Module 2: Understanding research ethics approval

Seeking research ethics approval 1

Part of the research protocol

- Background and justification for the research study
- How the results will be disseminated
- The research methods, process and timeline
- Logistical details about the interviews (where, when, recording method, etc.)
- Details about recruitment

The legal requirements

- The steps that will be taken to comply with GDPR

How ethical issues will be addressed

- The steps that will be taken to ensure anonymity and confidentiality
- Measures that will be put in place to support participants if they become distressed
- The steps that will be taken for informed consent

Supporting documentation that is required

- A poster for the pain clinic inviting people to participate
- A copy of the participant consent form
- A copy of the participant information sheet
- A list of indicative questions that will be asked during the interview

All applications to conduct research in or through NHS/HSC organisations, wherever they are based in the UK, use the online Integrated Research Application System (IRAS). This involves a single electronic submission of an IRAS form and associated supporting documentation.

Universities have their own systems for approval and these can vary between institutions.

While processes vary between the different types of REC, there are some factors that are common to all. That is because all RECs have the same basic requirements. They want to know about the research proposal, why the research is being conducted and exactly what it will involve. They will also want to see everything that

participants will see and scrutinise anything that researchers intend to ask or do. Moreover, they will want to see that researchers are complying with legal and ethical requirements.

The documents that are submitted will differ according to the research design.

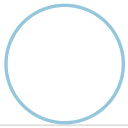
Consider the following example of a proposal to undertake qualitative interviews with people about their experience of living with long-term back pain. Categorise the items that the REC will want to see by dragging and dropping into the appropriate box.

Part of the research protocol	
Recruitment	✔
The legal requirements	
GDPR	✔
How ethical issues will be addressed	
Informed consent	✔

Supporting documentation that is required
Interview questions ✔

Restart View summary

The types of supporting documentation that the REC needs to see will vary between projects. For example, for a survey study this will include a copy of the questionnaire to be used, or, for research that is to take place in a supermarket, a letter of permission from the store manager.



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