University of South Australia

UniSA Human Research Ethics Committee – Standard Conditions of Approval

Human Research Ethics Committee (HREC) approval is always made on the basis of the following conditions

It is the Chief Investigator's responsibility to ensure that:

1. All investigators are aware of the conditions of approval, and that the research must be conducted in compliance with the HREC-approved project.

2. All research participants are provided with the current Participant Information Sheet and Consent Form, unless otherwise approved by the Committee.

3. If the approved project is a clinical trial, it is registered on a publicly accessible register complying with international standards before the recruitment of the first participant (e.g. Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/).
The National Statement on Ethical Conduct in Human Research defines a clinical trial as a research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

4. The HREC is advised in a timely manner of any complaints received or ethical implications that arise during the course of the project.

5. The HREC is advised of any Adverse Events within 72 hours of the event using the Adverse or Reportable Event Form.

6. The HREC is informed as soon as possible of any new safety information, from other published or unpublished research, that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project.

7. Variations to the approved project do not proceed until approval is obtained in writing from the HREC. Project variations are to be requested using the Project Variation form.

8. Reports on the progress and completion of the project are provided to the HREC. The project has approval for three years (unless otherwise stated) contingent upon annual review.

   - An Annual Report is to be provided every 12 months after the listed commencement date for the approved protocol. Ethical approval will lapse if an Annual Report is not submitted.
   - A Project Completion Form is to be submitted within three months of the project's completion.
   - An Extension Request Form is to be submitted if you require more than 3 years in which to complete the research. This form must be submitted at least 1 month prior to the expiration of the ethics approval for the project

9. The HREC is advised promptly of the emergence of circumstances where a court, law enforcement agency or regulator seeks to compel the release of findings or results. Researchers must develop a strategy for addressing this and seek advice from the HREC.

10. Your research **MUST NOT commence** until the UniSA HREC has granted full and final ethics approval, and the researcher has acquired all other requisite approvals. Please be advised that the UniSA HREC approval constitutes to be an ethics approval only.

For example, you may be required to gain approvals and permissions through other HRECs or committees external to UniSA, or other UniSA internal approvals relevant to your research and activities. Please be advised that the onus of acquiring and maintaining the records of the requisite approvals and permissions lies on researchers. These may include, but are not limited to, the following examples:

- UniSA Animal Ethics Committee approval if your research also involves animals.
- UniSA Institutional Biosafety Committee approval if using GMOs.
- UniSA Radiation Safety Committee approval if using radiation.
- UniSA Chemical Advisory Safety Committee approval for any requisite governance of chemical management activities.
- Permission to recruit UniSA staff, students and/or for the use of UniSA data.
- Permissions to interact with and/or recruit from external organisations.
- Internal and/or external written agreements, or contracts for collaborative research projects.
- Relevant screening checks for research work involving children, aged care or vulnerable groups.
- Undertaking TGA processes relevant to the study for the use of any unapproved therapeutic goods.
- Relevant external HRECs and committees (including research involving Aboriginal communities, research in education, defence or child protection requiring relevant departmental clearances, research in a hospital or local health network).
- Any legal, governmental, visa, ethical, cultural or research approval requirements when conducting research in another country or with a foreign entity including assessment for foreign interactions.
- Confirmation of insurance cover from the UniSA Insurance Office where you have been advised that individual insurance assessment is required.

Please see the following website for information regarding such special considerations and contact other organisations/committees for further advice https://i.unisa.edu.au/staff/research/research-ethics/human-research-ethics/getting-started/application-considerations/