Manchester Institute of Education (MIE)
Policy on Informed Consent

Introduction

Since the central requirement for research involving human participants is that people participate voluntarily, the consent process is one of the most important parts of planning a research proposal. The process must assure that the potential participants understand the research, its risks, benefits, and alternatives, and can confirm his or her willingness to participate.

A process--not a form

As participants retain the right to withdraw from research throughout, informed consent is an ongoing process. It starts well before any forms are signed and continues until the person's participation is complete.

The informed consent process is distinct from the consent form. It involves identifying potential participants, finding out whether they are capable of giving consent, and if so, informing them of the purpose, risks, benefits, and alternatives to participation in a format that is accessible to them. The consent 'form' (or alternative) formalises the agreement to participate and should be designed to record participants' understanding of the research, their role in it, and what they are consenting to. Obtaining 'informed consent' is not just giving a prospective participant a consent form and getting it signed.

For consent to be informed, the participants must genuinely understand the research. Hence researchers should strive to convey information to participants, not merely disclose it to them. Participants should be able to say what they are consenting to.

When to discuss participation

To achieve understanding of research, potential participants should not be presented information at the last minute. While some individuals may be inclined to agree to participation immediately, this in all fairness does not give them a real opportunity to reflect on the implications of being a participant. People need time to think about whether or not they want to participate. Some may wish to discuss the decision with family, close friends, or colleagues. They should not feel rushed or coerced by our anxious wait for their response. Potential participants need time to digest the information, ask questions of us and others, and make an informed decision. **MIE recommends a period of at least two weeks between first approach to a potential participant and data collection, should be allowed**. In some circumstances this timeframe is not feasible. However, the guidance above should be taken into consideration and an appropriate time period allowed for the participant to reflect on information and seek advice or answers to queries before giving final consent.

It is important that the person seeking to recruit participants gives individuals an opportunity to discuss the research. Where appropriate for some target groups, perhaps those with literacy difficulties, the researcher should spend time going through the information with them and should *not* simply give an information sheet to the participant to read on his or her own. Available evidence indicates discussion is the most effective way to ensure consent is "informed". The onus is on the researcher to ensure the study is explained to the participant and that the participant does understand by asking questions.

To ensure the person understands the research, questions should be open-ended and non-directive. Rather than asking for yes or no answers, these questions ask for explanation and often can be answered in a variety of ways; they do not already contain the correct answer. Open-ended questions are often introduced with "what," "where," "how often," "when," and "please describe." Examples of open-ended questions are:

"Describe in your own words the purpose of the study."

"Just so that I'm sure you understand what is expected of you here, would you please explain to me what you think we're going to ask you to do?"

"What is the possible benefit of the research?"

“What are the possible risks of taking part?"

"What more would you like to know?"

In contrast, examples of closed ended and far less useful questions are:

"Do you understand?"

"Do you have any questions?"

Instead of furthering the discussion, closed ended questions tend to bring it to a stop.

Information Sheets

Information must be comprehensible. Even highly educated people need to have technical information presented in simple terms when it uses language they are unfamiliar with. How information is best expressed will of course vary with regard to the population. In research with adults, more complex terminology can be used, but some adults with learning difficulties and most children need to have information presented as simply and straightforwardly as possible. The level of detail should be appropriate to the nature and detail of the study. One size will not fit all so we suggest you match its length to the complexity and risk of your study. Studies where participation is limited and there is less than minimal risk, are likely to need a brief information sheet (for example the explanation of a questionnaire study may be summarised on the front of the questionnaire itself and completion of the questionnaire regarded as consent).

Writing style

The information sheet is best written as an invitation (the use of “we” may help). Use the active tense and avoid the passive. Write it in simple, non-technical terms that a lay person will understand easily. Use short words, sentences and paragraphs with clear subheadings to make the text manageable, and a font size for easy reading. If you intend to recruit elderly participants you may need to use size 16 font. As a guide, the language level used should be no more difficult than that used in the information leaflets aimed at the general public or in tabloid newspapers. Avoid large sections of unbroken text or long lists. Diagrams or pictures might be better.

Content and length: Be clear and concise. Use bullet points and indentations for clarity. Question and Answer format is often very useful too. Within a leaflet it is important to confine your information to a few key messages. Make sure you include graphics and

illustrations, preferably in colour if your budget will stretch to this.

Language: Languages other than English need to be considered in the light of local community/users needs. Use of simple words rather than complex ones and avoiding jargon should help those who have limited use of the English language. If professional terms have to be used, include a simple explanation.

Layout: You should bear in mind that The Disability Discrimination Act requires that information should be made accessible for those with disabilities. For a leaflet, you should consider the needs of those with a visual impairment.

Illustrations: If you intend to include illustrations, bear in mind the social/age/gender mix of potential participants.

Checklist for content and presentation:

- I have matched my writing to the needs, abilities and age of the reader
- The purpose of the document is clear to the reader
- The document is laid out clearly with headings and a summary of the important points
- My sentences have no more that 15-20 words in them, on average
- I have used "I", "you", "we" and made the writing more personal
- Where appropriate I have used clear directions
- I have started with a simple outline of the document, perhaps explaining its purpose
- I have liaised with other professionals, teams, departments and agencies and involved users, as appropriate
- The document complies with University guidelines
- The document is sensitive, in that it will not cause offence to anyone's religious belief, political persuasion, racial group, age, marital status or sexual orientation
- I have included contact names/numbers for further information
- I have made sure that people with visual, reading or language difficulties can read the document, or obtain further assistance
- I have tested the document with a sample of those who will use it
- I have included a publication date

Presentation

Consider the appropriate page size – MIE usually recommends an A4 layout, but it may be that A5, or another paper-size and layout would be more suitable. All consent forms and information sheets should have a date in the header/footer to ensure the most recent is used, and numbered pages.

Guidance, based on the MIE Information sheet template, is given below.

Participant Information Sheet Template (Competent Adults).
This template should be adapted to the research project and include only relevant headings.

Title of Research

Participant Information Sheet

You are being invited to take part in a research study [as part of a student project – *participants should be told about the overall aim of the research and whether it will be for a degree*]. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please contact me. Thank you for reading this.

Who will conduct the research?

Insert the name of the researcher(s) and the Manchester Institute of Education address.

Title of the Research

If the title is not self-explanatory to a lay person a simplified title should be included.

Ask yourself: "Does this explain the study in simple English?" One consistent title should appear on all the documents and be comprehensible to a lay person. If acronyms are used in the title they must be spelled out in full the first time they appear. The title should not consist of an acronym alone.

What is the aim of the research?

Provide an explanation of what you, the researcher, are hoping to achieve by the research

Purpose is an important consideration for participants, and we recommend that you present it clearly and succinctly, in the brief context of other work in your field. It is entirely reasonable for projects to be primarily for educational purposes. This purpose should be made clear.

Why have I been chosen?

Provide a statement explaining how the participant was chosen and how many other participants will be involved.

What would I be asked to do if I took part?

Provide an explanation of what is going to be done by you, the researcher and a clear explanation of what the participant is expected to do during the research. Also include an explanation of the risks, pain or discomfort, or potential for embarrassment/distress due to discussion of sensitive issues, if any, that the participant may experience.

What happens to the data collected?

Provide a clear explanation as to how the data will be used.

How is confidentiality maintained?

Provide a statement on how you will maintain confidentiality, where data will be stored and kept secure. If interviews or observations are to be audio or video-recorded say how and when the recordings are to be destroyed.

It is becoming increasingly difficult to maintain confidentiality due to use of electronic means of capturing, storing and transferring information. It is therefore extremely important that researchers make every effort to safeguard confidentiality for all research participants. The researcher should describe the level of confidentiality of the research data and the measures that will be taken to ensure that confidentiality is maintained. Participant data should be stored on an encrypted device for security. This should be explicit in the information provided to participants.

Confidentiality is also an issue while participating in the research. For example focus groups can result in participants being identified by other participants. Confidentiality cannot be assured in such cases.

What happens if I do not want to take part or if I change my mind?

You should inform potential participants that it is up to them to decide whether or not to take part, it is entirely voluntary. If they do wish to take part you should indicate that you will first discuss the study with them and answer their questions – give an indication as to when this will happen. It should be made clear that if they decide to participate they will be given the information sheet to keep and asked to sign a consent form. In some circumstances a signed consent form is not appropriate. Where this is the case, the procedure for recording participants' consent should be explained.

It should also be made clear that if they decide to take part they are still free to withdraw at any time or choose not to answer certain questions without giving a reason. If there is a professional relationship between you and the potential participant, you should include reassurances that refusal or withdrawal from the research will not affect the service they receive.

In some circumstances, such as research involving focus groups, it will not be possible to withdraw a participant's data if they change their mind about participation. In such cases, the contribution has become part of a group discussion and cannot be extracted. This should be made clear in a statement in this section.

Will I be paid for participating in the research?

Provide a clear statement of payment arrangements for compensation for the participants time and inconvenience and any out-of-pocket expenses, if applicable.

You should explain if expenses (e.g. travel, compensation for inconvenience, etc.) are available and you should consider whether any gift vouchers you are intending to give as a thank-you for participation, should be detailed in the information sheet. The compensation should not be of such a value as to persuade a person to volunteer against their better judgement.

What is the duration of the research?

Provide details on the duration of the study (e.g. 3x ½ hour interviews; 1 questionnaire etc) If there are a number of activities that the participant will be required to participate in then it is often helpful to present this in a table.

Where will the research be conducted?

Provide details of the location.

Will the outcomes of the research be published?

Provide details of anticipated outcomes in respect of publication of findings.

You should tell the participants what will happen to the results of the research, for example that they will be presented in a thesis, and whether you intend to publish the results elsewhere. You should provide reassurance that individuals will not be identified in any report/publication unless they have given specific consent for this. You should also indicate how the results will be made available to participants themselves.

It is reasonable to argue that informing participants of results acknowledges their contribution, shows respect and sees them not simply as a means to the researchers' ends. MIE recommends that you only give general, and not individual, feedback.

Disclosure and Barring Service Check (if applicable)

Provide a statement declaring that, where the researcher may have access to children or vulnerable adults they have undergone a satisfactory DBS check.

Contact for further information

Insert details here about how to contact you, your supervisor or someone who can advise about the research project. Do not use a personal address, email or telephone number; use an 'official' address or email account and, if you need to give a mobile number purchase a cheap mobile/SIM card and use it only for your research.

What if something goes wrong?

You should provide contact details for any agency which might provide assistance if the participant subsequently wants help or advice. This might be yourself, or in the case of vulnerable participants, a specialist agency.

You should state that in the first instance, participants should contact your supervisor.

You should also provide information in case a participant wishes to complain. The following is accepted text:

If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Practice and Governance Co-ordinator by either writing to 'The Research Practice and Governance Co-ordinator, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester M13 9PL', by emailing: Research-Governance@manchester.ac.uk, or by telephoning 0161 275 7583 or 275 8093

Information Sheets for Children

An information sheet should be designed for the appropriate age range to reflect their comprehension and development, for example:

- Young people 11-15 years;
- Children 6-10 years;
- Children 5 years and under– the value of this is uncertain and written information may be pointless. Parents will clearly have to provide consent. The children will be able to give 'assent', that is, on the day state whether they would like to take part in research activities, or not.

Ideally such material should be shorter than that designed for adults, although the same headings/areas should be used as for the competent adult. It will help if you show your information sheets to some children of similar age to check that they are fit for purpose. ***Consider the child's world.*** It is important to indicate how the study will affect the child at home, school and his/her social activities.

Consent Forms

Consent – why should we seek it?

Research evidence indicates that the public value their right to choose if they wish to participate in research. Participation based on consent contributes to public trust in research.

Consent or Assent

Be clear whether you are you seeking *consent* or *assent*. Consent requires a full explanation of the study. Assent (seeking the child's agreement) requires a clear explanation (comprehensible rather than comprehensive) as consent will be sought from the parent. MIE recommends that usually young people can provide consent, whereas children provide assent.

Documenting the participant's consent with a consent form

Once a participant understands a study and has expressed a willingness to participate, researchers must document the participant's consent with a consent form (and/or appropriate alternative). Including a date with the signature/record of consent avoids confusion about whether the participant began to participate before giving informed consent.

A researcher may need to prepare several consent forms, depending on who the participants are likely to be. For example, a single project may require a form for the guardian or parent of a child to give permission for a child, a consent form for the competent adult subject, and a simplified assent form for the 6 to 10-year-old or for the adult who is not competent to give consent alone. Foreign language versions of consent forms (and/or appropriate alternatives) will be needed if people who do not speak English are to be recruited.

An example consent form is given below.

Project Title

CONSENT FORM

NB Consent forms need to be adapted to the communication needs of the target group. The example assumes no specific difficulties with communication or literacy. Only include statements that are relevant to your research.

If you are happy to participate please complete and sign the consent form below

	Please Initial Box
1. I confirm that I have read the attached information sheet on the above project and have had the opportunity to discuss the information and ask questions. My questions, if any, have been answered satisfactorily.	
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason [and without detriment to my treatment/service] *only required where the researcher provides a 'service' to the potential participant.*	
3. I understand that the interview/observation(s) will be audio/video-recorded	
4. I agree to the use of anonymous quotes.	
5. I agree to my GP being informed of my participation in the study.	
6. I agree that any data collected may be passed to other researchers.	
7. I agree that my data may be published in anonymous form in books or journal articles.	

I agree to take part in the above project

Name of participant	Date	Signature
Name of person taking consent	Date	Signature