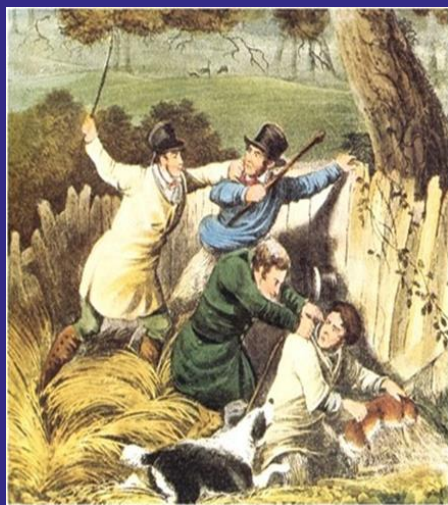


THE ETHICAL REVIEW OF RESEARCH



(from the researcher's side of the fence)

A model of research review and how it might help the researcher



TWO AIMS

FOUR STEPS

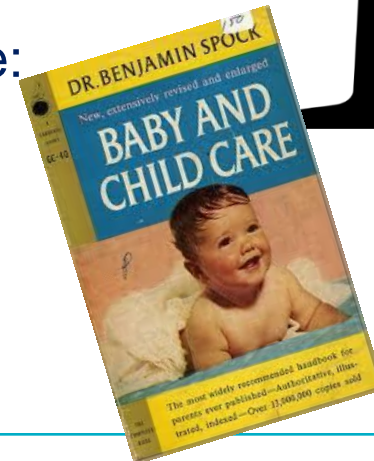
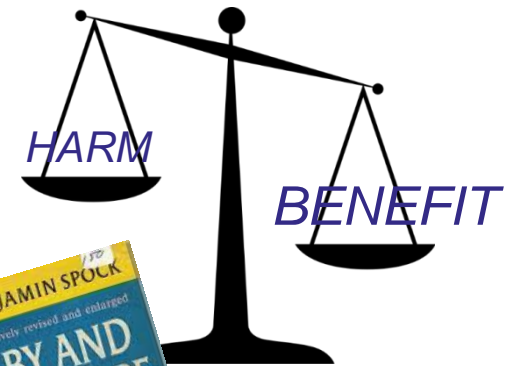
EIGHT “Es”



Two aims: to protect research participants AND facilitate ethical research

We must weigh up the harms and benefits for participants then balance these consequences for participants against the risks of unresearched health care to current and future patients. Our review is thus a complicated matrix, encompassing and accommodating risk and benefit to many people: participants, patients, the public, clinicians and researchers.

<http://www.testingtreatments.org>



Step 1 Construction

“what it’s all about ?”

“what are the facts of the matter?”

To do this REC members say they read

- Title - use I.P.O.C.
- Participant Information Sheet
- Answer to IRAS question A6-1 (A 6-2)
- Answers A15 to A26
- Protocol - (for the brave?)



Step II: deconstruction and analysis domain by domain (i/ii)

A picture can't provide an ethical analysis, it doesn't permit judgments so we can't reach any decisions.

For this the study has to be broken down into what we might call its constituent “ethical domains”. Within each we can then ask specific questions and draw conclusions.



Step II: deconstruction and analysis domain by domain (ii/ii)

1. Independent review
2. Social or scientific value
3. Suitability of the Applicant and Supporting Staff
4. Recruitment, access to health information
5. Inclusion and exclusion of potential participants.
6. Risk benefit ratio
7. Informed consent and participant information
8. Care of research participants
9. Payment
10. Compensation
11. End of trial arrangements



Step III: Decision making when considering ethical dimensions of your work

Questions you might ask yourself

How would I decide if I were there?

How do I feel about this study?

How would I decide if I were the participant?

What have I / we decided before?

What would an ethical analysis suggest is fair?

What judgements have experts made?

What published evidence is there?

What is possible?

8 “Es”

Ego

Emotion

Empathy/

Experience

Ethics

Experts

Evidence

Expediency



The Application



The value of eight “Es”

A structure for debate

A counterbalance to prevalent “Ego”

A means to assess the strength and foundation of our positions

A means to go “beyond opinion”

A method or structure to turn to when in difficulty

A means to resolve dispute

A means to address new issues



Step IV: REC debate and talking to the researcher

Before the researcher attends

Discussion with the researcher

After the researcher has left the meeting



If you disagree...



Preparing your case

Before the committee:-

Prepare a short, comprehensible summary of your study. Clarification of misunderstandings may resolve any argument on its own.

Anticipate different views - what will their arguments be? Develop counter-arguments but try to see the project from other points of view.

Use the 8 “Es”



When you meet the committee

Stick to issues NOT people

Clarify the positions and differences if necessary

Establish whether it's worth arguing – don't argue if the differences will not affect the debate or decision.

Go beyond differing opinions to “interests” and seek “reasons” for different positions. These are easier to influence.



**Finally: how to ruffle some
feathers, should you wish
to**



Start by questioning the REC's authority

Follow it up by questioning their competence

Claim that there are no ethical issues in your research

Don't complete the application form

Expand and expand your application

Say I've just cut and pasted.....

Write your application in American

Use jargon



Fail to adapt a protocol to UK health care

Declare “Well I didn't write the protocol”

Tell the REC that science isn't their business

Deny conflicts of interests (or imply you're above them)

Don't turn up

Send the wrong person





Thank you for listening

