General Principles of Research Ethics

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Why do we need ethical approval?

- Recognition of basic rights
  - Nuremburg Code (1947)
  - Declaration of Geneva (1948)
  - Declaration of Helsinki (1975)
- Research Governance Framework
  - Sets out principles, requirements and standards
  - Defines mechanisms to deliver them
  - Describes monitoring and assessment arrangements

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Health Research Authority

- "... protect the rights, safety, dignity and well-being of research participants, whilst facilitating and promoting ethical research."

- Independent review to ensure research meets the required ethical standards

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Ethical considerations…

- The research subject's welfare
- Vulnerable groups
- Equitable distribution of benefits and burdens
- Informed consent
- Confidentiality and privacy
- Protect researchers
- Ensure quality for dissemination

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Does the project need to gain ethical approval?

- If the work is to be carried out within the NHS
- **Speak to the local NHS R&D department**
  - Research
  - Service Evaluation
  - Clinical Audit
- **Do this as early on as possible once the research question has been defined…**
- HRA decision tool
- http://www.hra-decisiontools.org.uk/research/

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General definition of research

- Intent
  - Derive generalisable, **new**, knowledge
    - Audit and service evaluation measure standards of care
- Treatment/service
  - New interventions are considered research
- Randomisation
  - If there is any form of randomisation of participants it is research

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Student research

- undergo the same review process as other research projects
- reviewers recognise that student research has an educational and training value
- proposals will not necessarily be of the same scientific importance or quality as those submitted by professional researchers
- the scientific review of an academic supervisor is deemed to be adequate

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What to do next…

- Define the roles
  - Sponsor
    - This is the individual, company, institution, or organisation that takes on responsibility for initiation, management and financing (or arranging the financing) of the research
  - Chief Investigator (CI)
    - This is the individual who is responsible for the conduct of the whole project in the UK (the academic supervisor)
  - Principal Investigator (PI)
    - The Principal Investigator is the person responsible individually, or as the leader of researchers at a particular site, for the conduct of a study (the student)

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What to do next…

- The students need to create an account and start looking at the form…
  - The best chance to communicate with the committee
  - Is exhaustive
  - May contain things seemingly not ethically relevant
  - May contain things seemingly not relevant
- However
  - Is not optional
  - Is the first thing the committee will know about the project

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What is important?

- When filling in the ethics form it is important to always consider the research from the participants perspective
- What do committees look at?
  - What's happening to the patient?
  - Do they know what's going to happen?
    - Informed consent – understandable information
  - Is what's happening justified?
    - Risk vs. Benefit/Discomfort vs. Benefit
  - Is there a scientific basis for the study?
    - Repeating existing work?
    - Poor research is unethical
  - Coercion and Inducement
  - Confidentiality and Dignity
  - Dissemination

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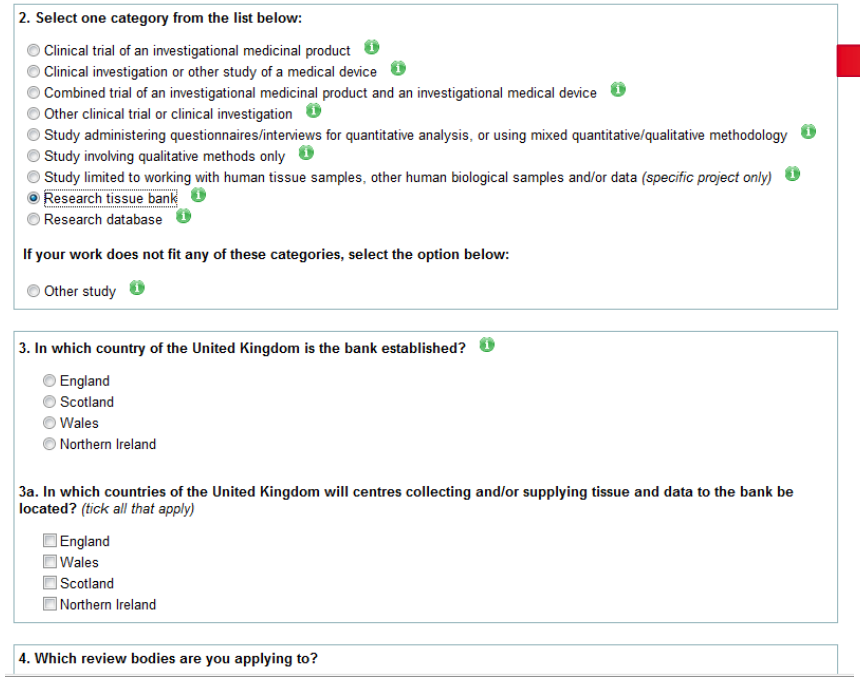
Filter Page

- The choices made will affect the form that needs to be completed



2. Select one category from the list below:

- ○ Clinical trial of an investigational medicinal product
- ○ Clinical investigation or other study of a medical device
- ○ Combined trial of an investigational medicinal product and an investigational medical device
- ○ Other clinical trial or clinical investigation
- ○ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- ○ Study involving qualitative methods only
- ○ Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
- ◉ Research tissue bank
- ○ Research database

If your work does not fit any of these categories, select the option below:

- ○ Other study

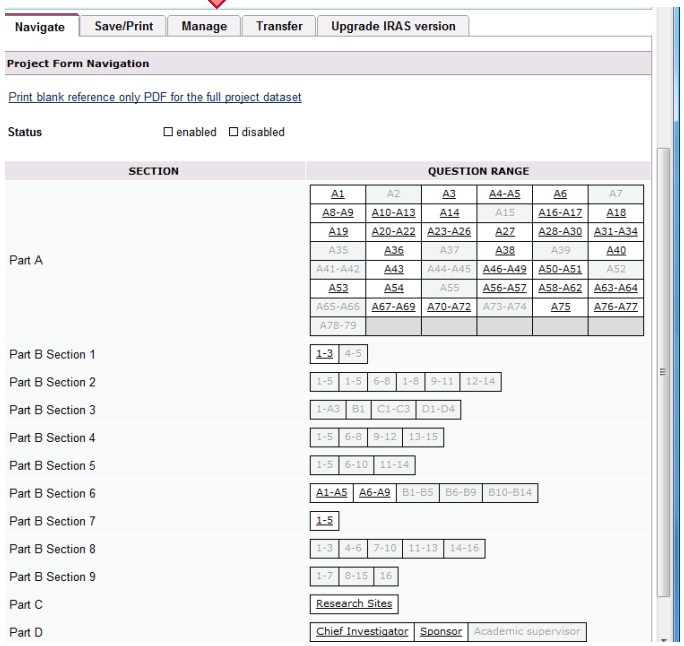
3. In which country of the United Kingdom is the bank established?

- ○ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland

3a. In which countries of the United Kingdom will centres collecting and/or supplying tissue and data to the bank be located? *(tick all that apply)*

- ☐ England
- ☐ Wales
- ☐ Scotland
- ☐ Northern Ireland

4. Which review bodies are you applying to?



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Project Form Navigation

Print blank reference only PDF for the full project dataset

Status ☐ enabled ☐ disabled

SECTION	QUESTION RANGE
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Part B Section 5	1-5 · 6-10 · 11-14
Part B Section 6	A1-A5 · A6-A9 · B1-B5 · B6-B9 · B10-B14
Part B Section 7	1-5
Part B Section 8	1-3 · 4-6 · 7-10 · 11-13 · 14-16
Part B Section 9	1-7 · 8-15 · 16
Part C	Research Sites
Part D	Chief Investigator · Sponsor · Academic supervisor

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General tips

- Make sure lay language is used throughout
  - Flow diagrams? Pictorial summary?
- Be honest about the ethical issues
- What is it the participant will need to consent to?
- Keep primary objectives simple, modest expectations are not unethical!
- Scientific justification needs to be straightforward – not copied from a protocol!
- Consider risk and benefit
  - Researcher risk…
- Dissemination
  - Reporting back to communities or the cohort?
  - What will happen to the dissertation?
- **Ask for advice** R&D or Ethics Committee

Consent and Information sheets

- There are standard formats and online guidance
- http://www.hra-decisiontools.org.uk/consent/
- Information sheet:
  - The form is a useful starting point
  - Can delete anything irrelevant
  - Standard wording for indemnity, ethics approval etc
  - Be explicit in quantifying any risks or discomforts
    - Give lay examples for radiation doses or blood volumes
  - Help the participants (and committee) understand the project, use pictures, photographs etc
- **Use lay language**

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Summary

- Decide whether the projects needs ethical approval
  - With agreement from local R&D department
- Define the roles – dependant on University policies – later today
- Student needs to create an HRA account and engage with the forms
- Complete the forms using lay language
- Consent form
- Participant information sheet
- Wait for the review!
  - CI should attend the committee meeting to support the student