GETTING ETHICS APPROVAL: A STUDY ON RESEARCH ETHICS COMMITTEE’S RESPONSES

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The history of ethics committees

- Research Ethics Committees (RECs) were established by the Department of Health in 1997 to review health and medical research.

- In 2001 the Research Governance Framework extended this to include social research.

- The role of a REC is to review research protocols and address any ethical issues in accordance with ethics frameworks and research ethics codes.
THE BOX OF TISSUES: SINGH, 2007
REC's are therefore accountable for the decisions make and the process they follow, as they can be subject to complaints.

They send a letter to the applicants with an outline of the recommended changes and the research team is expected to comply with these recommendations in order to acquire a favourable decision.
Mary Dixon-Woods was successful in achieving funding to evaluate the letters sent out to research teams

- Mary Dixon-Woods
  - Alan Bryman
  - Richard Ashcroft
  - Clare Jackson
  - Emma Angell
- Natalie Armstrong
- Carolyn Tennant
  - And Me 😊
This study

- Uses discourse analysis to look at the content of the letter to see how RECs manage accountability for their decisions

- Naturally occurring institutional data – text

- 260 letters, from applications for research on cancer, paediatrics and human tissue
KEY FINDINGS

1. The process behind the decision

2. Holding the applicants accountable for the decision

3. Expertise
HOLDING THE RESEARCH TEAM ACCOUNTABLE

- Ethics
- Mistakes
- Missing information
ETHICS

“It is unethical for blood samples to be retained indefinitely for a future, as yet, unavailable test”

“Members feel that it is not acceptable to allow participants only one hour to decide whether or not to take part in the study.”

“Without this information presented in the clearest terms, this research, in this patient group would be unethical.”
LESSONS LEARNED

Consult your ethical code of practice

Use the NRES website and guidance

Really think about the ethical issues – consent
“Incorrect phone number on GP letter (page 2) please correct.”

“There are a number of typographical errors on the PIS.” (PIS - Patient Information Sheet).

The flow chart is incorrect – shows 2 doses to be the same although they should be different.”
LESSONS LEARNED

- Proof read your application
- Ask a colleague to proof read
- Check all of the facts and additional documents
MISSING INFORMATION

“Copies of the questionnaire should be provided”

“A suitable Consent Form needed to be submitted for approval.”

“A copy of the researcher’s CV was not provided. The committee was unable to determine the competence of the applicants therefore to carry out this very sensitive study.”
LESSONS LEARNED

RECs want to see everything!

Use the guidelines for creating consent forms and PISs

Include questionnaires, interview schedules, CVs, etc
CONCLUSIONS

- The likelihood is that the REC will find something in your application that concerns them or that they want further information about.

- Don’t encourage it however by missing out important information, making mistakes or not following the guidelines.

- The key ethical concerns seem to be informed consent, confidentiality – particularly data storage, using laptops, passwords etc, coercion – particularly related to the clinical role.
“I can offer no solutions to these problems. All I can say to junior colleagues embarking upon research is that no matter how noble your intent, no matter how keen your enthusiasm, no matter how compassionate your approach, don’t forget the box of tissues.” (Singh, 2007: 82).