Ethics Made Easy

Understanding the Ethics Application Process

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Objectives

• Understand:
  • Ethical basis of REC review
  • NRES remit & scope
  • NRES process
  • Completion of the REC application
  • Questions
WMO Declaration of Helsinki 2008

• Statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects

• Includes research on identifiable human material or identifiable data.

• ‘It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.’
WMO Declaration of Helsinki 2008

• Duty to protect
• Appropriate prior research
• Caution re harm to environment
• Clear protocol
• Ethical review
• Competent researchers
• Vulnerable populations /incompetent subjects
• Assessment of risks & benefits
• Importance vs risk
WMO Declaration of Helsinki 2008

• Registration of clinical trials
• Stopping rules
• Voluntary participation
• Informed participants
• Privacy & confidentiality protected
• Identifiable tissue/data – consent
• Commitment to publish
WMO Declaration of Helsinki 2008
Research combined with care

• Good reason to believe study will not harm

• New interventions tested vs best current PROVEN intervention except where:
  • No proven intervention or
  • Placebo necessary AND no risk of serious/irreversible harm

• Inform patients of results & offer beneficial intervention

• Be clear what is experimental & what is routine

• Freedom to refuse/withdraw without affecting care or relationship
National Research Ethics Service (NRES) Remit

• Facilitating ethical research which is of potential benefit to participants, science and society.

• Protecting rights, safety, dignity and well-being of research participants within the NHS.

• Research not Audit / Local service evaluation

• Research involving:
  • NHS patients, recently deceased on NHS premises,
  • Data/tissue
  • Relatives & carers,
  • Staff,
  • Premises & facilities
NRES submission process

• Complete online form IRAS
  • [https://www.myresearchproject.org.uk/Signin.aspx](https://www.myresearchproject.org.uk/Signin.aspx)

• Covers REC, R&D, MHRA, NIGB, GTAC, ARSAC

• Gather required documents

• Complete applicants’ checklist

• Phone local REC to book slot (proportionate review?)

• Obtain signatures/electronic authorisation

• Send application pack to REC

• Send SSI pack to R&D

• Attend REC meeting to answer questions

• Respond to written questions, amend documents

• Await REC approval letter (if applicable send to R&D)
NRES process – 60 days

- Study booked in by phone to REC system
- Pack received by REC (4 days) - Clock starts
- Validation(5 days)
- Included in meeting agenda
- Paperwork copied to REC members (14 days)
- REC meeting
- Decision:
  - Approval
  - Approval subject to conditions
  - Provisional approval
  - Rejection
  - No decision (need independent peer review)
- Correspondence (10 days)
REC & R&D approval

After 1 April 2009

CI
- REC application → Favourable opinion

PI
- SSI Form in application to NHS R&D → NHS permission for research
- Is SSA needed?
  - Yes: SSI Form to local REC + SSI Form in application to NHS R&D → Site listed in Form SF1 issued by main REC
  - No: SSI Form in application to NHS R&D
Completing the REC form

- May need input from:
  - Chief Investigator (signatory)
  - Sponsor’s representative (signatory)
  - Patient & public involvement group
  - Scientific peer reviewer
  - Statistician
  - Clinical Radiation/Medical Physics expert (sig)
  - Educational Supervisor (sig)

- Set aside a whole day to complete the form
Completing the REC form

- Filter questions customise form
- Print reference copy to collect required info.
- Lay language throughout – remove/explain jargon
- Don’t put ‘see protocol’ or cut & paste protocol
- Summary of main ethical & design issues
  - Think of some! There will be some.
  - Explain how dealt with/ justify approach taken
- Scientific justification = importance of study
  - summarise previous research
  - explain why this study is needed next
Completing the form contd.

• Don’t try to downplay the risks – assess & minimise them
• If no direct benefit to participants - say so
• Recruitment approach by clinicians to preserve confidentiality
• Consent may be taken by researcher if patient agrees to be contacted
  • Written
  • >24h to consider

• Data security, custody & storage
  • During the study – personal data
  • After the study – study data (usually anonymised)
Completing the form contd.

- **Indemnity**
  - Sponsor’s negligence
  - Investigators’ negligence
  - Non-negligent harm from study intervention

- **Documents**
  - Patient information & Consent form, letter
  - Protocol
  - Chief Investigator’s CV
  - GP letter & info
  - Indemnity insurance certificate(s)
Patient Information

• Follow the guidance:


Use the standard wording where appropriate

• Delete non-applicable sections

• Aim at a 10 year old reader

• Check facts vs final protocol and REC form

• Proof read

• Get a lay-reader to check (PPI?)
Thank you! Any Questions?

The text-book on medical ethics is out of stock... but I could get you one in the black market.

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