PART 2 ETHICAL CONSIDERATIONS


6 Communicating with research ethics committees

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Chapter topics
- Research ethics committees and institutional review boards
- The need for research ethics committees and institutional review boards
- Engaging with research ethics committees and institutional review boards
- Applying to research ethics committees and institutional review boards

Introduction

Engaging with research ethics committees (RECs) or institutional review boards (IRBs) is a core part of the research process for most, if not all, researchers in the health field. While the principles of research ethics have a long history, the development of formal review processes is a much more recent phenomenon. Central to ensuring success in these interactions is knowledge of the relevant REC or IRB’s policies and procedures. Equally important is identifying and addressing the key ethical issues raised by the proposed research.

Health research covers a broad range of topics, research methods and therefore ethical issues; however there are a number of key elements that RECs and IRBs will typically focus on. These include several of the issues discussed in the previous chapter, such as consideration of vulnerable groups, potentially invasive or distressing research procedures, and issues regarding data protection. It is essential that researchers consider these issues carefully and outline how these will be addressed as part of the process of seeking approval.

Research ethics committees are a forum for safeguarding the rights of patients and clients who may be involved in research projects. However, students and early-stage researchers may be unaware of the complexity and importance of applying to a hospital or university research ethics committee. This chapter addresses the steps needed in applying for ethical approval. Using a standardized research ethics application, it takes the student step by step through the process and identifies the level of information needed to apply to a research ethics committee. It explains in clear and accessible language the type of information required by an ethics committee and how to ensure that patients are protected throughout the research process.

The Development of RECs and IRBs

Before focusing on the challenges of REC/IRB review and possible solutions, it is important to reflect on the factors influencing the development of these structures.
of medical, health and social RECs and IRBs. The online nature of the process, as well as the use of a centralized system, offer numerous benefits to researchers, not least those conducting multisite studies and trials. The use of a centralized system or common application procedures is evident in a number of countries internationally, including New Zealand, where health and disability-related research is governed regionally by four Health and Disability Ethics Committees (see www.ethics.health.govt.nz) with shared procedures, and Australia, in the form of the National Ethics Application Form (see www.neaf.gov.au). In Ireland a standard application form exists for clinical trials, and since 2009 work has been ongoing on the development of a similar system for health-related studies (other than clinical trials), referred to as the Research Ethics Committee Standard Application Form (REC-SAP) (Standard Application Form Consultation Group – Pilot Form Sub-Group 2010). While applications for clinical trials can only be submitted to approved committees, a range of health and academic RECs and IRBs are using or reviewing the suitability of the non-trial standard form (see www.molecularmedicineireland.ie/research_ethics for more information).

This brief consideration highlights the changing context for RECs and IRBs during the last 20 years. Indeed, one paper by Rosnow et al. (1993) offers a reflection on some of the changing issues faced at the time by these committees as they respond to changing norms and standards. Issues highlighted include the implications of research on the topic of communicable disease for expectations of confidentiality and the demands of public health legislation, the changing views of placebos in clinical trials, and also the growing importance of design issues in the deliberations of committees. Understanding the context and history of the REC/IRB system is an important step in engaging with the process.

In considering the process of engaging with RECs and IRBs a key feature, and one which stays with researchers, is their experience of the process. It is necessary to reflect on and perhaps deconstruct the views and experiences that may influence the way in which researchers will engage with the process. Anecdotally, researchers often use the phrase ‘getting through’ the ethics review process, and refer to tensions and difficulties throughout the process. However there are a number of interesting studies that explore researchers’ experiences more systematically. Box 6.1 provides examples of researchers’ perceptions of the process of dealing with ethics committees.

**Box 6.1 Researchers’ perceptions of research ethics committees**

For the interested reader a paper included in the special issue of the *Journal of Applied Communication Research* (Vol 33(3), 2005) provides a broad insight into the views of one group of researchers through a series of narratives submitted for the issue. Keenan’s (2005) analysis of these narratives highlights themes that will not be unfamiliar to researchers in health research. It is interesting to note that while there was evidence of both positive and negative experiences, the negative were expressed more frequently. While the dominance of negative experiences may hold intuitive appeal to some researchers, empirical studies have identified that this may not be reflective of the general experience of engaging with committees.
of committee meetings, the deadline for submission of information in advance of the meeting, and the expected time taken to review and feed back to researchers. Masterton and Shah (2007), in a very pragmatic paper on approaching RECs and IRBs, stress the importance of incorporating these time frames into the planning process. Another important part of the preparation is to be aware of your role in the decision process. Some committees will call the researcher to answer questions on the proposal (thus allowing for clarification), while others will make the final decision on the basis of the documentation submitted. Researchers should note that decisions made on the basis of documentation only serve to reinforce the need for familiarity with the process and procedures to avoid unnecessary delays.

### Possible outcomes

Researchers should also be familiar with the possible outcomes of the process. For example, some committees may simply reject incomplete applications without information on the material that was included. Clearly this has the potential to impact on the time frames mentioned above. Possibly the most common response from an REC or IRB is to stipulate issues to be addressed by the researchers before approval can be confirmed (Hunter 2011). A paper by Sansone et al. (2004) reports on a review of the responses by one REC over a five-year period (the committee in question was a hospital committee in a suburban part of the Midwest US). They found that in almost 85 per cent of cases there was at least one stipulation to be addressed. The nature of the types of stipulations that are common will be considered later (particularly as they represent a very useful list of ‘dos’ and ‘don’ts’ for researchers); however researchers will need to be aware of the implications of stipulations. RECs and IRBs may distinguish between major stipulations, which may require a repeat of the review process (with all of the associated delays), and more minor stipulations that represent areas for clarification. These clarifications can commonly be approved by the Chair of the committee rather than requiring a full review—clearly a more positive outcome from the researcher’s perspective.

### Procedures for low-risk research

Before considering the process of applying for REC or IRB approval, researchers should explore whether the committee from which they are seeking approval has procedures for consideration of research that meets criteria for low-risk review or exemption from full review. This refers to procedures by which studies that meet key criteria regarding the nature of the research and the level of risk may be entitled to an expedited review, or indeed may only require that the committee be notified. An examination of practice in other countries conducted as part of a review of REC/IRB structures and processes in Ireland (Research Ethics Committees Review Group 2008) highlighted the presence of procedures for ‘expedited review’ in the US, Canada, Australia, New Zealand, the UK and Ireland. Expedited procedures generally include a shorter application form and one or two members

### Applying for REC/IRB approval

The remainder of this chapter focuses on the process of applying for approval to an REC or IRB. A central emphasis will be the challenges that arise during the process and possible solutions that will guide researchers. Given the variation in documentation and procedures evident in different countries, it is necessary to structure this consideration around common issues. However, before considering the context of the form, researchers must be familiar with the policies and procedures of the specific committee they are applying to.

#### Procedural knowledge

The first practical step in preparing a submission to an ethics committee is to gather any available information on the specific committee that holds jurisdiction over the research. Typically this will be the researcher’s place of work or the setting through which potential participants will be contacted. While this appears somewhat obvious, anecdotal evidence is a common complaint by RECs and IRBs that those submitting for review have not familiarized themselves with the process. Work by Kotzer and Milton (2007) highlights the importance of researchers’ knowledge of relevant procedures. They frame the committee structure as a resource, while stressing the need for researchers to be familiar with the relevant procedures and for RECs and IRBs to streamline those procedures. They go on to report an evaluation of an initiative designed to increase staff knowledge of committee guidelines. Worryingly, they report no significant improvement over time and in some cases a decline, though they do raise concerns about the effectiveness of the design and cite poor response rates and small samples as possible influences.

#### Time frames

In gathering information it is important that researchers pay particular attention to the time frames indicated by the committee. Key elements include the scheduling
Preparing your submission

Central to the ethics process is the ethics application form. Whether the REC/IRB decision-making programme is based on documentation only or not, it is essential that the researcher fully and clearly completes the ethics application form and provides all necessary supporting documentation. While these forms can be complex and are often detailed, it is important to recognize that the information is being requested to assist the committee in making their decision. Masterton and Shah (2007) stress the importance of clear communication, which avoids technical terms and jargon that may not be common to all members of the committee (an important consideration if the REC or IRB is a multidisciplinary one). Researchers should remember that the decision to be made by the committee is whether the appropriate standards of practice have been met, and if elements of the study are not clear then the REC or IRB cannot form an opinion on this issue. Greaney et al. (2012) stress the implications of such a lack of care for the timely completion of the review process.

While there is significant variation in the structure, language and requirements of research ethics application forms, it is possible to identify a number of common sections for completion. These include (but are not limited to):

- General information, which will often request details of the research team members, partners and collaborators.
- Cost and resource implications, funding and insurance/indemnity.
- Methodological details, i.e. a description of the study (possibly in plain language), study participants and research procedures.
- Medical information (for example the use of human biological material, medical devices and medicinal products).
- Data protection and security considerations.
- Ethical issues, where the application is required to identify the study’s main ethical concerns and detail the solutions to these issues.

In addition, researchers are generally required to provide supporting documentation such as samples of materials, information and consent documentation.

The first point to note for researchers completing an application is that some sections of ethics application forms are mandatory and must be completed for all applications. These generally include the general information and study details and key sections such as data protection, costs and ethical issues. Most application forms will come with comprehensive guidance notes that will assist the novice or unfamiliar researcher. While this may not be the case for all RECs and IRBs, the researcher should note if a particular committee provides templates or sample documents to aid the process of securing review.

Consideration of methodology

Anecdotally, a significant source of tension between researchers and RECs or IRBs, and indeed within committees, is the debate regarding the consideration of research methodology as part of the review process. Masterton and Shah (2007) refer to the debates regarding the need for RECs and IRBs to comment on research design. Clearly, if a committee is to consider the appropriateness of the proposed research they must also examine aspects of the methods used.

Key methodological issues that may be requested by the REC or IRB include the proposed population, the planned sampling techniques, and the data-collection procedures. However, Masterton and Shah also refer to concerns regarding competence and supervision, particularly for research conducted by less experienced researchers. In order to avoid difficulties it is important that applications describe the methodology of the study clearly and concisely, remembering that the committee will, more than likely, be made up of members from different disciplines as well as lay members. With this in mind the researcher should consider the need to provide a clear rationale for particular choices, for example the use of deception where the scientific rigour of the study demands it. Sharkey et al. (2011) describe in some detail the rationale behind many of the choices made in their study of an online discussion forum for young people who self-harm, including conducting the study anonymously so as to encourage participation and respect the centrality of anonymity to online social interactions.

Sample size and methodology

Another important area, which is highlighted by Masterton and Shah, is the area of data analysis. Some researchers may feel that the inclusion of questions regarding sample size and power reflect a more quantitative framework; however, central to these questions is the competence of the researcher to oversee the analyses needed. Whether the research is qualitative or quantitative the researcher should be able to provide a rationale for the sample size, whether this is based on statistical power, previous research, or in the case of more qualitative studies the demands of data saturation. Again, in these sections, a clear rationale for the choices made can address any concerns the REC or IRB may have about the ability of the study to draw a credible conclusion.

Data protection

As highlighted earlier, the issue of data protection is one where legislation has had a significant impact on the research process. A particular challenge in this area is the scope for interpretation of the relevant legislation. In the case of the UK, Parry...
and Mauthner (2004) report that the use of data for research purposes falls under an exemption that allows its use without explicit consent, though researchers are required to consider the potential for ‘harm’ and the sensitivity of the data. In Ireland this is not the case, though central to the legislation is the principle that data can be used as long as the use is not at odds with the initial reason for collection. Another key aspect of data protection is the level of identification possible from data, and the risk to which the data is exposed in line with the requirements suggesting that anonymous data and its use is more in line with the requirements.

A final concern for many RECs and IRBs is the procedures for accessing this area. Masterton and Shah (2007) highlight this in the context of databases containing medical information. All data protection legislation considers the responsibility of medical information. Data controllers must ensure access to existing information, and that researchers use the extent to which they can access this type of information. For example, a researcher who works as a practitioner in a particular setting may have access to patient records as a practitioner, however accessing this information for the purpose of research may not be acceptable to a committee, and in these situations researchers should consider the possible role of gatekeepers in supporting the process of accessing data.

Anonymity and confidentiality of data

There is no doubt that the key to addressing these issues to an REC or IRB’s satisfaction is to consider the nature of the data gathered for the purpose of the research, the procedures for accessing existing data and particularly the sensitivity of the data, including the level of identification necessary. In reflecting on data protection issues while preparing an application a researcher might consider the need for data to be identifiable and the associated demands for security depending on this and the sensitivity of the data. Related to this, it is also important to consider the distinction between anonymity and confidentiality. While many researchers may consider these terms synonymous, there is an important difference between information that is considered anonymous and data for which the researcher protects the identity and/or contributions of the participants (confidentiality). Scott (2005) presents an interesting consideration of issues of anonymity and confidentiality in relation to communication research, and considers some of the challenges of addressing this issue. From a practical perspective, Scott stresses the need for researchers to be clear on the level of protection being proposed for participants and how it is ensured. This detail will be important in the preparation of the application for review.

Limits of confidentiality

One point to note here is the concept of the limits of confidentiality. In Ireland and the UK the application of child protection guidelines typically means that researchers may have to breach confidentiality where there is a concern for the well-being of the child. Sieber (2004) describes the variation of requirements by state in the US and the extent to which RECs and IRBs will require researchers to warn potential participants of these requirements. Harbour (1998) considers this along with other issues that place constraints on guarantees of confidentiality, including having information relevant to the commission of a crime. A final point on the limitations of confidentiality relates to the impact of particular methods of data collection. For example, a researcher offering confidentiality to participants in a study that uses focus groups has perhaps not thought through the fact that in a group setting all members of the group will hear the contributions of other members, thus undermining the idea of confidentiality in these settings. Creaney et al. (2012) state that the implications of this type of method for privacy must be communicated to potential participants in advance.

Identifying ethical issues

An essential element in successfully securing ethics approval is the researcher’s ability to identify and respond to key ethical issues and dilemmas in the research. The previous chapter considered a number of specific issues common in health research. However, this section focuses on the issues themselves but the problem-solving process by which researchers consider these issues and present them to an REC or IRB. Figure 6.1 presents one framework within which researchers might reflect on their study in preparing an application. The figure highlights that the researcher must consider issues that arise as a result of the setting in which the research takes place, the people involved in the research (importantly the participants and the research team), the specific topic of the study, and finally the research process.

![Figure 6.1: A framework for problem solving in preparation for seeking REC/IRB approval.](image)

Box 6.2 provides an example of how the framework can be applied in seeking ethical approval.
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Box 6.2 A framework for problem solving in preparation for seeking REC/IRB approval

A staff member based in a local health clinic is planning a piece of research as part of a postgraduate course they are completing. They propose to conduct the research in the clinic (the setting). The researcher must consider whether there are any issues relevant to the setting that must be considered in the application for approval, such as the procedures for organizational approval.

Moving to consider the people, the researcher may be targeting members of vulnerable groups receiving services and the REC or IRB will want to see evidence that the recruitment and consent procedures have taken this into consideration. Remembering that the researcher is also part of this element, the committee may consider if the researcher (as a student completing a programme) has the skills needed to complete the project as designed and that appropriate supervision is in place. A final issue that can project as designed and that appropriate supervision is in place.

Moving to ethical issues relevant to the topic, clearly the focus for many researchers is on sensitive topics. Here the challenge is for the researcher to be open to the participants’ and the committee’s views on whether a topic is sensitive or potentially distressing.

In preparing the application for approval it is important that the researcher reflects on the possibility and probability that the topic may be distressing and, in the application, clearly describe the procedures they will introduce to ensure that any distress is managed. The need to develop procedures for the management of distress is discussed in Vass et al. (2003) with reference to a study of communication patterns in people with Alzheimer’s and their carers. While the topic would not necessarily be considered sensitive, the nature of the engagement between the researchers and the participants, and the particular vulnerability of the participants, could result in anxiety on the part of the participants. Recognizing this, the researchers describe the procedures by which participant anxiety will be managed, including the decision to terminate the interview if necessary.

The final element of the framework is the research process, and again the key to success is to identify any potential issues and address them clearly in the application. While health research can involve a range of processes that might be invasive, harmful or distressing (such as taking blood or tissue samples), less experienced researchers may fail to consider the ethical issues associated with more apparently ‘innocent’ processes. For example, in a study using interviews the researcher must be aware that the audio recording of an interview is potentially identifiable and must be transported and stored securely, while the demands of discussing a sensitive subject can be more challenging if a focus group method is being used.

So in preparing an application for REC or IRB approval it is essential to both identify and address the key ethical issues associated with the study. The framework described above aims to support the researcher to identify the range of issues involved; the challenge for the researcher is to provide clear evidence in the application that these have been addressed.

Supporting documentation

Clearly, a key aspect of successfully securing ethics approval is the quality of the submission to the committee. A common difficulty that committees face is a lack of information or indeed a lack of clarity in the documentation. This may present in the form of incomplete application or supporting documentation. The researcher should not underestimate the importance of the supporting documentation.

One factor that relates to many of the issues considered above is the responsibility of the researcher to ensure that participants are fully informed as to the nature of the research and the implications of deciding to take part. In preparing an application for approval the researcher must describe the steps taken to ensure the elements of the study are clear to participants (and indeed to the REC or IRB). Unsurprisingly, the information and consent documentation are considered closely by committees.

The review of REC/IRB decisions by Sansone et al. (2004) described above found that changes to consent documentation was the most common requirement and these included presentation and formatting, clarification of risks and procedures, and participants’ rights. Interestingly, a study by Albala et al. (2010) examined the quality of information and consent documents submitted to an REC or IRB over the course of 25 years, and found that these documents had quadrupled in length over time, and that the occurrence of discrepancies in risk levels (as reported by the application and the information sheet) had dropped over time.

Difficulties and delays can also occur if copies of research materials such as questionnaires or standardized tools are omitted. Anecdotally researchers using qualitative methods have experienced difficulties when the use of unstructured or semi-structured interviews mean that a comprehensive interview schedule cannot be included with the application. In this situation the researcher might consider outlining a topic guide that outlines the areas they intend to explore while recognizing that the participant may raise additional issues.

Negotiating with RECs and IRBs

The final aspect of engaging and communicating with an REC or IRB to be mentioned is the potential to negotiate with the committee. Many academics interested in research ethics will recognize that this area is one with very few definitive right answers. As a result, researchers should consider whether there is scope to negotiate with the committee, either in response to changes or clarifications being requested or indeed in advance of a decision (typically as part of the initial application). A key concern for RECs and IRBs is the rationale behind a researcher’s choice of proposed procedure, and it is worth noting that requests that are perceived as self-serving may be far less effective than those that argue that the proposed element is central to the balance of risk and benefit in the research. Furthermore, showing that the proposed element is grounded in the existing literature in the area, or indeed looking to the literature on ethics itself, can allow the researcher to present a strong rationale to pursue a course that might initially raise concerns among the members of the REC.
or IRB. In extreme cases researchers might pursue an appeal – for those in this situation the researcher must be pragmatic about the implications for the schedule of the research.

Conclusion
Research is a process of decision making, with researchers required to consider the different options related to the proposed course of study and identify the elements that are best suited to the proposed study. This includes the process by which ethical approval is secured from the appropriate REC or IRB. As outlined above, the ethics review process is typically detailed and key issues can emerge in health research. In preparing an application to a REC or IRB, key areas for consideration include elements of the people, process, topic and setting, and researchers should describe these issues and outline how they will be addressed as part of the application for approval. A central message of this chapter is that familiarity with the specific procedures and timescale of the ethics review process is crucial.

Key concepts
- Research ethics: ‘Principles of good conduct. In the context of research, ethics usually refers either to the protection of subjects or to honesty in reporting results’ (Vogt 2005: 108).
- Ethics approval process: this refers to the procedures laid down by health and academic settings covering ethical review and approval within the organization.
- Expedited review: this refers to a shortened review process, usually limited to low-risk research.
- Voluntary informed consent: ‘A communication process in which a potential participant decides whether to participate in the research project’ (Sieber 2004: 493).
- Vulnerable populations: refers to individuals who may require additional consideration in the research process. These groups typically include minors, or individuals with cognitive limitations or emotional difficulties.
- Data protection: this refers to issues regarding confidentiality and appropriate use of individuals’ data in the research process.

Key readings
  This book provides a detailed consideration of the legislative context for research ethics, ranging from consent and confidentiality to research involving human tissue.
  This book details a practical rather than a principle-based approach to research ethics, and includes debates on a number of key issues in research.
  An accessible guide to the topic of research ethics, which considers issues that can arise at different phases of the research process from development to dissemination.

Examples of papers on ethics review process in health care research
The following papers provide excellent examples of issues related to ethics in health care research.

Useful websites
- Website of the Irish Council for Bioethics. While the Council has ceased to operate, the website contains very relevant information – www.bioethics.ie
- Website for the UK’s Central Office of Research Ethics Committees – www.corec.org.uk
- This site contains a range of relevant information, in particular information on the RECSAF in Ireland – www.molecularmedicineireland.ie/research_ethics
- Home page of the integrated research application system in the UK – www.myresearchproject.org.uk
- Website of the Nuffield Council on Bioethics, an independent body based in the UK that considers ethical issues in areas relevant to medicine – www.nuffieldbioethics.org
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References


