

Managing Ethics in Research within the Department of Applied Psychology

Briefing on Informed Consent for Researchers

This draft was produced by RBS and JK in August 2007. It is based on the DoH guidelines on Informed Consent, interleaved with guidelines from an earlier document circulated by RBS (given here in a purple colour.) Thanks to Chris Burns for some insightful comments on the nature of the contract between the researcher and the subject. In the final version I would envisage only the paragraphs highlighted in black would remain: the additional material is for review purposes.

In this document, the DoH guidelines are given in a blue typewriter font (as suits the language in which they are written.)

The versions are interleaved here for purposes of comparison and to facilitate editing. In the final version I'd envisage that only the harmonised paragraphs (in black colour) would remain.

One of the fundamental ethical requirements if you are going to do research with humans is that you must obtain their informed consent. This means that the people you want to involve must understand and agree to be participants. If the people you want to involve are incapable of understanding and agreeing to such an informed consent, their legal representatives or carers must understand and agree for them.

However, it is useful to consider the relationship between an investigator and a participant as a sort of contract. Although the participant should be able to withdraw at any time without negative consequences, if they withdraw prematurely the contract ceases to be. The investigator must take care to mark a time at which the contract is formally closed and inform the participant of this moment during the briefing. After this point, the data belongs to the investigator under the conditions agreed in the *informed consent* briefing.

Some version of this form is a useful companion to the consent form. The idea behind the format is to facilitate informed consent by communicating with the people whom you wish to involve as participants in language that they can understand.

The points are taken from the US Department of Health guidelines for Research with Human Subjects (2005). References and the original wording are given at the end of this document.

Basic Elements of Informed Consent.

1. Background

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

Purpose of the study KISS (Keep It Simple, Stupid): no need to go into the theoretical complexities of the topic.

What will the study involve? Again, give the simplest possible explanation, avoiding jargon and unnecessary detail.

Who has reviewed this study? Department Ethics Committee? Local Hospitals Ethics Committee? Both?

Explain that this is a research study in which the person is invited to participate. Explain the purpose of the study (briefly! no need to go into the theoretical complexities of the topic) and what the person will be expected to do (avoiding jargon and unnecessary detail.) Tell them how long it will take. If you are going to be doing something that has never been done before and you don't know how it will turn out, you should explain this. Every study involving humans must go before an ethical review board, so explain to the person which boards have approved it without overdoing the authoritarian implications!

2. Risks

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

What are the possible disadvantages of taking part? If you think there are none, say so, but not in a black-and-white way (I do not envisage). If they may feel distressed, mention the possibility and refer to the next section.

If participating may occasion risks or discomforts to the person, you should point this out (without overdoing the drama, surely, but also without trivialising the matter.) If you think there are none, say so, but not in a black-and-white way (I do not envisage).

3. Why me?

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

Why have you been asked to take part? Because they are specifically or generally suitable to provide data for your study.

Explain why the person has been invited to take part usually because they are specifically or generally suitable for providing you with data. Also briefly explain any benefits that they or others might get from their participation in the study.

4. Alternatives

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

If your study involves a treatment that might cure or make the person feel better about something that is a problem to them, and there are alternative procedures or treatments, then you must point these out so that the person does not get the idea that this is their only way out.

5. Confidentiality

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

Will my taking part in the study be kept confidential? Yes! (But remember, there's no such thing as absolute confidentiality don't ever make promises you may not be able to keep). Usually the relevant term is anonymity rather than confidentiality.

What will happen to the data? Kept confidential from third parties (including workers' superiors, if relevant); will it be destroyed after a period?

What will happen to the results? i.e. the write-up - seen by whom? If it may be published, say so.

Will the person's taking part in the study be kept confidential? You should try hard to make this so, but remember, there's no such thing as absolute confidentiality don't ever make promises you may not be able to keep. Usually the relevant term is anonymity rather than confidentiality. Explain that all the data will be destroyed at a certain moment (when?) and that no third parties will be allowed to see the data (make sure of this!) Explain as well who will see the write-up, and whether or not you are intending to publish the results.

6. Compensation and Remedies

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

If your research will involve a likely risk to the person, you should make sure that the person knows how they will be compensated for any damage done to them. If there is a danger of physical injury, you should make sure the person knows how this kind of injury is treated medically, how you will assist them in seeking medical help, and where they can get more information about the treatment.

7. Available Help

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

What if there is a problem? Tell them what they can do - contact you? The Samaritans? GP?

Any further queries? Give your name and contact details (but delete the specifics from the copy of the form in your submitted thesis).

Facilitate the person in case there is a problem, later, or they want to ask you something about the study. Explain to the person whom they can contact - you, The Samaritans, other support agencies, their family doctor, etc. and provide complete contact details just in case. It is wise to delete specific details about contact addresses of people (including yourself) from the copy of the consent form you will include in your submitted thesis.

8. Voluntary Participation

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Do you have to take part? The answer is no! Explain about signing a consent form. Ideally they get to keep the information sheet and a copy of the consent form. They should have the option of withdrawing before the study commences, or discontinuing after data collection has started. Where data is identifiable (e.g. from interviews yielding qualitative data), it's useful to allow for afterthoughts by letting them withdraw within two weeks of participation and ask to have their data destroyed.

Does the person have to take part? The basic ethical principle is that participation should always be voluntary, although it may be *remunerated*. Explain to the person about the importance of signing a consent form. Ideally they get to keep the information sheet and a copy of the consent form. They should have the option of withdrawing before the study commences, or discontinuing after data collection has started without it causing a loss or harm to them. It is also useful to agree a time after which the contract between the person and the investigator becomes closed, and the data is at the disposal of the investigator, under the terms of the informed consent agreement.

The issue is a little more complicated if the person is being paid money for participating. If money is being paid, then the informed consent agreement should also have a little more of the character of a contract. The investigator should determine when the person will get paid and seek a receipt for the payment. It makes sense that the contract becomes closed when the money has changed hands.

Source:

[Regulations and Ethical Guidelines for the Protection of Human Subjects](#) (45 CFR 46) Dept. Health and Human Services, 2005. *Please note this link takes you out of these pages; use your browser's BACK button to return.*

Original text:

46.116 General requirements for informed consent. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.