THE UNIVERSITY OF MELBOURNE

Faculty of Medicine, Dentistry & Health Sciences

Melbourne Dental School

Ethics Application Overview

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PRIOR TO AN APPLICATION

ROLES AND RESPONSIBILITIES OF STUDENT RESEARCHERS & SUPERVISORS

Preparing a human ethics application whether for a PhD project, other post-graduate project and all graduate research projects is a joint process, in which the supervisor(s) and student(s) work in collaboration, both play active roles.

For students undertaking research that involves humans, learning how to formulate an ethics application is a fundamental element in learning how to do research. Students should have a significant role in the preparation of the application as a way to take intellectual ownership of their research project.

For supervisors, guiding the student effectively through the ethics application process is a central task of supervision. Both student and supervisor(s) are named researchers on the ethics application. Each takes responsibility for the quality of the application and the conduct of the research. Correspondence from an ethics committee will be directed to both student and supervisor(s) and both are responsible for responding to that correspondence, in collaboration.

The University of Melbourne Central Human Research Ethics Committee expects that, at minimum, supervisors and students take the roles described below when formulating ethics applications. It may be appropriate in some disciplines for the supervisor to play a greater role than described.

ROLE OF SUPERVISORS

1. Advise the student about the ethics review process, timelines, where to find application forms and meeting deadlines etc. Introduce the student to the National Statement on Ethical Conduct in Human Research and other relevant guidelines.
2. Discuss with the project with student and study design prior to the ethics application being commenced.
    a. Jointly decide on the key elements – sample, recruitment strategies, method of data collection and data analysis.
    b. Jointly identify any potential benefits/risks, advantages/disadvantages to participants, and agree on strategies to manage and minimise potential risks (such as appropriate support for participants).
    c. Identify and organise any other approvals (e.g. from agencies where research will be conducted, or where recruitment will take place) which may be needed.
3. Read drafts of the ethics application prepared by the student, and revise it with the student so that it is of a suitable standard to be submitted.
4. Check the final version carefully before signing it as ready for submission. Remember that the supervisor is a named researcher on the application and takes joint responsibility for ensuring that it meets the requirements of the National Statement on Ethical Conduct in Human Research.
5. Assist the student to respond to any correspondence from the ethics committee, including answering questions asked by the committee and making any changes that are required.
6. Attend an ethics committee meeting with the student, if the committee asks researchers to attend.

ROLE OF STUDENTS

1. Prepare for the ethics application by learning about the approval process and ethical considerations relevant to the area of research e.g. by reading relevant parts of the National Statement, other published literature and sample ethics applications.
2. Write or contribute to writing the ethics application, including
    a. Lay summary
    b. Background (including reference to relevant literature and previous studies)
    c. Plain language statement/s
    d. Consent form/s
3. Provide drafts of the application to the supervisor and revise the application in consultation with the supervisor to ensure that it is properly completed and of suitable standard for submission. Allow enough time to meet submission deadlines.
4. Submit the application.
5. Respond to any correspondence from the ethics committee, in conjunction with the supervisor, including answering questions asked by the committee and making any changes that are required.
6. Attend an ethics committee meeting with the supervisor, if the committee asks researchers to attend.

WHO APPROVES APPLICATIONS

MELBOURNE DENTAL SCHOOL HUMAN EHTICS ADVISORY GROUP (HEAG)

Applications that can be approved by the Human Ethics Advisory Group (HEAG) include:

- Minimal Risk; Research that is of low risk to participants and researchers may be approved via a Minimal Risk review process through the HEAG. In these cases the HEAG gives final approval. These applications do not need to be submitted to the HESC for approval. Note: Any Minimal Risk Application that seeks a waiver of consent can only be approved by the HESC.
- Project-within-Program; once a Program Application has been approved by the HESC, the HEAG can then approve projects that fit within the Program Application.
- Request for Amendment; for applications already approved by the HEAG. The HEAG can approve minor changes to projects, if the amendment is associated with a Minimal Risk project or a Project-within Program and the amendment presents no additional risks. The HEAG (not the researcher) will determine if the proposed changes are minor. If the HEAG considers the changes to be major, the HEAG will inform the researchers of this decision. In this case the application can only be granted approval by the HESC after submission of the application to the HEAG for endorsement. If a researcher is unsure whether a change is minor or major, the Chair of the HEAG should be consulted for advice.

The HEAG will send a copy of the above applications to the HREC for their records.

THE MELBOURNE DENTAL SCHOOL HEAG CONSISTS OF THE FOLLOWING MEMBERS	
Prof John Clement (Chair)	
Prof Mike Morgan (Head of School)	Prof Ivan Darby
Prof David Manton (part-time member)	A/Prof Nicola Cirillo
A/Prof Mina Borromeo	A/Prof Joseph Palamara
Dr Melanie Hayes	Dr Jaafar Abduo
Mr Rowan Story (part-time member) (external representative)	Dr Hanny Calache (DHSV representative)
A/Prof John Harcourt (part-time member) (external representative)	Ms Cassie Kearns (Academic Programs Officer (Postgraduate))

HEALTH SCIENCES ETHICS SUB-COMMITTEE (HESC)

Applications that must be submitted to the Human Ethics Sub-Committee (HESC) via the HEAG (after being recommended for approval by the HEAG) include:

- Minimal Risk: applications that seek a waiver of consent.
- Project Applications: Additional modules must be completed if the project is a CLINICAL TRIAL. A checklist should be completed prior to completing any application in THEMIS and submitted with the application. This checklist is available to help you ensure your application is complete.
- Program Applications: For use by researchers seeking ethical approval for a program of research encompassing multiple research projects.
- Request for Amendment: For applications already approved by the HESC i.e. Project Applications or Program Applications. Amendments should be submitted initially to HEAG for endorsement, and then forwarded by the HEAG to the relevant human ethics sub-committee for approval.
- Registration Applications: Registering projects that have already received external ethics approval (If a project has received ethics approval from another institution, the HREC will approve the registration of the project at University of Melbourne, subject to the HEAG not requesting amendments. These applications should be submitted initially to the HEAG for endorsement), prior to submission to the HEAG. A copy of the ethical clearance from the external institution must also be provided.

WHEN CAN RESEARCH BEGIN

Projects may not start until human ethics approval has been obtained. If the project can be approved by the HEAG, the HEAG will send a letter to the researchers advising them that ethics approval has been granted and research may commence.

If the application needs to be reviewed by the HESC, the HEAG will inform the researcher that the HEAG has endorsed the application but research may not commence until the researcher receives an official letter of approval from the HESC.

TYPES OF APPLICATIONS

MINIMAL RISK (INCLUDING USE OF EXTRACTED TEETH)

Minimal Risk research is research in which any foreseeable risk to participants and researchers is no more than inconvenience. Inconvenience can include:

- filling in a form
- participating in a survey
- giving up time to participate in research

If, after completing the checklist in THEMIS, a project is considered to be Minimal Risk, THEMIS will ask the researcher to complete the Minimal Risk Application for review by the HEAG. Note that the HEAG (not the researcher) decides whether the application is eligible for Minimal Risk review. If the proposed research could lead to discomfort it is NOT considered to be Minimal Risk and a Standard Project Application should be completed via THEMIS.

Projects involving the use of extracted teeth are generally classed as Minimal Risk. However, some additional information will need to be provided to the HEAG.

GUIDELINES FOR CONSIDERATION WHEN USING EXTRACTED TEETH	
Question	**Answer**
Is the use of these teeth for research covered by an already approved Program application?	Check with your supervisor if there is an already approved program application within the school that would cover your project. If there is, please complete a Project within Program Application. Clarify whether the teeth are already extracted, collected and stored OR whether they are not yet extracted, but the consent and place of extraction will be covered by the previously approved program.
Are the teeth you plan to use already extracted, collected and stored (de-identified) by the Melbourne Dental School (this can include teeth collected by private practices on behalf of the Melbourne Dental School)?	You will need to complete Module 3 and attach a copy of the consent form (as per sample printed on university letterhead) used to collect the teeth. If you don't have a copy of the consent form, the provenance of the teeth will need to be explained in Module 3.
Have the teeth you plan to use come from overseas?	As well as Module 3, the HEAG will need to see translations of consent forms and appropriate approvals and assurances that the teeth were obtained as a result of treatment, NOT removed solely for the purposes of the research project.

If you are submitting your project as a Minimal Risk project, do NOT select the "Collection or Use of Biospecimens" option from the Research Checklist at Step 2 in THEMIS. Instead, complete this additional checklist and attach it to the front of your hard-copy application.

In some cases projects involving extracted teeth will need to be submitted as a Project Application, e.g. if the project involves risks that are greater than inconvenience. In this case, select the "Collection or Use of Biospecimens" option together with any other relevant items from the Research Checklist at Step 2 in Themis.

PROJECT APPLICATION | PROJECT APPLICATION (INCLUDING CLINICAL TRIALS)

If the proposed research could lead to discomfort of participants or involves higher risks, a Standard Project Application must be completed via THEMIS.

Examples of discomfort include:

- minor side-effects of medication
- the discomforts related to measuring blood pressure
- anxiety induced by an interview

TYPES OF APPLICATIONS

PROJECT APPLICATION | PROJECT APPLICATION (INCLUDING CLINICAL TRIALS) CONTD.

High risk research is research which involves, but is not limited to intervention of a physical nature and/or access to sensitive and/or personal details of other human beings. It has the potential to involve:

- physical harms: including injury, illness or pain
- psychological harms; distress, fear related to disclosure of sensitive or embarrassing information or learning about a genetic possibility of developing an untreatable disease
- devaluation of personal worth through humiliation, manipulation or being treated disrespectfully
- social harms: discrimination to access benefits or services, damage to social networks or relationships, or social stigmatization
- economic harms: including imposition of direct or indirect costs on participants
- legal harms: including discovery and prosecution of criminal conduct

Further information can be found in the National Statement on Ethical Conduct in Research Involving Humans.

Clinical Trials

A clinical trial is a form of human research designed to find out the effects of an intervention. It can involve testing:

- a drug including oral hygiene products with a therapeutic claim
- a surgical procedure (including biopsies)
- other therapeutic procedures and devices, including restorations
- a preventive procedure
- a diagnostic device or procedure (e.g. sampling and analysing gingival crevicular fluid)

Additional information is required by the HEAG and HESC to enable review of clinical trials. Clinical trials include “Clinical trial involving control comparison group” and/or “drug trial”. THEMIS will guide researchers to complete the Standard Project Application and the DHSV Module Two form (Projects Involving Drugs and Therapeutic Devices) for drug trial applications only. Clinical trial applications not of a “drug trial” nature will need to download the DHSV Module Two form from the forms section. Researchers intending to submit an application that involves a clinical trial are advised to contact the HEAG early on in the application process for guidance.

For further information about Clinical Trials, please refer to the National Statement on Ethical Conduct in Human Research, Chapter 3.3 (https://www.nhmrc.gov.au/book/chapter-3-3-interventions-and-therapies-including-clinical-and-non-clinical-trials-and).

If your research involves the use of Ionizing Radiation that would NOT normally form part of routine treatment, additional information must be provided to the HEAG. The Use of Ionizing Radiation Form must be attached in Themis. The form contains guidelines for completion.

PROGRAM APPLICATION

A Program Application is for use by researchers seeking ethical approval for a program of research encompassing multiple research projects.

PROJECT WITHIN PROGRAM APPLICATION

A Project within Program Application is for use by researchers whose research project fits within a pre-approved Program Application and is one of multiple research projects that fall under the “umbrella” of the approved Program Application.

REGISTRATION APPLICATION

Projects that have already received external ethics approval (i.e. ethics approval from another institution or organization and where the approving institution will remain responsible) can be registered with the University of Melbourne, subject to the HEAG not requesting amendments. Registration Applications should be submitted via Themis initially and to the HEAG for endorsement. (See http://www.orei.unimelb.edu.au/sites/default/files/public/human-ethics/RC_Human_Registration_External.pdf prior to submission to the HEAG). A copy of the ethical clearance from the external institution must also be provided.

SUBMITTING AN APPLICATION

COMPLETING & SUBMITTING AN APPLICATION

Step by step procedure for completing and submitting an application:

- Prior to applying for ethics approval, researchers must complete a Checklist form.
- Once you have entered and submitted your application via THEMIS, print your application.
- Add all supporting paperwork (information which is attached when entering the application to THEMIS i.e. application form, Plain Language Statement (PLS), Consent Form, TGA approval, survey or questionnaire etc., any additional approval from external organizations.)
- The Responsible Researcher must sign the application form
- Upload the signed application, including all the supporting paperwork to Themis. Once your application has been submitted, the Academic Programs Officer (Postgraduate) will circulate the application to the HEAG for review. Any amendments or suggestions from the HEAG will be sent as an email to the researchers requesting the relevant changes be made. The Academic Programs Officer (Postgraduate) will change the status of the application in THEMIS to "Revisions Required" to enable modifications to be made by the researchers.
- Researchers must amend the application in accordance with the HEAG recommendations, then resubmit their revised application in THEMIS, outlining where changes have been made. The changes must be indicated by using the Track Changes facility in Word.
- It is required that when responding to the HEAG's feedback, researchers should attach a cover sheet to the revised application whereby each individual point of the feedback is addressed so as to inform the committee of where and how changes have been made.
- Once the revised version of the application has been approved, the Academic Programs Officer (Postgraduate) will then forward the application to the Chair of the HEAG and the Head of Department for signature.
- Applications which are considered as Minimal Risk by the HEAG are sent to the HESC for ratification. The HEAG Administrator will issue a formal approval letter to the researchers. Once approval has been granted, researchers may commence their project.
- Applications which are higher risk (eg Project Applications) are sent to the HESC for consideration at the next HESC meeting (held monthly as per the below table). The HESC may require researchers to provide further information or make amendments to their application. Formal approval will be issued by the HESC. Research is NOT to commence until approval has been granted.
- If the application form researchers submit is a Minimal Risk application and the HEAG considers the application to pose a higher risk, the committee will recommend the application be re-submitted as a Project Application. This will involve entering further information into THEMIS which includes completing a Project Application form. IN THIS CASE DO NOT CREATE A NEW APPLICATION. USE THE EXISTING APPLICATION AND CHANGE THE TYPE OF APPLICATION IN THEMIS ACCORDINGLY.
- If the HEAG considers a Project Application to be Minimal Risk, then it will approve the application as though it is a Minimal Risk. The Academic Programs Officer (Postgraduate) will notify the HESC in such cases in order to expedite the application's progress.

APPLICATION DUE DATES

Meeting No.	MDS Application Deadline	Applications Due at Office for Research Ethics and Integrity	Health Sciences HESC Meeting Date
1/2017	23 January 2017	30 January 2017	14 February 2017
2/2017	20 February 2017	27 February 2017	14 March 2017
3/2017	20 March 2017	27 March 2017	11 April 2017
4/2017	24 April 2017	01 May 2017	16 May 2017
5/2017	22 May 2017	29 May 2017	13 June 2017
6/2017	17 July 2017	24 July 2017	08 August 2017
7/2017	21 August 2017	28 August 2017	12 September 2017
8/2017	18 September 2017	25 September 2017	10 October 2017
9/2017	23 October 2017	30 October 2017	14 November 2017
10/2017	13 November 2017	20 November 2017	05 December 2017

SUBMITTING AN APPLICATION

USING PATIENT RECORDS

Where researchers are accessing patient records without consent, for the purpose of a research project, a Module P form must be completed in order to request a waiver of consent. In Module P, researchers need to explain and justify why they will not be seeking the consent of participants. Under the Victorian Health Records Act 2001, human research ethics committees can approve access to medical records without consent for research purposes.

Additionally, a formal letter from the Organisation's record holder to confirm that it will be able to give the researchers, including students, access to the records must also be submitted with the ethics application. The University's Health Sciences HESC will require confirmation from the record holder that it is prepared to provide the researchers with access to the relevant records.

Where researchers are accessing patient records from DHSV, a Statement from DHSV Head of Department form needs to be completed. This document requires the signature of the Head of the relevant hospital department. In order to obtain the relevant department Head signature, contact the appropriate administrator.

A signed copy of the Statement from DHSV Head of Department must be provided to DHSV either upon obtaining the relevant signature or upon approval of the ethics application (by the University).

Upon obtaining approval from the University's HESC, researchers must forward the following documentation to DHSV's Executive Office for final approval:

- Copy of ethics approval from the University
- Copy of the application form submitted to the University
- Copy of the signed Statement from DHSV Head of Department (if not already provided)

DHSV will determine whether the application can be expedited or whether full ethics clearance is required. Researchers are not permitted to commence their project until such approval is obtained (in addition to the University's HESC approval).

Documentation should be addressed to:

Ms Pamela Beeston

Executive Officer, DHSV HREC

DHSV Corporate Office

720 Swanston St

Carlton VIC 3053

Any application requesting a waiver of consent can only be approved by the HESC. Therefore Minimal Risk applications that involve a waiver of consent will be sent to the HESC for review and approval.

QUICK REFERENCE CARDS

For detailed instructions on entering your ethics application via THEMIS, refer to the quick reference cards provided on the THEMIS website (https://staff.unimelb.edu.au/information-technology/using-university-systems/themis-support-guides/research-records)

Once you have entered the application, it then needs to be submitted to the Human Ethics Advisory Group (HEAG) for consideration.

HUMAN ETHICS APPROVAL

Navigating the application process

THE UNIVERSITY OF MELBOURNE

1 BE PREPARED

- Most of the information required to gain ethics approval is about being able to clearly articulate the design of your study
- Who? What? Why? Where? How? Content? Data? Risks?

2 REFER TO WEBSITE RESOURCES

- Visit orei.unimelb.edu.au/human-ethics
- Check your local Human Ethics Advisory Group (HEAG) website

3 UNDERSTAND YOUR APPROVAL PATHWAY

- Minimal Risk applications are approved by your HEAG
- Standard Project applications are reviewed by your HEAG and then referred to a Human Ethics Sub-Committee (HESC) for final approval

4 THEMIS SETUP & FORMS

- Log onto Themis and set up your ethics application ID
- Download the application form
- Determine application type (Minimal Risk or Standard Project)

5 CHECK YOUR ATTACHMENTS

- Missing or inadequate documentation is a common reason for approval delays
- Refer to the Plain Language Statement and Consent Form templates available at http://go.unimelb.edu.au/i6pa and your local HEAG resources

6 MEET HEAG & HESC DEADLINES

- Plan ahead and refer to the committee deadlines
- Remember that any Standard Project application will need to be reviewed by both a HEAG and a HESC

7 ENSURE APPLICATION CONSISTENCY

- Ensure that the information in your application form is consistent with the information in your attachments
- Ask someone to proof-read your application before submission

8 SEEK ADVICE EARLY

- Contact your local HEAG administrator if you are unsure of requirements or deadlines

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The University of Melbourne

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