TIPS FOR OBTAINING ETHICS APPROVAL IN THE MINIMUM TIME FRAME

The following tips will assist you in developing a clear ethics application and, therefore, in obtaining ethics approval in the minimum timeframe.

Work out which ethics committee should review your application
You should first confirm that the University of Sydney is the most appropriate HREC to review your application by consulting the Ethics Office website. If in doubt, contact the Ethics Office to ask them for advice.

Obtain access to the University’s online application system
All application, modification and annual report forms for the University of Sydney HREC are submitted and managed online in the IRMA system. Paper copies and emailed versions are no longer required or accepted. This means that if you are going to get ethics approval from the University HREC, you will need a Unikey and access to the online system (IRMA). If you don’t have a Unikey, you can request one online. If you don’t have IRMA access, complete this online form.

Start early and allow enough time
Don’t leave ethics to the last minute. You should start thinking about ethics as soon as you start thinking about and planning for your project, because ethics should be integrated into all stages of the research process.

Make sure that you allocate plenty of time for the process of writing your ethics application, undertaking ethical review and obtaining approval. A high quality ethics application takes careful planning. You need to allow yourself sufficient time to develop a well-designed and well-documented ethics application that addresses all relevant ethical issues for your project, and to discuss these issues with your co-researchers.

Once you have submitted your application, you will also need to allow time for all co-researchers and the Chief Investigator to sign the declaration to “approve” the application (in place of a physical signature) in the online system. All of these declarations must be in place before the application can be assigned to a meeting. External investigators who do not have access to IRMA can sign the form available for download on the Ethics Office website. After this, the application will need to be reviewed by a committee and they will provide you with feedback which you will need to respond to. All up, gaining ethics approval will usually take at least 4 - 6 weeks from submission to final approval. In some circumstances, it will take longer.

Think critically about ethical issues
The ethical review process gives you a valuable opportunity to think through all the potential ethical implications of your research, from your research question right through to issues that might arise when you are recruiting participants, collecting data, writing up or disseminating your findings. Some key ethical issues for you to consider are: how you will protect participants’ privacy and the confidentiality of their information, how you will avoid real or perceived coercion in recruitment, how you will minimise and manage risk in your project, and whether the risks of your project are outweighed by the potential benefits.
Be your own most critical audience and use your mentors, supervisors, friends and colleagues to help you think through the potential ethical issues. In most fields there are texts that outline common ethical issues in relation to particular methodologies and data collection methods. Use them to help you identify potential ethical issues in your research and then try to think about these issues from other perspectives. This is where your mentors, supervisors, friends and colleagues can be very helpful. You might also want to ask some people who know nothing about your research to get the perspective of a lay person. Ask them how they would react if someone came to them and asked them to participate in a project like this. What kinds of concerns might they have? What questions would they have? Be sure to consider these perspectives when you write your application.

You should also be familiar with the guidelines, codes and legislation that govern research in the places where you intend to do it. In Australia, it is crucial that you understand and apply the ethical principles for research that are set out in the National Statement on Ethical Conduct in Human Research (NHMRC, 2007). It is also crucial that you act in accordance with the Australian Code for the Responsible Conduct of Research (NHMRC, 2007), which sets out expectations related to research integrity. Use these documents to your advantage; not only to identify potential ethical issues, but also to identify possible solutions. You also need to consider whether there are any other specific codes, guidelines or legislation that are relevant to your project (e.g. privacy legislation), and make sure you comply with them. Some of these are outlined on the Ethics Office website. You should also review your professional code of ethics and any others that are potentially relevant to your work.

**Know your research and methodology**

Your research question must be clear in your mind before you can communicate it to others, particularly those who have limited specific knowledge or experience in the area. Think about it from different perspectives and use this to inform your ethics application. In the application questionnaire, make sure you explain your methodology clearly and in lay terms, including details about participant selection, recruitment, data collection and analysis.

**Communicate clearly in lay language**

It is important that you communicate clearly with the HREC and your participants. Use plain language in the application questionnaire and your supporting documents. The ethics committee members reviewing your project may not be experts in your specific research field, and your research participants need information to be expressed to them in lay terms in order to provide informed consent. If you have questions about how to communicate clearly with participants and the HREC, you can contact the Ethics Office.

**Use the guidelines available to help you**

The Ethics Office has developed a number of guidelines to assist you in considering ethical issues, developing solutions, designing your research project and preparing your supporting documentation. You are encouraged to use these guidelines and seek advice from the Ethics Office at all stages of conducting your research.

**Use the correct templates for supporting documentation and adapt them to your project**

Once you have completed the application questionnaire, you will need to upload all required supporting documentation for your application in the “Documents” tab. The type of supporting documents you need will depend on the nature of your project, but might include any of the
following: Participant Information Statements (PIS), Participant Consent Forms (PCF), interview questions, advertisements, letters/emails of invitation, questionnaires, signed external researcher approval forms (for researchers external to the University) and safety protocols.

The Ethics Office provides templates for certain supporting documentation (Participant Information Statements and Consent Forms), which are revised from time to time. Make sure you are using the most current version by obtaining these templates from the Ethics Office website each time you do an application. Applications on superseded documents may be returned to researchers, thus delaying your ethics approval. There are various templates available for different types of participants and research methods. You can (and should) modify the templates to suit your project, however please ensure that all necessary information is included. Follow the instructions on the first page of the templates; making sure you write these documents in plain English rather than technical jargon and address the participant directly. All supporting documents should be on the Chief Investigator’s letterhead (bear in mind that students cannot be Chief Investigators), and you should use your University email address for correspondence. Make sure you proof read all of your supporting documents for spelling and grammatical errors before you submit them.

Ensure your application is self-explanatory and self-sufficient
Your ethics application and the supporting documents must be capable of being read, reviewed and approved as self-explanatory documents that justify the research proposal. Where further explanation or clarification is needed to assist the ethics committee in reviewing your application, the inclusion of references and attachments to the ethics application is encouraged. However, you must ensure that your responses in the application are able to stand alone and do not require the ethics committee to refer to detailed explanations in attached documentation.

Ensure your application is complete and any attached documents are labelled correctly
Ensure you submit all required supporting documents with your application, because missing documents delay the ethics review process. Please clearly label each document when you save it to your computer and then upload it to the “Documents” tab in IRMA. This is important not only because clearly labelled documents help in reducing processing time for your application, but also because these labels will appear on your ethics approval letter.

Summary
* Review the questions (PDF) that will be on the application and prepare your answers.
* Review the Guidelines for help with specific topics
* Consult the National Statement on Ethical Conduct in Human Research
* Clinical Trials: Consult the Clinical Trials website and Clinical Trial submission deadlines if the study involves a CTN or CTX
* Make sure you have a Unikey and access to IRMA.
  If you don’t have a Unikey, request one online. To request access to IRMA, complete this online form.
* Create a new application online in IRMA and complete the application questionnaire in the “Questionnaire” tab of your application.
* Prepare your supporting documentation, using the templates available online.
* Upload all of your supporting documentation in the “Documents” tab of your application.
* Submit your application early to allow enough time for all researchers on the application (including yourself), as well as your Faculty Approver, to “approve” it online in IRMA.