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NHS Research Ethics for Medical Students/Novice Researchers What to consider when developing your project

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ABSTRACT

Clinical research is a very important aspect of developing clinical care and treatments. Over the last few decades, in part due to un-ethical studies and trials, there are now strict codes and practices that are essential to safeguard patients involved in clinical research. However, NHS Research Ethics can be a confusing area for novice researchers to navigate their way through. This article, written by two members of The East of Scotland Research Ethics Service, provides information on research ethics and important things to bear in mind when developing projects. It forms the second part of the Scottish Universities Medical Journal 'Clinical Research for Beginners' series.

Key Words: medical research; ethics

Background

The NHS Research Ethics Service was developed in response to the exponential growth in regulations, laws, codes of practice and guidelines for medical research: the first Research Ethics Committee (REC) was formed in the UK in 1996. In 2000 the Central Office for Research Ethics (COREC) was established within the Department of Health, becoming the National Research Ethics Service (NRES) in 2007. Up until then, local RECs had their own local REC application form and where local administration support was provided for individual REC by each NHS Health Board (in Scotland)/NHS Trust (in England). The Ethics Service continues to evolve, introducing new and streamlining existing processes and RECs, resulting in a leaner, more efficient and consistent national service facilitating and supporting research. There are four regional REC Centres in Scotland, the North of Scotland (NoSRES); East of Scotland (EoSRES); South of Scotland (SoSRES) and the West of Scotland (WoSRES). In 2011 the number of RECs in Scotland were reduced from 11 to 9, whilst introducing Proportionate Review for studies that present no material ethical issues.

What you need to consider when developing your study

When you start to think about your study question, make sure that you have a realistic timeline – you will need to ensure that you will be able to obtain all the necessary permissions and complete your study within your timeline[1]. The importance of planning in clinical research has been discussed in a previous 'Clinical Research for Beginners' article in this journal[1]. Realistically speaking, if you need a full NHS REC review it takes approximately 3 – 4 months from writing your protocol/proposal and supporting documentation to receiving a favourable ethical opinion, without which you will not be permitted to start you study.

Is your study research?

One of the first things you need to consider is, is your project research? Research as defined by the National Research Ethics Service[2] usually:-

- attempts to derive new knowledge/facts including studies that aim to test hypotheses as well as generating new ones
- addresses clearly defined questions, aims and objectives
- quantitative research may involve evaluating or comparing interventions
- qualitative research usually involves studying how interventions and relationships are experienced
- may involve randomisation

If any of these points apply to your study it's likely an NHS REC review is required. You should be aware that your study may also require additional ethical review by other review bodies e.g. University REC, Local Authority REC, etc.

Once you have decided what your study question is, we advise you to seek guidance from your local Research Ethics Service office and Research and Development (R&D) office, who will be able to advise and assist you in whether or not your project is considered to be research and which approvals your study will require e.g. Ethics, Caldicott Guardian, Medicine Health Regulatory Authority (MHRA) – for Clinical Trials of Investigational Medicinal Products (CTIMPs) or Medical Device studies. You will also require a Sponsor for your project this may be your University and/or Health Board. Information regarding the Sponsor for your study can be obtained from the Research Governance Manager within the R&D department.

If your study is research you will need to complete an Integrated Research Application System (IRAS) form. The advantage of IRAS is that you will in the near future be able to submit your REC, R&D and MHRA (if you are undertaking a Clinical Trial of an Investigatory Medicinal Product [CTIMP]) simultaneously via e-submission. IRAS requires that you create an account (www.myresearch project.org.uk); your account will effectively be your portfolio of research projects that will span your research career. Don't be daunted by IRAS……a lot of the questions are yes or no tick boxes. One of the most important sections of the form that you will need to complete is the project filter - make sure that you tick the box that reflects the type of study you plan to undertake – this will ensure that the relevant questions are generated for your application. Make sure that you have ticked the box for the integrated form – this will allow the other forms (e.g. R&D, Site Specific Information [SSI] and MHRA – for CTIMPs & Medical Devices) to have the information common to each form to be populated, and will save you having to complete the information repeatedly.

The form is quite self explanatory, **A6-1** asks for a summary of the research written in lay language – make sure you *do* write in lay language - don't simply cut and paste from your protocol – it's obvious to REC members that you've done this and your protocol may/will not be written in lay language!

A6-2 asks for you to summarise what you consider to be the main ethical issues arising from your study. Demonstrate to the REC that you have considered what the ethical implications are for example, recruitment – how and when will potential participants be approached? Consent – who will take consent? When will consent be taken? How long will participants have to consider taking part? Risk - what are the risks to the participant and/or the researcher? Data – collection and storage, who will have access, where will the data be

stored? Is the data anonymous or anonymised? etc. Try to look at your study from the participant's point of view.

If you decide that you would like us to review your form before you submit it you can transfer your application into ***the EoSRES IRAS account*** (email: *eosres.tayside@nhs.net*) via IRAS.

If you do find that you get stuck whilst completing your REC form, please contact us and we will talk you through where you are encountering a problem and if necessary, we will log on to a blank form to see what the issue is and talk you through the problem.

Guidance documents are available from EoSRES for:-

- Student/Research Projects – How to write a study protocol
- Student/Research Projects – Constructing a Participant Information Sheet
- Handling Data in Research Projects
- Template Consent Form

You can request these documents via the Ethics Helpline (*ethicshelpline.tayside@nhs.net*).

What if your study is not research?

You may be undertaking one of the following:

Clinical Audit[2]:

- designed and conducted to produce information to inform delivery of best care
- designed to answer: 'Does this service reach a predetermined standard?'
- involves routine interventions that are considered best clinical practice and chosen by the clinician and patient
- usually involves analysis of existing data but may include administration of simple interview or questionnaire

These studies do not require an NHS REC review but may require Caldicott Guardian approval

Service Evaluation/Service development[2]:

- designed and conducted solely to define or judge current care
- designed to answer 'what standard does this service achieve?
- Intervention/treatment is chosen by clinician and patient according to guidance, professional standards and/or patient preference
- usually involves analysis of existing data but may include administration of a simple interview or questionnaire
- there is no allocation to intervention or randomisation: the health professional and patient have chosen intervention before service evaluation

Studies looking at service evaluation/development do not require an NHS ethical review

Public Health – Surveillance[2]:

- involves systematic, statistical methods to allow timely public health action by identifying and understanding the associated risks of disease outbreak
- may involve collecting personal data and samples with the intent to manage the incident
- may involve analysis of existing data or administration of interview or questionnaire
- does not involve an intervention or randomisation

This type of study does not require an NHS REC review

Usual practice in Public Health[2]:

- designed to investigate outbreak or incident to help in disease control and prevention and answer: 'What is the cause of this outbreak?' and treat
- systematic, statistical methods may be used
- any choice of treatment is based on clinical best evidence or professional consensus
- may involve administration of interview or questionnaire to those exposed
- may involve allocation to control group to assess risk and identify source of incident however treatment unaffected
- may involve randomisation but not for treatment

Studies involving usual practice do not require an NHS REC review

What is Caldicott Guardian Approval and when do I need it?

A Caldicott Guardian is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. The Guardian plays a key role in ensuring that the NHS, Councils with Social Services responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information. (www.webarchive.nationalarchives.go.uk) The rule of thumb is that if you are going to be accessing patient identifiable data and do not have consent from individual patients to do this, you will require Caldicott Guardian Approval.

Data protection – what do you need to consider?

You should only collect data that you require for your study. Will your data be anonymous (no identifiers) or anonymised (identifiers assigned)? Will you be taking written informed consent from participants? You will need to keep any identifiable data separate from your anonymised data for example written informed consent forms should be kept securely in a locked filing cabinet on NHS/University premises, preferably in your supervisor's office, with electronic data on a secure NHS/University password protected and/or encrypted computer.

If you require further advice on data protection and storage contact your local Data Protection Officer/Information Governance Officer.

Proportionate Review (PR)

PR was introduced earlier this year and is for studies which contains 'no material ethical issues (NMEIT)' (i.e. there is minimal risk, burden or intrusion for the participants), it can be reviewed and approved by a Proportionate Review Sub-Committee (PRSC) on behalf of the REC within 14 days of receipt of a valid application.

No Ethical Material Issues Guidance[3]

The following types of application always require review at a full REC meeting:

- Clinical trials of investigational medicinal products (CTIMP's)
- Clinical investigations of medical devices prior to CE marking
- Research involving adults lacking capacity and subject to the Mental Capacity Act 2005
- Invasive basic science studies involving healthy volunteers
- Research involving exposure to ionising radiation which could be additional to that received in routine clinical care for any participant
- Research tissue banks
- Research databases
- Prison research
- Studies funded by the US department for Health and Human Sciences

Applications that may be suitable for PR review:

- Research using data or tissue that is anonymous to the researcher
- Research using existing tissue samples already taken with consent for research
- Research using "extra tissue" (e.g. further blood taken at time of routine sampling or tissue taken at "clinically directed" operation)
- Questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences
- Research interview / focus group that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences
- Research surveying the safety or efficacy of established non drug treatments, involving limited intervention and NO change to the patients' treatment

N.B: Research involving children may be considered for Proportionate Review where it meets the above criteria

Benefits of proportionate review[4]

- Offers an ethical review in proportion to the risks and ethical issues involved in the research.
- Enables NRES to provide a more efficient and responsive service.
- Allows researchers undertaking projects raising no material ethical issues to receive an ethical opinion more promptly and reduce project timelines.
- Makes better use of the time of REC members, allowing full REC meetings to concentrate on research raising more significant ethical issues.

How and where to apply for proportionate review

Proportionate Review applications will be reviewed by a Proportionate Review Sub-committee (PRSC). The application form is completed via the IRAS website and the project filter page will determine if question **A6-3** should be completed; this confirms whether the study is suitable for PR or not. You should follow the same procedure as detailed on the NRES website (www.nres.nhs.uk) on 'How to book in an application'. The REC Centre staff will run through some questions to check the application is ready to be submitted and suitable for PR. If the application is suitable, the application will be allocated to the next PRSC and a REC reference number given. The researcher should send their application to the REC office to again check the suitability for PR. If the study is suitable, the application will then be sent to the PRSC members. If, however, the Scientific Officer/Co-ordinator considers that the study is not suitable for PR, the application would be transferred, with your agreement to the next available full REC meeting.

Conclusion

There is a wealth of information to assist, guide and support you through the process of gaining an NHS ethical opinion. The key points to take into account are:-

1. Seek advice early

2. Make sure that you have allowed sufficient time in your timeline to gain all the necessary approvals that you will need

3. Make sure that you have sponsorship in place for your study – without this you will not be able to apply for an NHS REC review

4. Apply for your approvals simultaneously – NHS Research Ethics/Research & Development (R&D)/Caldicott Guardian approval/University Research Ethics Committee/(UREC)/ Social Care etc.

Good luck with your research career!

References

1. Cochrane LA & Puvaneswaralingam S (2012). Clinical Research for Beginners - The Importance of Planning. Scottish Universities Medical Journal. 1 (2). p. 154-164

2. Defining Research, National Research Ethics Service, 2009 *(www.nres.nhs.uk/applications/is-your-project-research***)**

3. CALDICOTT REPORT SCOTTISH OFFICE Department of Health, 1997 *www.dh.gov.uk/en/Publicationsandstatistics/.../DH_4068403*
www.connectingforhealth.nhs.uk/systemsandservices/infogov/caldicott/

4. National Research Ethics Service – Proportionate Review – no material ethical issues tool (NMEIT) (www.nres.nhs.uk/applications/proportionate-review/)

Useful Documents

Governance Arrangements for Research Ethics Committees (GAfREC) 2011 Harmonised Edition (www.dh.gov.uk/en/Publicationsandstatistics/.../DH_126474)

Research Governance Framework for Health and Social Care, 2011 Harmonised Edition *(www.publichealth.hscni.net/.../hsc-research.../research-governance***)**