Nuffield Centre for International Health and Development
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UNIVERSITY OF LEEDS

Researchers in Development Seminar
Ethics in Fieldwork: Introduction

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Introduction

The ethics approval process is a part of good research practice and should be integrated into planning and managing a research project. We have created an online component in which we will go over the main elements of ethics in research and help you fill in the Ethical Approval Form. This component has a strong focus on project fieldwork and will, for instance, not cover NHS approval processes. Please be aware that we will be presenting the issues a little more black and white than they really are. This is to make it more accessible for you. There are many subtleties in ethics and we will consider your arguments carefully if you do divert from what you read in this component.

The aims of the ethical approval process are:

- Protect the research subject (from physical harm or mental distress)
- Protect the researcher (from complaint or harm)
- Protect the organization sponsoring the research (your host and the university)

We have divided the ethics teaching into three sessions according to the three main elements of ethics in research:

1. Principles of safety and well-being
2. Principles of consent
3. Principles of anonymity, confidentiality and data protection

Link to form

A10 What are the main ethical issues with the research?

Each session has a summary box at the end and links to main questions on the ethical approval form sections relate to (as you can see above)[1]. We suggest that you have a copy of the following open on your desktop or printed ready for you to look at while you read:

1. The ethical approval form
2. Model participant consent form
3. Model participant information sheet

Methodology and ethics

When choosing questions to include in a research survey, the researcher should consider that the data is being collected for a specific piece of research and that the information requested is adequate, relevant and not excessive. For example, if conducting research into obesity, it may not be relevant to ask about the participant's political opinions or religious beliefs. Therefore it is important to do your literature review carefully before writing your short summary of the research. The aims and objectives or research questions should then follow naturally from this. From this you then develop your methodology and your question guide.

A9. Give a short summary of the research

C1. What are the aims of the study?

C2. Describe the design of the research

(Question guide designed, by you, from the above)

Acknowledgement:
The material used in this component is based on the Research Ethics teaching by Professor Darren Shickle

[1] Please be aware that the links will not be exhaustive. The main links will be given only. It is for you to consider if it is relevant in other questions as well.

Session 1: Safety and Well-Being

Session 1: Safety and Well-Being

1. Protecting participants from harm

Researchers have a responsibility to protect participants from any harm arising from research. As a general rule, people participating in research should not be exposed to risks that are greater than or additional to those they encounter in their normal lifestyles. There are two measures for consider harm, unusual discomfort or other negative consequences in the prospective participant's future life, as a result of participating. You, as the researcher, have to make sure you obtain the following:

1. Independent review e.g. from the appropriate Research Ethics Committee;
2. The informed consent of the prospective participant.

Both are part of the ethical approval form you fill out as part of your assessment of the research methods module. Informed consent will be discussed in session 2: The Principles of Consent.

In general the way in which you collect the data should be reasonable i.e. not ask participants to miss work or travel great distances. You need to make it very clear on the Participant Information Sheet what is expected of them.

Link to form

C3. What will participants be asked to do in the study?

Depending on the nature of the research, researchers have a responsibility to ask participants about any factors in the research, such as pre-existing medical conditions, that might create risks to them if they participate, and they must subsequently be advised of any special action they should take to avoid risk. Consider this in your ethical approval form. Remember that it is possible to consider whether your host needs to act as a gatekeeper for selecting participants that are less suitable for your study. For

instance, if you are working with a clinic you could design a participant recruitment process. The clinic manager could for instance de-select participants with previous mental illness or those who have lost a child.

Link to form

C.7 How will potential participants in the study be: (i) identified, (ii) approached, (iii) recruited?

C.8 Will you be excluding any groups of people, and if so what is the rationale for that?

Before participating, people should be informed of procedures for contacting you as the researcher within a reasonable time period if, following participation, they experience stress, harm or have related concerns. This means you need to have a support structure in place. You need to discuss this with your host. For instance can they have a designated nurse or counsellor who you can refer to?

You also need to make sure they can contact your host to give them the opportunity to check up on your credentials of make a complaint about you. You should also give them this contact in case they wish to withdraw from your study.

Link to form

See model of Participant Information Sheet

If during research a researcher obtains evidence of physical or psychological problems of which a participant is apparently unaware, you need to stop the interview as naturally as possible. You are not qualified to offer assistance (even if you have counselling qualifications you are not in your own country!). Make sure you discuss with your host, before starting your research, what the procedure is for these kinds of cases.

Link to form

C. 15 Will individual or group interviews/questionnaires discuss any topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study?

2. Asking sensitive questions

In the case of research methods such as interviews and questionnaires, the content and line of questioning may be highly sensitive, raise confidential, personal issues and intrude, or be perceived to intrude, upon a participant's comfort and privacy. There are a few things you can consider for this:

- Consider the harm and benefit of this line of questioning
- Confidentiality, anonymity and data protection (see section 3: Principles of anonymity, confidentiality and data protection)
- Considering privacy so the participant cannot be identified (where the interview takes place for instance)

- Methodology: consider 'warm-up' questions, less personal methods such as vignettes, focus groups etc.
- Make sure you have alerted the participants that sensitive questions may be asked in the participant information sheet before hand and
- Considering a system to provide support and further information.

Link to form

C17 what are the potential benefits, risks or harms for research participants?

C.20 How will the research team ensure confidentiality and security of personal data?

C. 15 Will individual or group interviews/questionnaires discuss any topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study?

C2. Describe the design of the research.

3. Protecting researchers from harm

As well as protecting participants, you need to protect your own safety and well-being. For this you will be filling out a risk assessment form where you will consider hazards and control measures at length. In general consider the following:

- Knowing the proper conduct for the country you are traveling to
- Making sure that people (family, supervisor and host) know where you are and how you can be contacted at all times
- The safety of the place and time of interviews (i.e. night time, at the participants home, and alone are generally less safe,)
- Carrying a local mobile phone
- Taking out travel and personal insurance
- Considering the safety of local transportation

Most importantly know your own limitations. You may see or experience incidents that are in some way shocking to you. Please remember that whether you are an experienced researcher/traveler or a novice, this can happen to all of us. This can be a whole range of things from seeing a street child or someone who is ill, getting an illness yourself, being reminded of something in your past etc. Make sure you always know where your support system can be found. This might include the host, your supervisor, a friend or family member you can call etc.

If you are using a translator you will need to consider the harms and benefits to them for being part of your research. This will be similar to the considerations under 1.1 'protecting participants from harm' as they live in the local community. You will also

need to think about their health and safety similar to what we discussed under this section.

Link to form

C. 6 Where will your research be undertaken?

C. 18 Does the research involve any risks to the researchers themselves, or people not directly involved in the research?

Principles of Safety and Well-Being Summary Box

Protect your participant by:

- Considering physical and mental harm to your participant
- Considering informed consent
- The Participant Information Sheet makes clear what is expected of the participants
- Give participants your local details
- Give participants the details of your host
- Discussing with your host:
    - Selection of participants
    - A support structure for participants
- Carefully considering sensitive questions

Protect yourself by:

- Considering health, risk and safety issues
- Filling out a risk assessment form
- Knowing your own limitations
    - A support structure for yourself

Protect translators

Session 2: Consent

1 Obtaining consent

Prior to a person being able to participate in research activities you, as the researcher, are responsible for obtaining that person's consent to participate.

The first step in the process of seeking informed consent is determining if the subject is able to give consent (see sections 3 – 6 for where this is/may be difficult). Consent must be given freely and voluntarily and under no circumstances must coercion be used to obtain a person's consent to participate in research.

Informed consent is where a prospective participant, prior to participating in research, is fully informed about all aspects of the research project, in which s/he is considering participating, that might reasonably be expected to influence his/her willingness to participate. In addition, the researcher should normally explain all other aspects of the research about which the prospective participants enquire. Such aspects will include some or all of the following:

- the nature and objectives of the project
- the methodology of the project and how it is to be conducted
- who is undertaking and who is sponsoring the project
- the potential risks and inconveniences that may arise
- the potential benefits that may result
- why the prospective participant has been approached
- what participation in the research will require
- how confidentiality will be protected
- who to contact if something goes wrong
- what is expected of the participants

Link to form

C. 11 Will informed consent be obtained from the research participants?

Information should be explained in writing (and also verbally where possible). Make sure that the university logo features on the top of your information sheet. Written information is usually best understood in the form of questions and answers, for example set out in a 'participant information sheet'. Written information should be in lay terms i.e would any member of the general public understand the sheet? For people who do not understand English you might want to consider having the Participant Information Sheet translated by your host or by your translator (make sure you ask your host about which language is most appropriate. In some countries people read English better than their own mother tongue). Also consider whether the sheet may need to be read out to those who cannot read.

See Model of Participant Information Sheet

C14 What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English or who have special communication needs?

Prospective participants should be given sufficient time in which to consider whether or not to participate. The procedure is that participants have 24h to consider. If it is a sensitive topic you may need to give them longer. However sometimes, and in particular circumstances, it can be about an hour. For instance, if you do not have a very sensitive topic and you are trying to catch people visiting a clinic who live far away. The crux is to give people time to reflect. Make sure that you consider this carefully.

C13. How long will participants have to decide whether to take part in the research?

Additionally participants can withdraw from the study during or after data collection. For this you must make sure that participants have the contact details of your host. In terms of focus groups, you need to make it clear that participants can leave at any point but it is not possible for you to extract the information from before the point of leaving.

Figure 1: focus group

Link to form

C13. How long will participants have to decide whether to take part in the research?

1.1 Written, oral and witnessed consent

Wherever possible, and proportionate to the nature of the research activity, an individual's consent should be obtained in writing. Where written consent is not possible oral consent should be obtained, ideally in the presence of at least one witness.

Witnessed consent is required for particularly vulnerable participants who have intellectual or cultural difficulties in speech or understanding, but who are deemed capable of giving consent.

Thumb prints alone to show consent are **not** to be used for research. Where local customs allows, you could both audio record and link with a thumb printed consent form. File forms and audio files separately from the interview data.

Link to form

C14 What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English or who have special communication needs?

C20 How will the research team ensure confidentiality and security of personal data?

Model Participant Consent Form

1.2 Implicit consent

For research purposes, explicit consent is usually required. However, consent could be implicit. For example, if a person receives, completes and returns a postal questionnaire, the act of completion and return implies that they have consented to participate in the research (provided they have received adequate information to enable them to give informed consent, provided they are competent and understand the information, and provided that their participation is free and voluntary).

C11. Will informed consent be obtained from the research participants?

1.3 Ongoing process

The consent process should not cease once the initial consent has been obtained. The practice of giving information about the research project to the participants should be an ongoing process performed by the lead researcher and/or by members of the research team. This is particularly necessary following the availability of important new information that may be relevant to the participant's willingness to continue participating in the research project. If a researcher doubts whether a person participating in research still consents to participating s/he should clarify this with the person in question.

In case of your fieldwork this may be quite difficult. Therefore it is important that you consider absolutely every use of your research before you start. For this reason it is important to consider, for instance, how the information is going to be disseminated.

Researchers should make plain to people, prior to their participation, their explicit right to refuse to participate in and/or to withdraw from the research at any stage, irrespective of whether or not payment or other inducement has been offered, and that this right will be respected.

C11. Will informed consent be obtained from the research participants?

C13. How long will participants have to decide whether to take part in the research?

2. Coercion

A potential participant should be free to decide whether or not to participate in the research without any undue influence. There must be a balance between the giving of advice and allowing the person to make their own decision. The quality of the consent of participants who are in a potentially dependent relationship with the researcher (e.g. employees, patients, students) requires careful consideration, as willingness to volunteer may be unduly influenced by the expectation of benefits or rewards.

When research is being conducted with detained persons (e.g. prisoners) particular care should be taken, paying particular attention to the special circumstances that may affect the person's ability to freely and voluntarily give informed consent.

People volunteering to participate in research may be paid for their inconvenience and time. Payments made to individuals, to enable them to participate in research activities, must not be so large as to induce the individuals to risk harm beyond that which they would usually undertake. Financial payments might cover reimbursement for travel expenses and / or time. Risks resulting from participation should be acceptable to participants even in the absence of inducement. The promise of compensation and care for damage, injury or loss of income as a result of participating in research activities to participants should not be considered coercion by inducement. This is difficult in low and middle income countries. You need to recognize that it is willingness that is rewarded NOT participation – which may be coercive if a 'gift' or payment is enticing enough. It is important to consider this with the local host[2].

Link to form

C16. Will individual research participants receive any payments, fees, reimbursements of expenses or any other incentives or benefits for taking part in this research?

3. Research involving incompetent adults

Where a prospective participant (e.g. institutionalised adult) is unable to give informed consent to participate a 'legal representative' may give assent on his / her behalf. Such a 'legal representative' should be able to give assent for and authorise an intervention on the patient. However, the assent of the participant, who is unable to give informed consent, should also be sought where possible. In the case of an adult this could be a person designated by the adult, a relative or an independent person nominated by, for example, the hospital at which the research is being undertaken.

However this remains a very difficult issue. We will be looking at four main issues:

1. The harms and benefits of your research as a whole.
2. You as a researcher and your previous experience with this vulnerable group.
3. How your methodology caters for this vulnerable group
4. The support measures you have in place

Link to form

A8. Will the participants be from any of the following groups?

[2] bearing in mind that the ethics committee will consider your justification for any gift, taking into account local circumstances.

4. Research involving children

If the involvement of infants and children under the age of eighteen in a research project is justified, where appropriate and feasible the informed consent of one of their parents or their legal guardian should be obtained for inclusion of the child in the research. However, in some circumstances, obtaining the informed consent of a parent may be inappropriate (e.g. research with children who are a ward of the state) or unfeasible (e.g. research involving homeless children).

Wherever possible, a researcher seeking to undertake research with children under the age of eighteen should also obtain the child's free and voluntary assent to participate. However, the ability of a child to give free and voluntary consent depends very much on a child's level of competence and competence varies with age. Other factors include the child's own experience and confidence, the type of research s/he is being invited to participate in, and the skill with which a researcher talks with as child and helps that child to make free and voluntary, informed decisions. It is important for the child to be given information regarding the research project according to his/her level of understanding (from staff that have experience in liaising with children) and the person taking consent must respect the child's wishes.

In the case of research in educational settings, any special school policies or procedures should be followed.

In case of children under the age of 16 it is a little more difficult. This does not mean that your research is not possible. There may be an alternative way to address your research questions. You need to discuss this with your supervisor. The following has to be considered:

1. The harms and benefits of your research as a whole.
2. You as a researcher and your previous experience with this vulnerable group.
3. How your methodology caters for this vulnerable group
4. The support measures you have in place

Link to form

A8. Will the participants be from any of the following groups?

5. Covert research

In certain research disciplines (e.g. psychology), to ensure the viability of a piece of research and that it will contribute to knowledge and understanding, it is sometimes necessary to withhold information on the true objectives of the research from the

people participating in it. In such types of covert research it is inappropriate to obtain informed consent from the participants. Wherever possible such covert research should be avoided. In such circumstances (i.e. where covert research methods are necessary) you, as a researcher, has a special responsibility to:

- Justify that alternative procedures to avoid the withholding of information or deliberate deception are not available or are not feasible for the research;
- Justify why the withholding of information, or an element of concealment or deception, is integral to the viability of the research.

Link to form

C10. Will the research involve any element of deception?

6. Research in public contexts and with groups

In certain types of research obtaining consent from every individual participating is impractical or unfeasible (e.g. observing a large crowd or observing discussions on the internet). In such types of research, researchers should ensure the following:

- That such research is only carried out in public contexts;
- That where possible approval is sought from relevant authorities;
- That appropriate individuals are informed that the research is taking place;
- That no details that could identify specific individuals are given in any reports on the research unless reporting on public figures acting in their public capacity (e.g. reporting a speech by a named individual);
- That particular sensitivity is paid to local cultural values and to the possibility of being perceived as intruding upon or invading the privacy of people who, despite being in an open public space, may feel they are unobserved.

The privacy and psychological well-being of people participating in observational research and people participating in research activities in which a researcher may actually be acting as a fellow participant, for example as part of a wider group, must be respected. In such research, every effort should be made to ensure that the group leader(s), or others in positions of responsibility, as well as other individuals of a group, understand they are being observed for research purposes. It may be more difficult to explain to people participating their right to withdraw at any stage. However, in such types of research, researchers are expected to make a reasonable attempt to do so.

As an example you might be observing in a hospital. Make sure you have permission from the director of the hospital to do this. He/she may want to call a meeting with certain members of staff to discuss and obtain further permission.

Link to form

C11. Will informed consent be obtained from the research participants?

Principles of Consent Summary Box

Obtaining consent:

- Is your participant able to give consent?
- Consider how long participants will have to decide
- Consider how participants can withdraw from the study
- Will consent be written? Audio recorded? Thumbprint + audio recording?
- Consider payments, reimbursements etc
- Carefully consider vulnerable participants
- Consider the need for covert research
- Consider research in a larger public context

Participant Consent Form/Information Sheet:

- Write a participant information sheet in lay terms
- Make sure that information sheets and consent forms have the university logo on them.
- Do this form and sheet need to be translated?
- Data protection: keep consent forms/tapes and interviews separate
- When designing the form and sheet consider dissemination

Session 3: Anonymity, Confidentiality and Data Protection

Arrangements should be made to carefully protect the confidentiality of participants, and their data. All personal information collected should be considered privileged information and be dealt with in such a manner as not to compromise the personal dignity of the participant or to infringe upon their right to privacy. The collection, storage, disclosure and use of research data by researchers within the UK must comply with the Data Protection Act (1998). This means that:

- You try not to keep data on your laptop as they can easily be stolen. This puts participants at risk. And if you do it should be not linked to the participant and it should be encrypted. It is better to either store data on the university Mdrive or on an encrypted data stick.
- Data should not be left on your laptop after you leave the course
- Passwords must comply with university guidelines
- Audio files must be transferred to an encrypted data stick
- Make sure you store paper copies just as safely as electronic files
- Think about how you will ensure confidentiality when using an interpreter
- Think about how you will ensure confidentiality in a focus group
- Data should be stored for 3 years

Link to form

C20. How will the research team ensure confidentiality and security of personal data?

C21. For how long will data from the study be stored?

Before consent is obtained, researchers should inform prospective participants of:

- Your, your hosts and your supervisors identity (e.g. 'x' at the University of Leeds).
- The purpose for which personal information provided is to be used (e.g. if video material might be used for teaching purposes, dissemination of data)
- Any potential risks that might mean that the confidentiality or anonymity of personal information may not be guaranteed
- Which individuals and organisations, if any, will be permitted access to personal information, and under what circumstances such access will be permitted

Model Participant Consent Form

Model Participant Information Sheet

Researchers must assure participants that any personal information collected, that could identify them, will remain strictly confidential and, depending on the research, access to the information will be restricted to you or to researchers directly involved in the research at all times, before, during and after the research activities. In certain types of research, where necessary and practical, personal information on participants, that could identify them, will remain anonymous at all times, even to the researchers themselves. A researcher may not disclose the identity of a person nor disclose any information that could identify that person without having obtained, prior to the person's participation, the person's consent in writing. If it is necessary, to a piece of research, to identify participants explicitly, then the researchers should explain why this is the case and how confidentiality will be protected.

You can do this by assigning numbers or letters (or a combination) to your interviews/surveys and keeping in consent forms separate and unlinked from your data.

All participants have the right to access personal information, whether or not it is confidential, that relates to them, and to be provided with a copy of the information on request. This is another reason why you need to make sure you and your host can be contacted. These contact details should be available on the Participant Information Sheet.

C20. How will the research team ensure confidentiality and security of personal data?

Researchers should be aware of the risks to anonymity, confidentiality and privacy posed by all kinds of personal information storage and processing which directly identify a person (e.g. audio and videotapes, electronic and paper-based files, e-mail records). Wherever possible data should be collected, stored or handled in anonymous form. Where linkage between datasets is required (e.g. in longitudinal studies) record

numbers should be used as far as possible, with special measures used to protect the key that would link a number to personal identifiers.

Name and address are not the only way of identifying an individual. There are other forms of information that can be used to identify an individual (e.g. date of birth or clinical diagnosis for rare diseases), especially if the area covered by a dataset is small. Similarly the keys for some record numbers (e.g. NHS number) are easily accessible. Thus while removing name and address provides a 'first-line' protection of privacy, identification of the data subject may still be possible.

A participant may also be identified by the very fact that you spoke to him/her and this was observed. Consider this carefully. For instance, if you are talking to nurses in a small clinic, evaluating part of their job they may be identified for being seen with you. If you report is in any way negative this may have adverse effects on the nurse.

You can think about where and how you interview someone and how you publically talk about your project as a whole (i.e. not talking about that research is about HIV positive people but for instance about HIV knowledge in general). The information sheet should have the correct information but can also be kept fairly general (eg. there has to be no information on there that someone has been selected because they are HIV positive[3]).

Link to form

C17. What are the potential benefits, risks or harms for research participants?

Principles of Anonymity, Confidentiality and Data Protection Summary Box

- Consider where you keep your data
- Separate your data from the consent forms
- Anonymize data
- Think about the interpreter and confidentiality
- Think about focus groups and confidentiality
- Data should be stored for 3 years
- Think about who has access to your data
- Think about the potential risks to the participant from being identified.

[3] Please be aware that this is a vulnerable group and the issues discussed in session 1 on Safety and Well-being has to be taken into account.