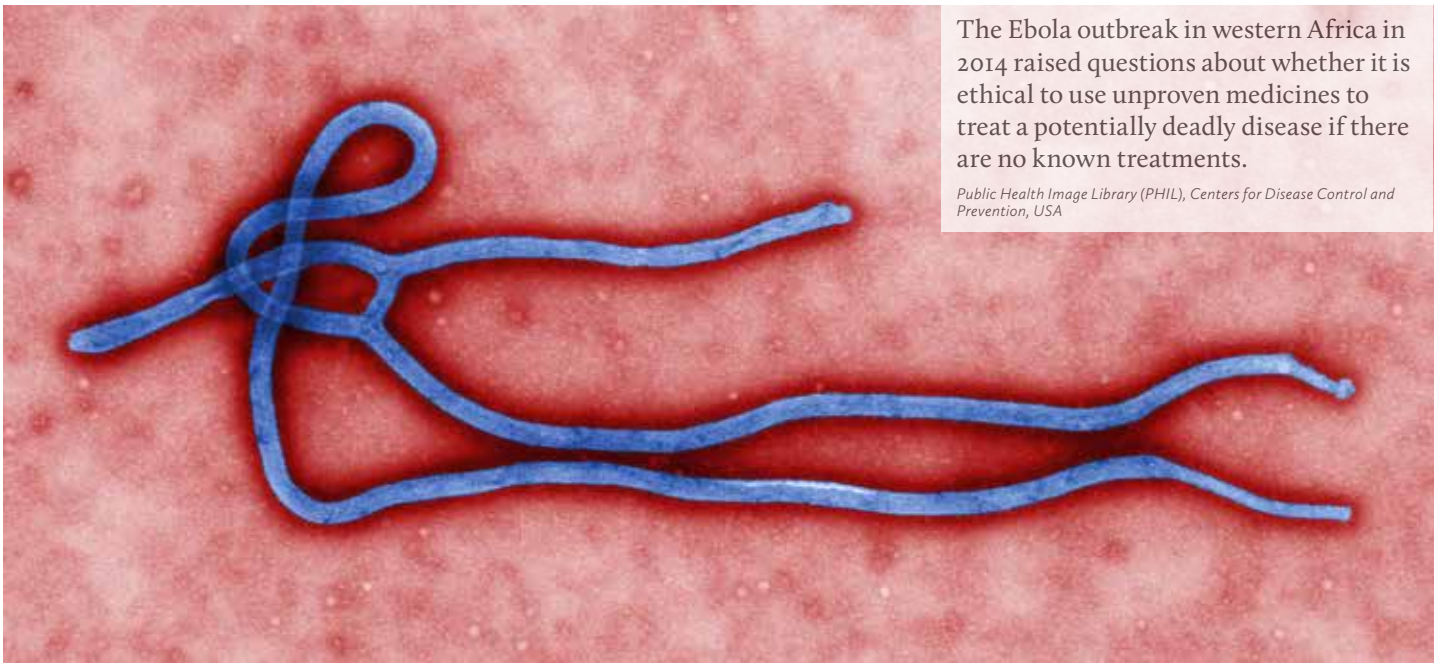
Ensuring your research is ethical: A guide for Extended Project Qualification students



The Ebola outbreak in western Africa in 2014 raised questions about whether it is ethical to use unproven medicines to treat a potentially deadly disease if there are no known treatments.

Public Health Image Library (PHIL), Centers for Disease Control and Prevention, USA

Research using an experiment, a survey or an observational study can be an exciting way of investigating a topic or gathering data to help you answer a question. Anyone who carries out research must consider the ethics of what they are doing, including you as an extended project student.

To ensure your project is ethical, look at our 'Questions you must ask' over the page

Research is all about exploring questions to which we do not know the answers; this means that the outcomes of research are uncertain. Along with this uncertainty, there is always an element of risk to people who participate in research, and even to the societies or environments in which research takes place. This means that all research should be designed and carried out ethically, fulfilling the researchers' responsibilities to:

- the participants in their research
- their colleagues
- wider society.

What are research ethics?

Research ethics are the moral principles that govern how researchers should carry out their work. These principles are used to shape research regulations agreed by groups such as university governing bodies, communities or governments. All researchers should follow any regulations that apply to their work.

Over the years, different people have set down ethical principles for researchers. One influential example is the Belmont Report, published by the US Department of Health & Human Services in 1978, which describes the basic ethical principles for research on human participants. This report forms the basis of the questions at the end of this guide that you should consider when planning your research.

Did you know: In 1796, Edward Jenner, an English doctor, injected an eight-year-old boy, James Phipps, with cowpox, which made people ill but wasn't fatal. He later injected James with smallpox, a deadly human disease, to demonstrate that the original injection of cowpox had protected him from smallpox.

Do you think that experiment would be allowed today? Why/why not?

To help researchers ensure that their work is ethical, many organisations produce their own guidelines: checklists of dos and don'ts which set out the practical steps a researcher should take to make sure that their research is ethical. Ethical guidelines protect the participants or subjects of research, from plants to animals and humans.

How does this apply to me?

When you are planning a piece of research you should spend some time thinking about its ethical implications, which means thinking about what you might need to do to protect people who take part and/or the environment, including animals and plants. On the next two pages, you will find a set of questions that will help you do this. Work through them carefully and think about how each one might apply to your research. You could also use the 'Useful links' to find out what guidelines other organisations have set out for researchers in your field. You may even want to focus your project on ethics!

As you work through the questions you might identify parts of your research that put yourself, your participants or the wider environment at risk and are therefore unethical. At this stage you might find it useful to discuss your plans with others, or maybe seek expert advice. You may need to alter your plans to make sure that your research is safe. This could mean making a change to the methods you use – for example, changing the way you record information about your participants or making a note of a point when you will need to be particularly careful or sensitive. Any data that you collect about individuals should be made anonymous (concealing people's identities) and handled confidentially (limiting who can access it). You should record all your observations and any actions you decide to take in your project log.

Did you know: All research carried out by universities, medical organisations and industry (such as pharmaceutical companies) will have gone through an ethical approval process (the precise process will vary in each case). For example, a researcher will write a report describing their research process, including how they will address any ethical concerns, and submit this report for review by a 'Research Ethics Committee' (or similar), which will decide whether the research can go ahead, or whether the approach should be modified first.

Why do you think it is important for research processes to be submitted for ethical review?

Evaluation

The guidelines and principles that researchers use change and develop to keep up with advances in knowledge and technological and cultural changes. Evaluating research and recording the lessons learned enables researchers to learn from shared experience and avoid repeating harmful mistakes.

At the end of your project, you should look back at your research and reflect on how you planned for and managed the ethical implications of your work. There may have been problems that you did not anticipate, or your work may have had an impact that you did not predict. Record what you think went well, what you found difficult and what you would do differently if you were to repeat the same research. You should share this with your peers and include and discuss it in your presentation.

Useful links

Educational activities to encourage discussion of bioethics from the Nuffield Council on Bioethics: **http://bit.ly/1qABEeP**

Guide to ethics in research from the Social Research Association: **http://bit.ly/1onGPKh**

Ethical guidelines for research involving human from the US Department of Health and Human Services: **http://1.usa.gov/1uhTwMs**

The Universal Ethical Code for Scientists by the Government Office for Science: **http://bit.ly/1weTXqf**

Engineering Ethics from the Royal Academy of Engineering: **http://bit.ly/1tqJpSI**

Guide to Environmental Responsibility for Expeditions from the British Ecological Society: **http://bit.ly/1weUolN**

Useful ways of thinking about the ethics of research involving human beings from Bryn Mawr College: **http://bit.ly/1rUHKZJ**

Guide to producing an informed consent form by the World Health Organisation: **http://bit.ly/1xDoiAo**

Questions you must ask

Respect for individuals

Has everybody who is taking part in your research freely agreed to take part with a good understanding of the risks of the research and their role in it?

This is 'informed consent'. You must ensure that all your participants give informed consent before you start your research. Explain your research to everyone involved; for example:

- what the aims and methods are
- what participants will be asked to do and why
- what the risks and benefits are
- how the information they provide will be stored and used.

It's OK to actively invite people to take part, but nobody should feel pressured into giving their consent.

If you suspect that any of your participants have not or cannot give informed consent (for example, if they have a particular learning difficulty) then it may not be appropriate to involve them in your research and you should seek further advice before continuing.

You might want to create a consent form for your participants to tell them about your research, which they can sign and date to act as a record of their consent. You can see example informed consent forms from the World Health Organization and Stanford University at http://stanford.io/1nIvOTy.

Using neutral language

When explaining your approach you must be careful not to unintentionally influence their responses (and your results). For example, saying "I'm looking at whether emotionally charged words are easier to remember than neutral ones" might suggest what you are expecting to find, as well as giving away that there will be a memory test at the end. Instead, you might say something more general, like "I'm looking at how people respond to certain words in different circumstances."

Acting in people's best interests

Have you completed a health and safety check and risk assessment?

You are responsible for the safety of your participants, yourself and others nearby. Make sure that you conduct your research with care and in accordance with health and safety regulations. If there are risks associated with your research – for example, if you are using toxic chemicals – then plan how you will minimise those risks and what to do if things go wrong.

What impact could your research have on your participants, the environment, or the wider community?

Consider what benefits or harm might result from your research: how might your approach affect those taking part, or the environment?

The results of your investigation might also have an impact on those involved, so you should think about who you will share your results with and how.

Benefits versus harms

You may decide to do some research in your local community looking at people's diets. In doing so you may find that some people eat more of a certain foodstuff, which could put them at greater risk of disease; for example, very sugary food can increase the risk of developing diabetes. The people who agreed to take part in your research might not have wanted to find this out, and being told that they are at risk of disease could be distressing for them. You need to decide whether your findings could have a negative impact, and if so, whether that impact is acceptable given the benefits you expect to see.

If you are gathering information about people, such as by using a survey or an interview, you should keep their information confidential and anonymous – unless they have said they are happy for other people to know how they responded, and as long as this could do them no harm. For example, someone may be at risk of developing a genetic disease later in life and be happy to discuss this openly with you without requesting confidentiality or anonymity; however, if an insurance company found out about this risk, that individual may not be able to receive health or life insurance, which could harm them. **Confidentiality and anonymity protects participants by maintaining their right to privacy.**

Confidentiality and anonymity

Keeping information **confidential** means that you limit who can see it. At its simplest, this could just mean keeping it somewhere safe (if it's on paper you might keep it all together in a single file) and not letting anyone else see it. However, someone might still find the file and read it. You may need to think about a more secure approach: if people fill in a paper questionnaire you could transfer their answers to an electronic spreadsheet that is protected with a password and then shred the original paper copies.

Making information **anonymous** means that it is impossible to identify people from it. You should consider whether you even need to collect information that could identify people – it may well be unnecessary, unless you intend to do repeat surveys and will need to contact people again.

Think about the following pieces of information and circle those that could help to identify people:

- Name
- Date of birth
- Height
- Weight
- Handwriting
- Gender
- Political views
- Favourite sport
- Music preference
- Favourite subject
- Ethnicity
- Postcode

You can see that nearly all of these *could* help to identify an individual, especially in combination. If you do need to collect that information, could you create a code that you keep separately so that anyone looking at the information would not be able to interpret it? For example, instead of 'female' or 'male' for gender, use '1' and '2' and make a confidential note elsewhere that this is what you've done. Often, information is collected by someone else and made anonymous to researchers themselves – this helps maintain participants' anonymity and also helps researchers to avoid bias.

Note that keeping *individual* information confidential and anonymous does not mean that you cannot report on *aggregated* information (i.e. the group data). For example, you could still report publicly that "50 per cent of girls prefer science subjects, while 55 per cent of boys prefer science subjects".

If you think your research could do harm, is it justified and should you continue? Have you done everything you can to reduce or remove the risk?

If there is a possibility that your research, either its methods or its results, could harm those who take part, the environment or others, you must think carefully about whether you should continue. Whether you do or not will depend on the seriousness of the risk – how likely it is and how severe the harm – and how this risk balances against the possible benefits of your work. Note that personal benefits to the researcher (you) should not form part of a risk–benefit calculation.

However minor you think the harm might be, you must make sure that you have done everything you can to reduce it or remove it completely. Consider whether there is an alternative method you could use that would be less disruptive; for example, you might be able to photograph specimens rather than gathering samples of plants or wildlife, which could harm a habitat.

Being fair

How will you choose your participants?

It is unethical to choose your participants from one particular social group, unless your research is specifically about that group. For example, if your research is about the smoking habits of people in a particular town, then it is obviously fair to recruit from that town. However, it would not be ethical to recruit only people of Bangladeshi descent from that town, or only women. If your research is about a very specific social group then you must justify that choice. For example, if you want to study women of Bangladeshi descent in your town who smoke, then you must be able to justify singling out this specific group. Such justifications might include a pressing health concern in a particular group that needs addressing, or a unique or rare characteristic in a group that would be important to study.

Are the harms and benefits of your research shared fairly between the participants?

Ideally, the risks and benefits of taking part in research should be distributed equally among participants, regardless of social group. For example, a study that explores whether paying people helps them to stop smoking might divide participants into two groups: one group that is paid, another that is not. If the participants are put in these groups randomly, that would be ethical. However, if the groups were based on ethnicity or gender, with all the payments going to one particular social group, that would be unethical. The same is true of distributing risks, even small ones. A study that explores the effect of running might divide participants into a one group that runs 1 km on a treadmill every day and a group that does not. The risk of running is quite small (people could fall on the treadmill etc.), but it would still be unethical to base the groups on social characteristics such as age or income.

wellcome.ac.uk/education
E education@wellcome.ac.uk
T +44 (0)20 7611 8888
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