Guidance with the Development of Human Research Submissions

Contents

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1. **Chief Investigator**
- Student Research: A student researcher cannot be listed as the Chief Investigator of a human research application. A UNSW supervisor must be listed as the Chief Investigator. In situations where a student has more than one supervisor the primary supervisor must be listed as the Chief Investigator and the secondary supervisor should be listed as a Co-Investigator.
- A UNSW employee or academic with a UNSW ZID and email address must be listed as the Chief Investigator of the research.

2. **Applying for human research ethics approval**
- The process for applying for ethics approval can be found on the human ethics website. The review pathway for your human research project is dependent on the level of risk associated with the project. At UNSW there are three pathways for ethical review. A list of the criteria that is used to categorise the different levels of risk associated with the research procedures can be found by accessing the following pages:
- **Pathway 1:** Negligible Risk Research – Review by an Executive Panel
- **Pathway 2:** Low Risk Research – Review by a Human Ethics Advisory Panel
- **Pathway 3:** More than Low Risk Research – Review by a Human Research Ethics Committee

3. **Determining the level of risk**
- To assist with classifying the risks associated with your research you will need to establish:
  - Who the target population of the research will be;
  - What data collection methods you will use in your research;
  - The nature of research activities that you will ask participants to complete;
  - The nature of the information you will collect from the participants;
  - The measures you will ask participants to complete or the questions that you will ask participants to answer.
- Once the above has been established researchers must need to refer to the categories of research included in the above links. If researchers have difficulty establishing the level of risk following these steps, the Human Ethics Team should be contacted to seek further assistance.
- The Human Ethics Team is unable to assess the risks associated with the Human Research without the above information. Please ensure that you have this information prepared before contacting the office.

4. **Developing a Human Ethics Submission**
- The following documentation must be drafted for review by your supervisor before the human research submission is submitted to your supervisor. Templates for all documents can be found on the human ethics forms and templates page:
  - Application Form
  - Project Description (low risk and more than low risk research)
  - Recruitment Materials
  - Participant Information Statement and Consent Form
  - Copies of any materials, tools, instructions, surveys, interview questions, interview protocols, safety protocols and letters of support must also be created or collected when developing an ethics submission.
- Included in the project description, the recruitment materials and the participant information statement and consent form(s) are help text in blue to guide you on the type of information that should be included in the document.

5. **Assistance in developing applications**
- **Human Ethics Website:** Guidance documents specific to recruitment, data collection, safety protocols, data storage, confidentiality and many more topics are provided on the human ethics website. The information that the Human Ethics Team uses to provide guidance over the phone and via email is sourced from these documents.
- **Human Ethics Team:** The Human Ethics Team provide a preview service where the Ethics Officer who acts as the secretariat for the ethics review panel or committee will provide feedback before final submissions are made. Researchers and students can access this

service by sending an email to humanethics@unsw.edu.au
- **Supervisor:** Student researchers should also seek guidance can be sought from their supervisor.

6. Submitting applications

- The Chief Investigator must submit the human research ethics application via email. Student researchers cannot submit a human research ethics application for review. In the **cc section** of the email, copy in any named student investigator and co-investigators listed on the application.
- An email or letter of support for the project from Head of School must be attached to the submission email. Some schools have agreements in place with the Human Ethics Team where this step is not required. Check with your Head of School or the Human Ethics Team to establish whether this is required.
- The person listed as the Chief Investigator must send the application using their work email address.
- Ensure your submission is made by the closing date relevant to the ethics review panel or committee. A list of submission closing dates can be found on the human ethics website.

7. Common points raised by ethics review panels or committees

- The application has been poorly written, has not been proofread and the plan for conducting the research is unclear.
- The data collection methods are not consistent with the activities or procedures research participants are advised they are being asked to complete at section 5 of the participant information statement.
- A clear plan for analysing the data collected in order to answer the research questions has not been outlined at section 3 of the project description.
- The inclusion criteria referred to at section 6 of the project description is not reflected in the participant information statement or screening tools.
- The recruitment strategy outlined at section 7 of the project description is not reflected through the examples of recruitment advertisements, email invitations or participant information statement and consent forms.
- The recruitment strategy indicates that screening will occur without consent.
- The risks and/or discomforts that participants may experience or that may occur are not outlined at section 10 of the project description or they have not been accurately reflected in the participant information statement.
- Interview protocols, safety protocols, supervision protocols or appropriate support services or strategies for providing care to participants have not been provided or reflected at section 10 of the project description.
- The data storage requirements or the research personnel that will have access to the data as outlined at section 11 are not consistent with the contract, funding agreement or the participant information statement and consent form.