Ethics Guidance and Checklist

Information to Consider When Applying for Ethics Approval for Your Research Project

The members of the Bendigo Health HREC are strong supporters of a robust local research culture. They devote considerable time and effort to reviewing applications, to ensure that research is conducted responsibly, ethically and with integrity and merit, in line with the National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 | NHMRC and the Australian Code for the Responsible Conduct of Research, 2018 | NHMRC (see National Statement 5.1.1).

Ethics approval sometimes takes longer than researchers anticipate and, from time to time, HRECs can be seen as "holding back research". Usually this arises when some of the detail necessary to meet the requirements of the *National Statement* is overlooked, or when an application lacks the overall clarity of methodological approach for approval to be given in its present form.

This document, prepared by the Bendigo Health HREC, aims to help minimise the time it takes for your application to go through the process of ethics review and approval. It covers the key issues that HREC reviewers have found as needing attention in a significant number of applications in recent years.

Application drafting and peer review

It is important that several (if not all) members of the research team read the application carefully prior to submission and where possible seek peer review by an experienced researcher.

Language

Whilst parts of a research application will include technical information, avoid jargon and unduly specialist medical terminology, and as much as possible use language that will be reasonably understandable to a diverse group of HREC members.

Research Protocol

We encourage researchers to start the application by completing a Research Protocol using the template provided on the Bendigo Health (BH) Research Ethics and Governance website and pay heed to the suggestions as to what might need to be considered in each section. Note that in completing items in the HREA (HREC application) or VSM (Victorian Specific Module) forms you can simply refer to sections in the Research Protocol in a significant number of item boxes, or cut and paste from the Protocol (and it is worthwhile stating this in the item box with reference to the Protocol section if that has been done).

Research design, data analysis and outcomes

- Ensure that the aims and objectives of the research, the data that will be collected, the methods of analysis and the perceived outcomes of the research are clearly explained and aligned.
- Have clear output goals such as reports, recommendations, conference presentations and publications, including sensible targets for where and when. Specify long-term outcomes that might be related to benefits to patients and/or health care staff in the future as a result of the research.
- Set and state clear timelines for completion of key components of the research to facilitate efficient and effective research right from the start.

- It is essential that the planning for any research project that requires sophisticated data analysis, either quantitative or qualitative, includes input from the expert(s) who will undertake the analysis. Using the appropriate research methods, collecting the appropriate data and collecting sufficient data to meet the aims of the research, is a vital ingredient in the process from the beginning. (See *National Statement* Section 1.1 (b).
- A crucial aspect of planning in some projects involves the determination of a sample size that yields a reasonable likelihood of detecting a desired effect, i.e. sufficient power. The viability of the project may be jeopardised from the start if this aspect of the planning is deficient.
- Apart from the need for statistical expertise in the planning in order that the aims of the project can be met, participant data cannot be "sent" to someone outside the team for analysis – you must have the expertise within your team.

Participant Consent

"The Statement on Ethical Conduct in Human Research (Chapter 2.2) states that if you want people to take part in your research project, you need to get their informed consent. This means that they:

1. voluntarily agree to take part in your project **and**
2. understand what your project involves."

- The most common forms of consent (but there are other variations) are "written consent", "verbal consent" and "implied consent".
  - Whenever participants undertake activities in order to collect data about them for research, written consent is the usual requirement.
  - In some circumstances, verbal consent may be appropriate but this is relatively rare.
  - Implied consent is typically associated with anonymous surveys (particularly staff surveys) – the submission of the survey is taken as consent to participate – arrangements ensuring confidentiality, data security, and anonymity must be spelled out clearly in the application.
- If any of these forms of consent apply, a Participant Information Sheet as part of a Participant Information and Consent Form (PICF – see below) is required that provides appropriate information to enable potential participants to make an informed decision about participating.
- The consent form itself must address each of the activities associated with participation and also any additional features for which consent is sought, such as extended use of data or retention of tissue/blood samples.
- Waiver of consent is sometimes sought, particularly in cases such as retrospective studies based on medical records, where it is impracticable to obtain consent. The application needs to demonstrate that the points in Subsection 2.3.10 in the *National Statement* have been considered. Thorough descriptions of steps that ensure participant privacy, anonymity, and data security are important.

Risks and benefits

- Ensure that you consider carefully any of the forms of risk listed under *Harm, discomfort and inconvenience* in Chapter 2.1 of the *National Statement*.
- Indicate the likelihood of any risks that are identified and describe measures that will be taken to reduce/minimise risk.

- Very often there may not be any direct benefit to participants from their contribution to the research. Be upfront in the PICF in recognising this.
- On the other hand, it is worth remembering that research that improves treatment, health service delivery or staff working conditions will be of benefit to others in the future (including participants) and so making a contribution may be rewarding to the participant.

Participant privacy, anonymity, confidentiality

- Make it clear to the HREC (and to participants in your study in the PICF) that the research team has arrangements in place to ensure that individual participants' data will not be revealed in dissemination of the results of the project.
- If the research involves a small number of participants (e.g. qualitative analysis) spell out how anonymity will be ensured.
- If small subgroups of larger samples/populations may be investigated (e.g. in survey analysis) and discussed in any dissemination of the results, spell out how potential "implied identification" of participants will be minimised. This would occur if subgroup characteristics might enable a person(s) outside the research group to imply the identity of participants.
- Be sure that you understand the terms identifiable, re-identifiable and non-identifiable data and use them appropriately (*National Statement* Chapter 3.1, "Identifiability of Data". Most commonly it is used to mean that identifiers have been permanently removed from the data and no coding file to enable re-identification is established.
- A strong case needs to be made for storing identifiable data.
- Explain why re-identified data is necessary/advantageous. There are many reasons why this may be the case (e.g., to correct errors, explore missing data, add variables following approved amendment to research, or when future use of data is sought in the application).
- Re-identifiable data will involve a coding file – explain how this will be securely stored separate from the participant data files.

Data security

- Demonstrate that participant data (electronic and hardcopy) will be stored in an appropriately secure manner. For electronic data this typically means on a password restricted BH or University server. Specify how external researchers will be provided restricted access to BH or University systems if that will occur.
- If email will be used to transfer data, state why this is necessary, and specify clearly that encrypted BH or University email will be used exclusively.
- Explain that the data will be stored for 7 years (15 years for clinical trial data) from publication and destroyed after that time (as required by NHMRC).

Recruitment and Participation

In recent years, the HREC has seen a number of projects where levels of participation have been substantially lower than envisaged. Poor recruitment/participation rates can compromise project effectiveness and publication potential. A strong and carefully constructed recruitment strategy must be supported by clear project documentation (including recruitment flyers and PICFs) that will be put to potential participants.

Inclusion

An important requirement of consent is that researchers reasonably believe that participants have understood the information presented in the PICF, together with any additional information provided verbally or in written form in response to questions put to researchers. This may tend to diminish participation by some groups, such as those who are less technically confident, have had less opportunity for education, or those for whom English is not their primary language. On the other hand, it is important to be as inclusive as possible in recruitment of participants on grounds of justice and fairness, and also in order to avoid bias in the research findings due to the sample of participants excluding particular groups from the population from which the sample is drawn.

Apart from these two considerations, meeting recruitment targets can be challenging, so casting the net as broadly as is reasonable makes sense. Consider ways to ensure that there are straightforward mechanisms in place for potential participants who need to ask questions or seek additional guidance, and describe the processes in the PICF so that they will feel comfortable in doing so.

Writing the Participant Information and Consent Form (PICF)

- With the PICF, you want to arouse the interest of potential participants and fully inform them of what participation involves in language that they can easily understand. Put yourself in the shoes of the patient or staff member who might be considering participation and write the PICF from that point of view. Remember that they only see the advertising/promotional material and the PICF, but not the research protocol, in making their decision about participation. Use language and terminology appropriate for the range of potential participants.
- In the Introduction and/or promotional material, sell the research – why is it important, what is the current position and what improvements to patient treatment/welfare, staff conditions or service delivery do you hope to identify.
- Make sure inclusion/exclusion criteria are spelled out clearly early on so that you don't waste the time of readers who are clearly excluded. There will be some overlap between the promotional material and first section of the PICF.
- Find the right balance in each section of the PICF: accurate, concise, thorough, but avoid unnecessary fine detail. Keep thinking: plain English.
- Ensure that there is no ambiguity in spelling out precisely what participation will involve and provide a realistic estimate of the time that might be required for each activity, including questionnaires. Remember: Have you been frustrated after deciding to fill in a 20 min survey and found that after 40 mins you were still going and unsure how much more there is? In this situation, did you continue to be patient and diligently provide the best data that you could?
- If participation requirements include treatment, activities and/or time commitment that are part of their normal treatment it is helpful to spell out what activities/time commitment are over and above the usual or what they would do as part of usual/routine treatment.
- IT IS VITAL that several (if not all) members of the research team look carefully at the PICF and ensure that it is well written, accurate and free of typographic and other errors. These characteristics are as important in the PICF as in a manuscript being submitted for publication. You are representing BH or your University in the advertising/promotional material and PICF that you place in the hands of potential participants.

Consent form (part of the PICF)

It must be absolutely clear what participants are consenting to, in terms of what is required of them and any extended use of their data/biospecimens beyond the current research project. Again, use language that the range of potential participants will easily understand.

Withdrawal of consent

Participants must have the option to freely withdraw consent. The process must be as straightforward as possible and stated clearly in the PICF. The Protocol and PICF must state whether or not data already collected will be retained or withdrawn from the research.

Informing participants of research findings

Given the commitment of consenting participants to the research, it is only fair and reasonable that a mechanism is in place to provide a summary of the research findings to those who would like to see one. This should specified in the PICF and be an option on the consent form.

Checking your application prior to submission

We recommend that you go through the checklist below before submitting your application for review via the ERM, the ethics administration software system 'Ethics Research Manager' in use in Victoria (see below, section "Submitting your application for review via ERM"). The checklist is designed to help you align your application, protocol and other documentation to tell the same story, and to make sure you do not forget some of the crucial parts of your application. The aim is to submit as complete an application as possible to avoid reiterations of the process.

The HREC and the RGO (Research Governance Office) are here to help but every resubmission adds to your waiting time while we have taken on to attend to other submissions. So, let's check your application once again against this checklist:

Ethics Application Checklist	
PROJECT OVERVIEW	**Tick for Yes**
Is the project clearly explained and summarised?	
Are relationships with other projects or sites clearly explained?	
Is it clear who/what is the hosting organisation?	
RESEARCHER DETAILS	
Are all researchers involved in this project listed correctly?	
Are signatures provided on the application form?	
Are researchers' respective roles in project clear?	
Are current CVs provided for ALL named researchers?	
Are roles within project clearly explained – e.g. supervisor/research student?	
PROJECT DETAILS	
Is the project timeframe appropriate and manageable?	

Is project proposal/protocol attached?	
Is there consistency between project proposal/protocol and application?	
Is the proposed data analysis approach clear and appropriate?	
Has there been peer-review of project to ensure practicability and integrity of approach?	
Are all required documents present?	
PARTICIPANTS	
Is the number of participants clearly explained (rationale) and appropriate?	
Are there any issues about recruitment of participants? Has it been explained how these will be addressed so that numbers are sufficient to ensure viability of project?	
Are there any dependent or unequal relationships between participants and researchers??	
Is consent appropriately addressed?	
Are consequences/risks/benefits of participation adequately addressed?	
COLLECTION/USE/DISCLOSURE OF INFORMATION	
Do arrangements for the collection, storage, use, access and disposal of participants' information meet guidelines set out in National Statement and Privacy Provisions?	
FINANCIAL AND RELATED ISSUES	
Is any potential conflict of interest appropriately explained?	
Where relevant, is the budget clearly explained? Is it clear where the funds are sourced from? Are the total budget parameters clear?	
Is project adequately resourced?	
Participant Information Sheet (first part of the PICF)	
Is the PICF correctly presented on appropriate letterhead?	
Is it written in plain English?	
Is it easy for the target audience to understand?	
Is the project clearly explained, including aims and purpose of the project?	
Are researchers, including student researchers clearly identified? Is it clear what organisations are involved?	
Does the PICF clearly explain what is involved in individuals' participation in the study?	
Does the PICF clearly explain voluntary participation and right of withdrawal without penalty?	
Are risks and benefits clearly explained?	
Are any costs to participants clearly explained?	
Is data storage, use and access clearly explained to allay participants' concerns about confidentiality?	
Does the PICF address confidentiality and privacy?	

Is it explained if and how the results of this project will be made available?	
Does the PICF clearly explain how a participant can make a complaint?	
Are names and phone numbers for Bendigo Health contact personnel clear and correct?	
Are arrangements in place for participants to retain a copy of the PICF?	
CONSENT FORM (part of the PICF)	
Is the PICF correctly presented on appropriate letterhead?	
Is it written in plain English?	
Are researchers clearly identified?	
Does consent form identify all processes to which participants are consenting?	
Where participants are required to provide separate consent for a number of activities within the project, does the consent form list each element for which consent is sought (including extended consent if relevant)?	
Is a separate form included for withdrawal of consent?	
Finally -- SUBMISSION of APPLICATION	
Has the completed application been reviewed prior to submission by a critical friend or team leader for quality, accuracy and internal consistency of documentation? (Strongly recommended to avoid reiteration of the submission and review process.)	
Are all items ticked as Yes? If so, you are ready to submit the application for review.	

Submitting your application for review via ERM

There are five steps to the submission

1. Create an account on ERM (https://vic.review.ethicalreviewmanager.com/)

2. Submit your proposal via ERM when you have ticked "Yes" to all of the items on the Checklist (above). It will be pre-reviewed by the RGO and processed for HREC review if ready and complete.

3. Address the feedback you may receive from the RGO, revise and resubmit. If the application is now ready and complete, the RGO will progress it to HREC review either in the next full HREC meeting (for all higher than low risk studies) or through an Expedited Review Panel of the HREC.

4. Wait for the outcome of the HREC review. The outcome can be an ethics approval with or without a request for minor amendment, a request for more information or no approval is given. In case the project is not given approval, you may need to reconsider some major issues in your proposal and resubmit a new application in due course.

5. Post-approval, keep in touch with the RGO and HREC on regular basis via ERM by submitting annual progress reports and, when required, requests for amendment. These will be reviewed as per your initial application.

Getting authorisation to conduct your study on site

Before you can start your project at Bendigo health, you need to acquire site specific authorisation (SSA) which is part of research governance procedures to ensure that research is conducted safely and responsibly. Research governance covers legal compliance plus financial and risk management issues and accountability of research projects on site. Practically, it runs the final check of your project feasibility on site at Bendigo Health. Research governance is separate from HREC ethics review.

SSA applications are submitted via ERM. The site specific assessment (SSA) form, or the LNR SSA for low or negligible risk studies approved by Bendigo Health HREC, is used to address research governance. A research agreement between institutions is also required. Templates for agreements/contracts can best be found via the research office at the institution associated with the project. Bendigo Health RGO may be able to provide a template.

The SSA applications are reviewed by the Research Governance Office and approved at the Executive Level. Site Specific Assessment applications can be submitted simultaneously with the ethics review, but ultimately will need the ethics approval and updated, ethics approved documents. The LNR SSA form cannot be used until the ethics approval has been received.

For more information, please refer to our Intranet site:
https://intranet.bendigohealth.org.au/ResearchEthicsGovernanceRGO/.

Any questions on the above, we are here to help

Any ERM-related queries should be addressed to ERM, Infonetica Help Desk:
(Helpdesk@infonetica.net).

Any questions related to HREC ethics review, research project development and preparing your application for ethics or site specific assessment, you can reach the Bendigo Health Research Governance Office via email at researchoffice@bendigohealth.org.au, via ERM correspondence or by phone on 03 54546412 (leave a message and we will call you back). If you already have an ERM ID number for your project, please write it in the Subject line of your email and mention it in your message. This helps us locate your project in the online system.