

Research ethics and how health research is reviewed

What? This is a proposed two-part lesson/workshop designed to give an introduction to research ethics, and how proposals to carry out health research are assessed and approved by research ethics committees. By focussing on a fictional childhood asthma study, students are encouraged to consider and discuss ethical issues that may be experienced by researchers, those who review health research studies, and those who are considering participating in health research, for example children and young people and their parents.

How? We suggest a structure with different activity options (films, role play exercise, discussion, further material) allowing the discussion to go into more or less detail depending on ability and prior knowledge – but you can pick and choose what you think is most suitable for your lesson and in what order.

Who? The activities below are suitable for students from Key Stage 3 through to undergraduate level or above. They may be particularly relevant to A-level Psychology and other courses which include modules on research or research ethics.

Part 1: The ethics of research involving children

Presentation: Research ethics and how health research is reviewed

A short presentation about research ethics and clinical (health) research which covers:

- What is clinical research?
- Who does clinical research?
- What are ethics?
- What is ethical research?

Reading: information on a proposed research study

These two optional documents provide background information about the proposed research (*they can also be given to students to read in preparation for the lesson*).

Option 1 (basic introduction): Students read the factsheet ‘**What’s it all about?**’. This summarises a proposed fictional clinical trial involving children affected by asthma.

Option 2 (detailed introduction): Students read the research protocol ‘**Improving asthma treatments for children and young people**’. This is a complete fictional research protocol written to show what an application for ethics approval might look like.

Film: further contextual information on the proposed research study

Students watch the first part of the film **Processes, Papers and Professors: how clinical research in young people gets approved** (from beginning until 04:30).

The film introduces Ruby, her parents and her doctor – they talk about her condition (asthma), the medication she takes to control her asthma, and briefly about the research study outlined in the documents above which Ruby would be a candidate for (*students could also watch this part of the video as preparation ahead of the lesson*).

Discussion: students discuss the proposed research study

The discussion could be held as option A or B, and question prompts might include:

- Can students (themselves or acting as a research ethics committee member if using role play) identify any ethical issues arising from this proposal?
- Would they be happy for children to be recruited to take part in this study?
- Are there any changes that the researchers should make to improve their proposal?

The document '**What about the research ethics?**' sets out some further prompts and questions about ethical issues raised by the proposed research, which may be helpful to enhance students' discussions.

Option A (role play): Students consider the research proposal as if they were a research ethics committee. In groups of six, each student is given a Committee Member role card and asked to discuss the research study proposed in the factsheet and decide whether to a) approve the research as proposed; b) suggest the researchers make some changes and resubmit the proposal; or c) refuse to approve the proposal.

Option B (open discussion): Students discuss the research proposal in plenary or in groups and are then asked to vote by show of hands on whether to a) approve the research as proposed; b) suggest the researchers make some changes and resubmit the proposal; or c) refuse to approve the proposal.

Part 2: How research gets approved

Film: a research ethics committee at work

Students watch the second part of the film **Processes, Papers and Professors: how clinical research in young people gets approved** (from 04:30 until end – about 12 mins). This film shows a mock research ethics committee discussing the research proposal and whether to approve it.

Reflection (in plenary or groups)

Students are invited to reflect on what they heard in the film clip showing a research ethics committee discussing the proposal. Questions to discuss might include:

- Did the REC in the film reach new or different conclusions from the students?
- Did they miss any ethical issues that the students thought important?
- Do students agree/disagree on the points made by the committee members in the film, e.g. about:
 - Calling participants 'subjects'
 - Incentives – rewarding the children who participate
 - The researchers' approach to risk (e.g. their approach to the 'washout' period)

Background and further materials

1. The YREC project

The fictional research study presented in the activities above was discussed by students in workshops held at a junior school, a secondary school, and a sixth form college in the autumn of 2013 as part of the Council's Youth Research Ethics Committee (YREC) project. Two further films which summarise the themes that arose in these young people's discussions are available online:

- **[Be a part of it: what young people think of clinical research](#)** (16:53 mins)
- **[Trailer: Be a part of it: what young people think of clinical research](#)** (3:27 mins)

Additional materials which were discussed in these workshops alongside the fictional research study protocol are available on request (email bioethics@nuffieldbioethics.org), including:

- mock letters to parents whose children would be invited to take part in the study
- mock information sheets for children and parents
- consent and assent forms for parents and children

Further information about the YREC project is available online at: www.nuffieldbioethics.org/children/YREC-films

2. Children and clinical research: ethical issues

The YREC project helped inform the report *Children and clinical research: ethical issues*, published by the Nuffield Council on Bioethics in 2015.

Alongside the report, the Council produced:

- An animation titled **[Health research: making the right decision for me](#)** (3:35 mins) which goes through some of the questions and issues that might be raised when a young person is invited to take part in clinical research
- An illustrated magazine (aimed at ages 14+) about the report's findings: **[Involving young people in health research – getting it right](#)**.

The report, animation, magazine and more information about this project are available at: www.nuffieldbioethics.org/children.



You can find other free bioethics teaching resources at <http://www.nuffieldbioethics.org/education>