Ethics Application Submission Manual

Human research conducted by students and staff of the University of Melbourne requires ethical approval. All applications for research ethics must be reviewed by the Melbourne School Psychological Sciences Human Ethics Advisory Group (HEAG) in the first instance. Depending on the nature of the research project and the type of application required, some research projects must also be reviewed by one of the University's Human Ethics Sub-Committees (HESC) (Psychology Health and Applied Sciences) before being granted approval.

Before planning and designing your project, please ensure that you consider the various ethical concerns relevant to your project. These include (but are not limited to): participant risk/benefit trade-offs, informed consent, issues specific to particular research methods (e.g., genetics), issues relevant to specific samples (e.g., those in dependent/unequal relationships with researchers), and various processes of research governance (e.g., conflict of interest, data management).

Student researchers should ensure that they discuss these issues with their supervisors. Such discussions should take place against the background of the broad values and principles that guide the ethical conduct of research: research merit and integrity, justice, beneficence and respect.

For more information on these issues, please see the National Statement on Ethical Conduct in Human Research (https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research), and the Australian Code for the Responsible Conduct of Research (https://www.nhmrc.gov.au/guidelines-publications/r39)

On the basis of these considerations you will determine the nature of the ethics application that you will need to submit.

If you are joining a research project that already has ethics approval at the University of Melbourne, you will need to submit an amendment, adding your name and details to the project, as well as any additional modifications.

If you are embarking on a new project, you will have to create and submit a new application. You will need to determine which of the following application types is most suitable:

- **Minimal Risk:** To be completed for an individual research project considered to be of minimal risk. If you are unsure whether your research does fit within the guidelines for submission in this category, by selecting that option and completing the related checklist (in Themis) you will be able to determine whether the project can be considered to be of minimal risk. A Minimal Risk application can be approved by a HEAG.
- **Standard Project:** All individual research projects require use of this form unless they are eligible for consideration as a project involving minimal risk or are part of an existing HREC approved program application. A Project Application requires HEAG review and HESC approval.
- **Program:** To be completed where a group of researchers (or a whole department) wish to seek approval for a program of research within which a series of related individual research projects will be undertaken. A Program Application requires HEAG review and HESC Approval. Related individual projects can then be approved by a HEAG. Honours students will not usually submit this type of application.
- **Project within Program:** To be completed for an individual research project which is part of an HREC approved Program of research. If you are unsure whether your research fits within this category by selecting the option and completing the related checklist you can determine whether you can proceed with the Project within Program application. A Project within Program application can be approved by a HEAG.
- **Transfer of External Ethics Clearance:** To be completed where a researcher needs to transfer an ethics clearance obtained from an HREC at another institution TO a University of Melbourne HREC as the Primary HREC (in which case the University of Melbourne will become responsible for the research).

- **Registration of External Ethics Clearance:** To be completed where a researcher needs to register an ethics clearance obtained from an HREC at another institution and where the approving institution will remain the responsible HREC.

Once this is determined, you can begin the application process.

Please note: applications that require review by the Behavioural and Social Sciences HESC (standard projects and programs) need to be submitted according to the deadlines outlined in the table on the MSPS research ethics page
http://psychologicalsciences.unimelb.edu.au/research/research-ethics

The following instructions apply to all application types.

Summary of the process (more detailed instructions below)

1) Upload the application into Themis.
2) Construct a single PDF of the entire application (see below for details). The responsible researcher (a member of University of Melbourne academic staff) needs to sign the application form within the PDF and email this PDF to ethics-psych@unimelb.edu.au (Please do not cc the chair of the HEAG).

PLEASE NOTE, we do not accept submission of these PDFs by students directly. While the student can complete the Themis submission, we require the responsible researcher (usually the supervisor) to email the PDF for review.

3) The PDF will then receive initial review by a HEAG member and any queries will be emailed to the responsible researcher.
4) Upon receiving any such queries, changes should be made as soon as possible (within 24 hours for standard project and program applications), and the responsible researcher should send (a) a detailed, point-by-point email (or attached document) explaining how the reviewer's concerns have been addressed and (b) an amended single PDF, to the reviewer with ethics-psych@unimelb.edu.au cc'd. If you are asked to make revisions to the PDF there is no longer any need to upload the revised documents into Themis.
5) Once you have satisfied the initial reviewer, a second review will be conducted by the chair of the HEAG. Any queries at this point will be dealt with in a manner similar to that outlined in steps 3 and 4.
6) Once you have satisfied the chair of HEAG, your application will be approved and signed.
7) If your application requires additional review by the Psychology Health and Applied Sciences HESC, then your reviewed application will be forwarded by HEAG to HESC and you may receive additional communication from HESC once your application has been reviewed by them. If your application does not require additional review by HESC, then the responsible researcher will be informed of approval and will be sent an official approval letter.

Please note: All correspondence with the HEAG should be conducted by the responsible researcher. For student projects, it is the supervisor's responsibility to make sure that students understand the various ethical considerations and procedures involved in conducting research. Applications that do not comply with the procedures outlined here will be returned without being assessed. Should students have questions about their ethics application or the procedures below, they should contact their supervisor.

Additional, detailed instructions

Uploading your application in Themis. To begin the submission process, log in to Themis and navigate to the Human Ethics workbench (via Research Self Service -> Ethics), from where you can begin your submission. You first need to decide whether you want to submit an

amendment or a new application. Next, you need to work through a series of screens that will help determine whether your application is minimal risk. You will need to upload information about the kind of samples you'll be using, general information about procedures and information about the researchers on the project. You will then be presented with a link that enables you to download the application form in word format. Complete this in Word and then upload the completed form into Themis. **There is no longer any need to upload into Themis any of your supporting documents e.g. consent form, PLS, advertisement etc.** (Although these do need to be done and added to the single PDF for review). What you upload into Themis will not be reviewed – it merely acts as a placeholder, allowing you to be registered in Themis and to obtain an ethics application ID number (aka HREC number) for your application. While Honours students can submit the application in Themis, the supervisor must email the PDF for review.

Creating single PDF for review. Combine all relevant documents into a single PDF for review. Your PDF should include, in this order: (a) he Themis 'Printable Summary Report' (see below for further details) (b) the application form (c) supporting documents including advertisements, Plain Language Statement (PLS), consent form, debriefing statement, materials, other.
The file name of the combined PDF must be the ethics ID of the application which you will obtain in Themis. You can use Adobe Pro to do this. This combined pdf will be reviewed so it needs to be complete. If the pdf is too large to email to us you will need to reduce its size. The following website provides eight methods of reducing the size of pdfs:
http://www.wikihow.com/Reduce-PDF-File-Size

Please remember: The *responsible researcher* must email this PDF to ethics-psych@unimelb.edu.au for review.

For amendments, please include the following in your PDF: application summary (which needs to be signed by the responsible researcher), and any documents that you have modified in the course of amending your original application. These may include: a modified application form, modified PLS, consent or debriefing, modified advertisements and modified materials. If no sections of the application form have changed, then you do not need to include it. Documents that won't be modified need not be included in the PDF.

For registrations, please include the following in your PDF: application summary, ethics application form from external HREC, a copy of the approval letter from the external HREC.

Obtaining a "Printable Summary Report" You can only obtain a printable summary report once you have successfully submitted your application in Themis. Once you have done that, go to the "List of Current Applications" section of your human ethics workbench home page in Themis and click on the "View" icon for the application in question. Then click on "View" again for the latest version of the application. On the left of the page, under "Project Details", click on "Printable Summary Report". This opens a PDF which you can then save or print directly (by hovering the mouse over the report page). For amendments, this application summary must be signed.

Please use PLS, consent and debriefing templates. Unless there is a compelling reason not to, you must use our templates of the PLS, Consent Form, and Debriefing Statement available on the departmental ethics website: http://psych.unimelb.edu.au/research/research-ethics
Doing so will help streamline the review process. Still, please be sure to check your PLS and consent forms against the checklists provided in the application form.

Ensure that your forms are signed. Standard project and minimal risk applications must be signed by all researchers, even on the initial submission. The signature may be electronic or scanned but you cannot just type your name. For amendments, the responsible researcher must sign the application summary (obtained from Themis – see below).

Research Experience Program (REP). If you are using REP participants in your study, you must (a) include a debriefing statement and (b) provide a short written report (1-2 pages) of the findings of the study to all participants. Additional details about these and related REP procedures can be found here:
http://psychologicalsciences.unimelb.edu.au/research/research-experience-program

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Timeliness of review process. We attempt to review applications in a timely manner, but we also rely on you and your supervisor to help us with this. To ensure timely review please (a) be aware of submission deadlines (noted above and on the MSPS website) for applications that require HESC approval, (b) try to complete any revisions of documents suggested by reviewers as soon as possible. This is especially important for those applications that require HESC approval. For these applications, we ask that you complete requested revisions within 24 hours. When the review process is complete, we will attach an approval letter to your application and upload it into Themis for you. If it is a project or a program application, we will send it off to HESC for their review. There is nothing further for you to do until you have heard back from them.

***Please remember to verify that your consent form and plain language statements actually do comply with the checklists in your application. *** We are regularly audited on this point and most of our initial applications fail in this regard. For project applications, please make sure that you submit your application by the relevant cut-off given on departmental ethics website.

Common errors. There are a few common oversights that slow down the ethics review process. To help speed things up, please:
- Use the ethics ID number (aka HREC number; obtained in Themis) in the subject of your emails and as the file name of your PDF
- Ensure that all forms are signed
- Include the Themis Application summary in the PDF
- Use the PLS, consent and debriefing templates available on the school website
- In addition, check that your PLS and consent forms meet the criteria noted in the checklists in the application form

Further information

For further information about ethics and research integrity at the University of Melbourne, please visit: http://www.orei.unimelb.edu.au/

For further information about local ethics procedures within MSPS, see http://psychologicalsciences.unimelb.edu.au/research/research-ethics

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