Sheet: “A summary of the research study findings will be available to all participants upon request. Should you wish to receive a summary of the study findings, please contact the chief investigator via the contact details provided.”

FAQ Human Research Ethics

Q: How should I report an Adverse Event?

A: Any adverse effects on research participants or reportable events must be reported to the Human Research Ethics Secretariat using the Adverse Event Form.