Please note due to the nature of guidance changing, this presentation is only current on the date of issue.

August 2018
Why do we have ethics committees?
The history

The 1948 Nuremberg Code

Nazi experimentation resulted in the 1948 Nuremberg Code

“The voluntary consent of the human subject is absolutely essential”

Subjects should give consent and the benefits of research must outweigh the risks.

It is not legislation, but it was the first international document which advocated voluntary participation and informed consent.
Tuskegee Syphilis Study (1932-1972)

400 low-income African-American males, 400 of whom were infected with syphilis were not told about their condition and were monitored as part of a study for 40 years.

Penicillin was available from the 1950s, a highly effective treatment for syphilis, but they were not offered this.
1964 Declaration of Helsinki

- World Medical Association guidance for research involving human subjects.
- Governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research."
- Research with humans should be based on the results from laboratory and animal experimentation.
- Research protocols should be reviewed by an independent committee prior to initiation.
- Informed consent from research participants is necessary.
- Research should be conducted by medically/scientifically qualified individuals.
- Risks should not exceed benefits.
2018 Here we are

Research protocols should be reviewed by an independent committee prior to initiation.

In the UK, research ethics committees are established to:

• Protect the rights, dignity, safety and well-being of all actual or potential research participants
• Protect the interests, needs and safety of researchers
• Ensure the equal distribution of the benefits and burdens of research
What is a REC (Research Ethics Committee) member?

• REC members are volunteers and there are usually 18 per REC
• Expert members are appointed because of their expertise in clinical research/clinical practice/pharmacy/statistics
• Members of the public are independent of the NHS: they are not health or social care professionals and have no professional interest in research
• They are appointed for up to five years at a time, and may not serve for more than ten years on a REC
• They must go on training annually
• To be quorate, there should be at least seven members including the chair/vice chair/alternate vice chair and a member of the public
• RECs meet monthly, at least ten times a year
What type of research do RECs review?

All research affecting NHS patients and their relatives/carers including:

• Foetal material
• Recently deceased on NHS premises
• IVF studies
• Access to records of past and/or present NHS patients
• Use of/potential access to NHS premises/facilities

More specifically:

• All CTIMPs (medicine trials) including Healthy Volunteer Studies
• Research using tissue under the Human Tissue Act
• Intrusive research involving adults unable to consent for themselves due to incapacity
• Research in prisons
Types of REC review

Full review
• Reviewed by the full committee at a face-to-face meeting
• Final decision within 60 calendar days

Proportionate review (PR)
• Sub committee review of low risk studies
• No Material Ethical Issues (NMEIT)
• Minimum of 3 members by telephone/correspondence
• Final decision within 14 working days
Proportionate Review

- Research using data or tissue which is anonymous to the researcher
- Research using existing tissue samples already taken with consent for research
- Research using extra tissue
- Questionnaire research OR research interviews/focus groups 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 patient’s treatment
What is a valid REC application?

- Integrated Research Application System (IRAS) form
- Study Protocol
- Details of funding, sponsorship and indemnity
- CV for Chief Investigator
- Participant Information Sheet and Consent Form
- Questionnaires and/or interview schedules
- Investigator’s Drug Brochure
- GP Information Sheet
- Invitation letter
- All with version number and date
What happens after the application is validated?

- The documentation is copied and sent to the REC members for review in advance of the meeting
- The applicant is invited to attend the REC meeting to answer any questions the REC might have
- Some RECs use lead reviewers to look at applications in more detail
What do REC members look for when reviewing the protocol?

- Is there a clear, specific research question?
- Clarity: who, what, where, why, when and how?
- Is the study design capable of answering the question?
- Who is doing the recruiting?
- Vulnerable participants?
- Consent process
- Inducement/coercion
- Use of placebos
- Equipoise
What do REC members look for when reviewing the information sheet

• What is the purpose of the study?
• Why have they been chosen and do they have to take part?
• What is being tested?
• What are the possible side effects, risks and benefits?
• Who can they contact for more information?
• What will happen if they do not take part or wish to stop after the study has started?
• Who will have access to information about them? – Will confidentiality be maintained?
• What will happen at the end of the study?
• What will happen if something goes wrong?
Decisions

- Favourable
- Unfavourable
- Provisional
- No decision
Deadlines

- The REC has 60 calendar days to give a final opinion
- Clock stops each time the REC gives a decision and starts when a response is received.
So where is the public involvement?

**Everywhere!**

- Defining research areas
- Developing the research protocol
- Reviewing information materials
- Attending REC meetings
- Communicating findings to the wider public
What do we mean by public involvement?

• The public being involved in the research process so that the work is done with or by the public
• It does not mean the research is done to, about or for them
• This is not the same as taking part in research as a research participant
Public involvement in the research process

This may include:

• identifying and prioritising research topics;
• being part of research advisory groups and steering groups;
• identifying outcome measures which are meaningful and relevant to patients;
• commenting on or developing patient information sheets and other documents which are used to communicate with participants;
• commenting on the feasibility of the research design including the burden placed on participants and the levels of risk/distress that participants might be exposed to;
• commenting on or helping to develop end of study information sheets for participants and lay summaries of findings.
Ethical review and public involvement (1)

• Ethical review is not required to involve the public in the planning or the design stage of research, such as helping to develop a protocol, questionnaire or information sheet, or being a member of a research advisory group, or preparing an application for funding or ethical review.

• This is because they are not acting in the same way as research participants.

• They are acting as advisers, providing valuable knowledge and expertise based on their experience of a health condition, and/or use of NHS/social care or public health services or in their role as a carer.
Ethical review and public involvement (2)

• The REC application form asks whether there has been any public involvement, and applicants are asked to describe how the public have contributed to the planning and design of the proposed research and will continue to do so in its conduct and management.

• RECs will draw on the information provided about how the public have been involved for assurances on aspects of the design and ethical probity of the proposed research.

• Public representatives are welcome to attend the REC meeting where the application is discussed along with the applicants, and the REC often finds this valuable and helpful.
Ethical review and public involvement (3)

- There are some situations where the involvement of the public may raise ethical concerns, for example, when they will be involved with collecting and analysing data, such as helping to analyse survey data, conducting interviews, facilitating focus groups or recruiting participants.

- In these situations, the REC will be seeking assurances that the following ethical issues have been fully addressed by the applicant:
  1) The well-being and safety of the people who are actively involved as researchers.
  2) The well-being, safety and preferences of the people who are taking part in the research as study participants.
Thank you

Any questions? Get in touch
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