Gaining ethical approval is a key part of being able to undertake research but can be complex. Understanding the process will help you to submit a successful application.

Ethical approval in studies raising consent issues

In this article...

- Bodies that provide ethical approval for research studies
- The ethical approval process
- What to expect when applying for ethical approval

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This article offers practical advice on applying for ethical approval for research involving participants who may be unable to give informed consent. It briefly outlines my own experiences and offers tips on using the Integrated Research Application System website, going to a social care research ethics committee meeting and resubmitting an application.

One of the guiding principles of research is that all participants should receive adequate information to enable them to choose freely whether they wish to be involved (Department of Health, 2005). Making this decision based on appropriate information is known as informed consent; however, not everyone is capable of giving informed consent.

I am a PhD student, and am investigating everyday communication between people who have severe-to-profound learning disabilities and other people, including care staff, other professionals, family and friends. As the people I am studying have intellectual impairments, it is unlikely they are able to give informed consent to participate in my research.

All studies that involve human participants need ethical approval and many research projects only go through a university’s review process. However, any research involving people who may lack the capacity to give informed consent needs ethical approval from the Social Care Research Ethics Committee (Social Care REC; www.scie.org.uk/research/ethics-committee) or a National Research Ethics Service Committee (www.hra.nhs.uk) or a similar committee to ensure it is ethical and conducted correctly. These committees consider research proposals involving people, ensuring participants are protected without denying their right to be included in research and to gain from the knowledge it provides.

This article offers guidance, based on my own experiences, on applying to a social care or NHS research ethics committee for approval to undertake research. It offers advice on using the Integrated Research Application System (IRAS), answering the questions on the application form accessed via IRAS, attending the meeting and completing any resubmissions. While it focuses on research that involves people who lack the capacity to consent, the application process is similar for applying to NHS or the Social Care REC so it should be helpful to anyone making such an application.

The Integrated Research Application System

Applications to the Social Care REC must be made online through the IRAS, which handles the permissions and approvals for health, social and community care research in the UK. It captures the information needed by a number of review bodies and its function is outlined in Box 1. Filters are used on the IRAS website (www.myresearchproject.org.uk) to ensure the data collected is appropriate to the specific research design and correct approvals are sought. It aims to:

- Eliminate the duplication of effort that

Consent is required to conduct research
can occur when entering the same information in several application forms;

» Ensure that regulatory and governance requirements are met.

Box 2 lists some key points to keep in mind when completing your application.

Allow yourself plenty of time to complete the application – you are likely to need to redraft it and it may take you some time to fully understand the IRAS system and any policies or law that are relevant to your research. You can only edit and save your form online and you can download and print it as a PDF after it has been saved.

The limitations associated with editing these documents mean it is difficult to change the form or share editing comments. If you are able to do so, it is worth copying and pasting some or all of the form into a word-processing document so you can perfect your draft before copying it back into the online form.

If you do work on your form in a word-processing program, do not use formatting such as bold, underlining, italics, lists or bullets points, or alignment; these will not copy into the online form and can cause problems with the formatting.

Guidance on using the IRAS

Online guidance is available for many questions on the application form and can be accessed via the guidance button beside the question. The guidance is shown in a pop-up window; it is worth printing this or copying it into a word-processing document so you can access it at any time.

The IRAS has a helpful e-learning module, which can be accessed by clicking the e-learning tab. This is a good place to start when first using the IRAS as well as to refer back to later. You will not need all the information at once, and it is there for you to dip in and out of, as you need it.

Each page of the online form has two “save” buttons; you must click one of these before moving on to the next page, or your work will be lost. This is another reason to complete your work in a word-processing program and copy it across when completed. Once it has been saved, the page will refresh itself. This is much easier to notice if you click the button at the bottom of the page, as it will take you back to the top of the page once the save is completed.

Addressing the questions on the form

Know Sections 30–33 of the Mental Capacity Act 2005

If you are completing research with people who may be unable to consent, you will probably already be aware of the Mental Capacity Act 2005. You should have knowledge and understanding of the five main principles of the act (Box 3).

However, training materials are not always targeted at researchers and can be misleading, as applying the act in healthcare is different from applying it in research. Although you should understand the five principles of the act, sections 30–33 should be your main focus as they are concerned with applying the act to research.

There is a whole section on IRAS (B.6) concerning adults unable to consent; this contains a series of questions closely linked to these sections of the act and your responses should demonstrate a clear understanding of the act. Legal language can be difficult to understand, so allow time to get to grips with reading the law and to access additional guidance documents to which the law directs you.

It can be useful to discuss the use of the law with somebody more familiar with it if possible, as well as someone who has experience of submitting applications.

 BOX 2. USING THE IRAS

» You can only complete the IRAS form online
» Advice is available to help you to answer some of the questions – click on the guidance button for each question
» The e-learning training module on the website is helpful
» Save your data as you work through the application form

 BOX 1. INTEGRATED RESEARCH APPLICATION SYSTEM

The IRAS is a single system for applying for permissions and approvals for health and social care/community care research in the UK. It:

» Enables you to enter the information about your project once instead of duplicating it in separate application forms
» Uses filters to ensure that the data collected and collated is appropriate to the type of study and, consequently, the permissions and approvals that are required
» Helps you to meet regulatory and governance requirements

IRAS captures the information needed for approvals from the following

review bodies:
» Administration of Radioactive Substances Advisory Committee
» Gene Therapy Advisory Committee
» Medicines and Healthcare Products Regulatory Agency
» NHS and health and social care research and development offices
» National Research Ethics Service/NHS/HSC research ethics committees
» Confidentiality Advisory Group, formerly the National Information Governance Board
» National Offender Management Service
» Social Care Research Ethics Committee

Source: Integrated Research Application System (2013)

Know the definition of “intrusive research” in the act

Under the act, research is considered intrusive if it would be unlawful to conduct it with participants who had not consented but were able to do so. In law your research may well be considered intrusive, even if you would not consider it to be so when using the lay definition of the word.

Acknowledge all risks

Research is very rarely risk free. Take time to consider and explain:

» Any possible risk;
» The actions you have taken to minimise that risk;
» The benefits that completing that action could provide.

Ensure your participant information sheets are simple and complete

A participation information sheet must be given to the lay people who will be taking part in your research. This should explain the key aspects of the research so they can decide whether to participate. The ethics committee starts its review of a project by examining participation information sheets, so these must be as clear and simple as possible, and contain all the appropriate information. Smajdor et al (2009) set out what makes a good participant information sheet and offer other useful tips for applying for ethical approval through the NHS or Social Care REC.

Check the guidance carefully and follow it closely

The Social Care REC reviews a wide range of research, so the guidance may not
always fit your research perfectly. However, the guidance outlines what should – and should not – be included so it is still worth referring to.

Repeat yourself if necessary
Some points may be relevant to a number of sections and you may need to repeat these within different questions to answer each one adequately. I chose to repeat these points and acknowledge when I had made them elsewhere. Starting paragraphs with phrases like “As noted in A6” allows the reader to choose whether to re-read the information or not.

Provide evidence
Completing the application will hone the structure and finer details of your research. The REC is looking for exact details of how you will achieve what you say you will, so vague sentences promising to carry out work or meet requirements will not be accepted. You need to produce all related documentation and protocols (detailed plans of how you will complete your research) and submit these with your application. I submitted 29 attachments with my application and was advised that this was not particularly unusual.

Take your supervisor with you
It is useful to take your supervisor to the meeting; SCIE (2013) notes that some students have difficulties when attending a committee without their academic supervisor. This may not be a reflection of the student’s general research skills or professional knowledge or experience; your supervisor may be able to answer questions you cannot, such as those about details of your institution’s policies. Bringing your supervisor also demonstrates that you are working within a team and that a new and relatively inexperienced researcher is not left without support and guidance.

Be prepared to defend your work
When the committee questions aspects of your research, decisions you have made and, quite possibly, your own skills and experience, it is easy to take the questioning personally. It is important to remain calm and confident and consider the point that has been made. It may well be a criticism but the panel may just be looking for clarification; even if it is a criticism, you may have a good answer to it and, in any event, it is likely that you will need to address it.

Attending the meeting
The Social Care REC has a busy schedule of meetings so you should book your meeting well in advance. Details of meeting dates (and submission dates) are on the Social Care Institute of Excellence’s website (tinyurl.com/SCIEEthicsApplication).

Although the number of committee members at meetings can vary, on average 10 or 11 members attend a full ethical review meeting, and it is not uncommon for 13 members to be present (SCIE, 2013).

In 2012-13, 20% of the decisions given by the Social Care REC were unfavourable (SCIE, 2013); it is likely that a significant proportion of these concerned applications by inexperienced researchers.

A variety of professionals apply for ethical approval – even established and respected researchers and academics have to go through the process for all new projects – so many people applying to the Social Care REC will have experience of doing so.

If your application is rejected, you will need to resubmit it, addressing the specific points raised by the panel. Try not to be discouraged if you receive an unfavourable decision – experience will make it easier to go through the process successfully in future.

Resubmitting an application
The Social Care REC will provide detailed reasons on why you have received an unfavourable opinion. This is helpful, as it clarifies which aspects of your application you need to work on. The panel will highlight the parts of your application that would benefit from more work; address these points carefully, systematically and as thoroughly as possible.

Conclusion
Applying for ethical approval can be daunting, but it is an important process to ensure research safeguards all participants. This is important for vulnerable participants – particularly those who cannot give informed consent for themselves. It can also help to refine the structure of your study and improve its quality.

Many people who have initial applications rejected have them approved when they resubmit, so do not assume that an initial rejection means you will be unable to undertake your research.

References

For more on this topic go online...
> Involving people with dementia in research
> Bit.ly/NTDementiaResearch

BOX 3. PRINCIPLES OF THE MENTAL CAPACITY ACT

• Start with a presumption of capacity
• Support individuals to make their own decisions
• Respect unwise decisions
• Act in a person’s best interests
• Act in the least restrictive way

Susannah Peters ■ p24

“I wanted to introduce a service that directly and immediately responded to patients’ needs”