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Research Ethics: Guidance for the Voluntary Sector

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Research: The systematic investigation into and study of materials, sources, etc., in order to establish facts and reach new conclusions.

Ethics: *Moral principles; rules of conduct.*

THE OXFORD MODERN ENGLISH DICTIONARY

CONTENTS

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1. Research Ethics: Why are they Important?

Voluntary sector organisations may get involved in research in many ways from surveying their members, to commissioning an external agency to evaluate their activities, or collaborating with a university to conduct an in-depth study. Whatever your involvement in research is, it is good practice to consider the ethical issues involved in its delivery. These guidelines have been produced to help the voluntary sector to do this.

Ethics are important in all research that involves people, but especially when participants may not be able to fully protect their rights themselves, such as children or vulnerable adults.

These guidelines outline three key processes central to carrying out research ethically:

- **Obtaining informed consent**

People need to be able to make an informed decision about whether or not to take part in research. To be able to do this, they will need to know and understand the purpose of the research and what it involves.

- **Protecting from Harm:**

Both those taking part in the research and doing the research should be safeguarded from harm (both physical and psychological).

- **Storing and Handling Data:**

The confidentiality and anonymity of participants should be protected when storing and handling data.

In managing each of these processes, a range of issues will arise. Although it's not possible to cover every potential issue here, three research scenarios have been developed to highlight some that might arise. These are summarised below and referred to throughout.

Finally, these guidelines outline the ethical approval process used by universities and the NHS. This is to help provide an understanding of their internal systems so that voluntary sector organisations know what to expect when collaborating with such organisations on a research project.

RESEARCH SCENARIO ONE

The Good Ethics Organisation is dependent upon the work of volunteers in its day to day running.

However, it has experienced increasing problems with the recruitment and retention of volunteers in recent years. To help tackle these issues, the organisation wants to better understand the experiences of its volunteers and perceptions of prospective volunteers.

Its manager is proposing to conduct a survey to explore these issues.

RESEARCH SCENARIO TWO

On The Ground is a community involvement organisation working alongside communities in areas of deprivation to provide training opportunities.

They want to improve the outcomes for those people completing their training courses, and think that gaining a better understanding of the needs of the local community will help them to do that.

They have decided to interview local people to find out more about their training needs.

RESEARCH SCENARIO THREE

Friendly Lunches delivers hot meals to people in their homes soon after they have been discharged from hospital. They are experiencing a delay between the time of discharge and receipt of a referral and want to investigate its cause.

They plan on conducting interviews with health and social care staff and patients themselves to explore this issue further.

2. Informed Research Participants: What do they Need to Know?

Obtaining informed consent is a key ethical principle that is essentially about making sure that those people you are inviting to take part in the research, know and understand:

- What the research is about and its purpose
- What taking part involves and the length and duration of their involvement
- How the data will be stored, used and the results disseminated
- Their rights to withdraw from the research at any time
- Any consequences of their involvement

Without facilitating this understanding, people will not have all the information they need to be able to make an informed decision on whether or not to consent to participating in the research. If you are carrying out research, it is your responsibility to make sure that you give people all the information they require.

How this information is best provided and informed consent obtained (either written or verbally), will depend on the nature of the research. The following guidelines should be considered:

- be open and honest about the purpose of the research:
  a) covert research (where the participants don't know they are participants) is generally discouraged. Sources of further information on what to do if you can't inform every participant about your research are listed at the end of this document
  b) if there are any potential conflicts of interest (e.g. if you are carrying out the research as part of a campaign with a clear objective), let participants know this
- provide a written document (an 'information sheet') that explains all the key facts about the research and provides your contact details
- in addition to the information sheet, participants should be given an opportunity to ask any questions about the research before they agree to take part
- it is recommended that participants are asked to complete a written consent form, especially if the research involves personal, sensitive or confidential data
- If your participants include children or vulnerable adults, you will need to take additional measures – consent may need to be sought from a responsible adult (sometimes referred to as a 'gatekeeper')

It's also important to make people aware of their right to withdraw their consent to participate at any time (no longer take part in the research) and they can do this without having to provide a reason and without any penalty (for example, their funding or support will continue regardless of their participation).

At the end of the research, you might want to feedback the findings to participants. Be clear at the start of the project (provide the details in the information sheet) about what you will feedback and make sure you have the contact details that you need to be able to do this.

The process of obtaining informed consent is discussed further in the context of the three research scenarios opposite.

RESEARCH SCENARIO ONE: THE GOOD ETHICS ORGANISATION

The survey will be sent to adults and will explore perceptions of the organisation and their experiences of, and motivations towards volunteering.

The invitation to complete the survey (whether sent via email or post) can provide the key information about the research, including how long the survey will take to complete (it's important to be honest about this, even if you are concerned that the length will put people off participating). This invitation can serve as the 'information sheet'.

As existing volunteers will be invited to complete the survey, it's important to provide clear information on confidentiality and anonymity (see Section 4 of these guidelines for further discussion of this).

It is recommended that this information is repeated on the survey itself.

As the survey is not exploring sensitive or personal data, consent can be obtained through a tickbox on the survey (directly following the key information), which asks them to confirm that they have read and understood the information provided and are happy to complete the survey.

RESEARCH SCENARIO TWO: ON THE GROUND

Face-to-face interviews are planned with local people to find out more about their training needs.

The invitation to take part in an interview should provide the key information about the research, including how long an interview will take. This invitation can serve as the 'information sheet'.

The information sheet should be presented again at the start of the interview itself and repeated verbally.

Although research should always aim to obtain written consent wherever possible, if the interview is being recorded (with the participant's permission), it may be appropriate (if it is not sensitive or personal information) to obtain verbal consent - start recording when you repeat the information provided on the information sheet and ask if they are happy to take part.

RESEARCH SCENARIO THREE: FRIENDLY LUNCHES

Face-to-face interviews with health and social care staff and patients are planned.

As in Scenario Two, if key details about the research are outlined in the invitation to take part, this can serve as the 'information sheet'.

The information sheet should be presented again at the start of the interview itself and repeated verbally.

As the interviews will explore potentially sensitive, personal and confidential information about hospital admissions and discharges, it is recommended that written consent is obtained.

Each participant should be asked to complete a written consent form. The consent form should ask the participant to confirm that they have read and understood each point on the information sheet and sign and date the form.

3. Protection from Harm: Safeguarding Participants

A further core ethical principle is protecting participants from harm – both physical and psychological. The potential exposure to harm should be considered for every research project at the outset.

Examples of the type of issues that may cause harm include research that explores sensitive subjects which are potentially distressing (such as bereavement). This can be minimised by ensuring that participants are aware that they do not have to answer any questions that they are uncomfortable with. In some cases however, it is not possible to anticipate what questions will cause distress. When preparing for research, identify helplines or sources of support relevant to the research topic. Then, if a participant does become distressed or anxious, you will be able to direct them to the appropriate help.

RESEARCH SCENARIO TWO: ON THE GROUND

During face-to-face interviews with local people about their training needs, sensitive issues may arise.

For example, if an individual discloses that they have poor literacy skills and they appear distressed at this issue, the researcher can provide them with details of where to go for further support (e.g. National Careers Service).

Research involving drug trials or medical procedures (such as a randomised control trial) where side effects may be experienced is another example of how research participation can cause harm. Such research must be subjected to rigorous ethical review to ensure that the appropriate safeguards (e.g. the provision of medical assistance) are in place. Sources of further information on the ethical issues involved in medical research are provided at the end of this document.

The next section of these guidelines discusses the process of storing and handling data, including the principles of confidentiality and anonymity. However, it is important to emphasise here that failing to handle data in accordance with data protection legislation can lead to some participants being identified. Through failing to protect their privacy, this can also cause harm to research participants.

More generally, if research causes harm, researchers are expected to take action to remedy it.

It's also important that researchers ensure that they are protected from harm when carrying out research. Again, the risks associated with each research project should be considered before you start the fieldwork. It may be appropriate and necessary, for example, to follow lone working procedures when you are carrying out research.

RESEARCH SCENARIO THREE: FRIENDLY LUNCHES

The interviews with patients may be conducted in their homes in relatively isolated locations.

To safeguard their safety, the person carrying out the interview should follow lone working procedures. This could involve providing a colleague with the address and telephone number of the patient and contacting them on entry and departure from their home.

4. Storing and Handling Data

Confidentiality and anonymity are also core ethical principles, and must be considered before, during and after the research. These principles refer to the protection of the identity and privacy of individual participants. This has important implications for the way you collect, store, analyse and report data - the Data Protection Act applies to personal data collected through research.

The confidentiality and anonymity assurances given to participants in every research project should be explained at the time of their invitation to take part (and ideally within an information sheet). More generally, the following guidelines should be considered:

- Data in both paper and electronic formats should be stored securely and only accessible to members of the research team
- Actions should be taken to protect the identity of participants (e.g. remove their name and other identifiable information from the data)
- Ensure participants are aware of how the data will be analysed and used, including details on if and how it will be published
- Only keep the data for as long as necessary (this will differ from project to project but it's important to comply with the Data Protection Act).

Most research policies and guidelines recognise that there are instances where it is not possible (nor in the best interests of participants) to maintain confidentiality. For example, a disclosure of abuse raises duty of care issues that researchers are obligated to respond to. Sources on further information on how to respond to such issues are provided at the end of this document.

Furthermore, participants are often selected because of their expert knowledge on a given subject. In some instances, it may be possible to identify a participant from their answers alone (even if their comments have not been attributed to their name). If a researcher is unable to protect the identity of a participant, this should be discussed at the outset to enable an informed decision on whether or not to consent to participate on this basis.

RESEARCH SCENARIO ONE: THE GOOD ETHICS ORGANISATION

Existing volunteers will be invited to complete the survey and will therefore be known to the researchers. If it is possible that they may be able to be identified from their responses - even if their name is not used - they should be made aware of this on the information sheet.

If the survey is distributed by post, then a secure and lockable space will be needed to store all completed surveys to ensure the confidentiality and anonymity of participants is protected.

If an online survey is used, actions will be needed to ensure that only members of the research team have access to the electronic data (e.g. use password protected files).

RESEARCH SCENARIO TWO: ON THE GROUND

Secure storage of the recordings of the face-to-face interviews and any other data will need to be arranged as in Research Scenario One.

If the recordings are transcribed, the transcription becomes another source of data requiring secure storage accessible to only the research team.

It may be necessary to remove identifiers from the transcription (e.g. place names or organisations) to protect the anonymity of participants.

5. Ethical Approval: The Review Process

Although members of the voluntary sector may not have a formal internal research ethics policies or procedures to follow, many organisations do – including universities, colleges and the NHS. This section aims to help provide an understanding of these internal systems so that voluntary sector organisations know what to expect when collaborating with such organisations on a research project.

UNIVERSITIES AND COLLEGES

Although policies and procedures will differ between institutions, all draw upon the core principles outlined in this guidance. Academic researchers will be expected to consider how these principles apply to their research project and submit an application form or research proposal to an internal ethics committee. They will have to do this for all research that involves human participants. This typically excludes research that is purely desk based and uses existing data sources (e.g. a literature review or analysis of data, such as the census).

Committees are typically composed of representatives from across a subject area (an institution can have several committees). The Economic and Social Research Council[1] suggests that the following information is submitted to the committee as part of the ethical review process:

- The research aims and information about the background to the research
- How the research will be conducted (the study design)
- Information on the participants (who, how many, recruitment methods)
- Identification of any vulnerable groups
- How the data will be collected and analysed
- Review of ethical issues specific to the project
- Risks to participants, third parties and researchers, and how they will be minimised
- How informed consent will be obtained
- Confidentiality and anonymity procedures during and after the research
- Expected outcomes
- How the findings will be disseminated

Following a review of the application, the research ethics committee will either provide approval, request clarifications or amendments, or reject it. Given this obligation on academic researchers, time for ethical applications should be built into the planning of any collaborative research project. The time taken for ethical reviews will differ between institutions and across projects, as an approximate guide, around six weeks should be allocated to this process.

[1] ESTC recommendations: http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf

NHS

If your research will involve human tissues and cells, NHS or social care services, premises and its users, contact your NHS locally for further advice and guidance. It may require approval from a NHS research ethics committee. You can find the contact details for your local committee on the National Research Ethics website and further information (http://www.nres.nhs.uk).

RESEARCH SCENARIO THREE: FRIENDLY LUNCHES

This research proposes to interview health and social care staff and its users and is therefore likely to require approval from a NHS research ethics committee.

The documentation that will have to be prepared as part of the application includes a research protocol, research participant information sheet and research participant consent form.

A detailed list of the type of research that requires such approval is provided on the Department of Health's website[2] and includes:

- Participants who have been identified from or because of their use of NHS and/or social care services
- Participants identified because they are relatives, carers of users of NHS and/or social care services
- The collection of tissue, or use of previously collected tissue, or information from users of these services
- Participants who are unable to provide informed consent
- The processing of confidential patient information
- Patients cared for in nursing homes and/or residents of residential care homes
- Some medical devices
- Medicinal products
- Human tissues and organs (from the living and deceased).

A NHS Research Ethics Committee application must be submitted to a local committee along with a research protocol and any supporting documentation (e.g. CV, information sheets, consent forms and evidence of insurance or indemnity). The research protocol is required to provide a full description of the project, including its methods, costs and ethical considerations. An ethical opinion on the application will be given within 60 days of its submission. Attendance at the ethical committee meeting where the application is considered may be required.

If approval (or a favourable ethical opinion) is given, submission of progress reports and an end of study and final report are required. Full details on the NHS process for ethical approval are available online[3].

[2] Research requiring approval: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_133993.pdf

[3] NHS processes for ethical approval: http://www.nres.nhs.uk/home/

6. A Summary

This document provides some guidance on the ethical issues to consider when planning and conducting research. It does not cover every possible issue that may arise in research, but aims to provide some guidelines to help you respond to those that do. The key stages of research and the considerations to be made at each of them are summarised as a checklist opposite. More generally, at the start of the preparations for any research project, consider the sensitivity of the research topic and whether or not formal ethical approval is required (as described in Section Five).

CHECKLISTS

GETTING INFORMED CONSENT

- ☑ Identify an appropriate 'gatekeeper' if the research involves vulnerable adults or children
- ☑ Develop written or verbal consent procedures depending on the sensitivity, personal and confidential nature of the research topic
- ☑ Develop information sheets outlining key details about the research
- ☑ Provide participants with an opportunity to ask questions about the research

PROTECTING FROM HARM

- ☑ Identify potential factors that may cause harm to participants and appropriate actions to minimise/remedy their impacts
- ☑ Take the actions necessary to ensure that those carrying out the research are able to do safely

STORING AND HANDLING DATA

- ☑ Store electronic and paper data securely so that only the research team have access to it and anonymity and confidentiality is protected

Take appropriate actions to maintain the confidentiality and anonymity of participants (e.g. remove identifiers from the data)

7. Further Information

The documents listed below provide further guidance and information on the ethical issues outlined in these guidelines. They have also been consulted in the preparation of these guidelines.

British Sociological Association
Statement of Ethical Practice, explaining key ethical principles.
http://www.britsoc.co.uk/about/equality/statement-of-ethical-practice.aspx

Economic and Social Research Council
The ethical framework of the principal funding agency for UK social science research and includes detailed information on ethical review processes.
http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx

UK Data Archive:
Detailed information on the process of obtaining informed consent and examples of information sheets and consent forms.
http://www.data-archive.ac.uk/create-manage/consent-ethics

Social Research Association
Guidance on ethical principles.
http://www.the-sra.org.uk/documents/pdfs/ethics03.pdf

General Medical Council
Provides guidance on the ethics of medical research, including protection from harm.
http://www.gmc-uk.org/guidance/ethical_guidance/6004.asp

The Research Ethics Guidebook
Guidance on ethical principles, including the implications of duty of care on confidentiality.
http://www.ethicsguidebook.ac.uk/

National Research Ethics Service
Guidance on the NHS ethical approval system and links to local contacts.
http://www.nres.nhs.uk/home/

Data Protection
The Data Protection Act 1998 in full.
http://www.legislation.gov.uk/ukpga/1998/29/contents

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