WRITING AN INFORMED CONSENT DOCUMENT

J-PAL RESEARCH RESOURCES

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This is an annotated copy of the official informed-consent checklist found on the website of the Office for Human Research Protections:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html

Annotations in green give some context and instructions.

INFORMED CONSENT CHECKLIST (1998)

§46.116 Informed Consent Checklist - Basic and Additional Elements
These are the elements that need to be communicated to the subject during the consent procedure.

- A statement that the study involves research
- An explanation of the purposes of the research

  Example: "I would like to invite you to participate in a research study on…."
  "Would you like to participate in a research study on…?"
  The **purpose you name should be fairly broad** for two reasons. First, you may want to use the data for other purposes besides the primary study later on, and this use should be covered by the consent form. Second, you don't want to prime your subjects to think about the topics in your study in a certain manner. For example, don't say "I would like to learn how you feel about doctors prescribing medications patients may not need" for a study on over-prescription of malaria drugs.
- The expected duration of the subject's participation

  This often changes after piloting, making an update necessary. If you overstate the duration by a lot, you may lose participants, but understating it can make subjects resentful, so it is **important to get a good estimate** here. Make sure that subjects aren't interviewed for more than 1.5 hours at a time; concentration flags considerably at that point.
- A description of the procedures to be followed

  Use **clear, simple language** and give subjects time to ask questions. A 6th to 8th grade reading level is best, even for fully literate subjects. A lower level of language proficiency should be assumed for populations who are not interviewed in their first language (often the case in former colonies).
- Identification of any procedures which are experimental

  This refers to medical research.
- A description of any reasonably foreseeable risks or discomforts to the subject

  It is important to be **clear and accurate**, but also **not to overstate risks**. Most surveys and lab-in-the-field experiments don't involve more than minimal and everyday risk, and only minor discomfort. The statement in the consent form must match the risks you describe in the IRB application.
- A description of any benefits to the subject or to others which may reasonably be expected from the research

  Compensation to the subjects for their time **does not count as "benefits"**. You may write, "besides [this compensation], there are no benefits to you from participating in the study."

  While research results can in the widest sense lead to better outcomes for those studied, it's **important to be accurate** here as well – it would be unethical, and might hurt the reputation of research and researchers to promise things that do not

happen, even unintentionally (e.g. "this research will help the government improve the situation of the poor"). It could be accurate to say that this research *may* help design policies that lead to improvements.

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

  Again, this mostly refers to medical research, but could be applicable to interventions being offered to subjects in an "intent to treat" type setting (for example, subjects might be given vouchers for a benefit provided by an NGO, but might also have the right to a similar benefit provided by their government).

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

  This one is really important. Note that J-PAL research protocols typically require that
  (a) all personal data **is encrypted and password protected**,
  (b) all **personal data is removed** from the data set before using it for analysis, and
  (c) the data is **published** in de-identified form.

  The language used in the consent form needs to make sure to explain point (a), and the handling of the data must be described so that it allows for (c). For example, the consent form should *not* say, "no one but the research team will be able to access the information you give us".

  Regarding the **language** to use, you may say

  - "After this survey ends, we will remove your name and personal details from the interview records, so they cannot be linked back to your person. Until your personal details are removed, the interview answers will be encrypted and kept on a password-protected computer", or
  - "Your personal information will never be shared with other researchers or the public"

  (note that I would avoid the use of the word "data").

  The consent form should *not* say that the data will be "anonymized", because in many cases a few variables and a location identify a person pretty much uniquely (e.g. gender, birthdate, number of children in a village). This means if someone is seriously looking to match the survey information with a person, it may be possible to do so.

  You should also not say that "no one but the research team" will be able to access the subject's personal information, because **US federal agencies *can* audit your project** and also see the data. In fact, IRB's will often ask for a statement that refers to federal agencies or officials.

  In an international context, of course you need to use language that makes clear which government you mean. More generally, it is actually a little tricky to explain the situation here. In some countries, people are quite suspicious of their governments, and suggesting that any government bodies might look at their data may deter them.

  You may choose to include in your study protocols that you will **destroy the personal information** of your subjects entirely, and then you can say that in your consent form, as well. This is not the recommended thing to do – for example, if an adverse event occurs later, you may want to have the contact information for your subjects – but in some countries and for some types of surveys, it might be the best option. Think for example of a non-democratic country and a survey on political attitudes.

  Another option is the one above, **only stating explicitly who *cannot* see the data**. This option seems acceptable if it does not put subjects at any risk, and you genuinely believe that the mention of the US federal government will only bewilder or frighten them without adding to their understanding of the study procedures.

  Please note, however, that you should *always* include this information explicitly in any context where the subjects are **even remotely at risk of criminal prosecution**. The reason is that federal agencies can subpoena data, and have done so in the past, if it helps them or the governments of other countries in criminal investigations. A famous case in 2011 was the subpoena of interviews with IRA members conducted by Boston College researchers, on behalf of the British government (see the New York Times article here).

  An important last point is that you as the research need to make sure that the data protection procedures you are promising to your subjects are actually in place. Oftentimes, study procedures, circumstances, and personnel on a research project change considerably over time. As a result, sometimes the procedures described in the consent form are not actually accurate (e.g. the new RA does not have an encrypted computer, or doesn't know about the need to de-identify the data, and so on).

It is recommended to **reread the consent form just before the data collection starts**, and make sure that all the statements in it are still accurate. It is useful to put oneself in the shoes of a subject, and think about how one would like someone else to treat one's personal data.

- 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

  Again, the most important thing here is to actually **have the procedures in place** that are being promised. For example, if the consent form says that a child can get treatment at a local clinic if a puncture wound from a malaria test gets infected, the researchers need to make sure that this is actually true and that the family can reach someone from the research team if they require care.

- Research, Rights or Injury: 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

  Typically, this is the **local contact info of a PI or research manager**, and a contact for the relevant IRB (illogically, some US IRBs insist on putting a US phone number, which typical subjects in developing countries can *de facto* not call, or won't call. In this case, it is best to provide a local contact even if the IRB does not require it).

- 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

  This is self-explanatory; again, the most important duty of the research team is to make sure that it is actually true. The **surveyors need to be trained** well, so they know that they should not pressure, bribe, trick, or cajole subjects in any way. Surveyor incentives should not rely heavily on rewarding completed questionnaires. Moreover, the survey question design always **needs to allow for the option to refuse an answer**.

Additional Elements as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

  This again applies mostly to medical procedures.

- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

  For reasons of selection bias, you should not normally exclude subjects from the study unless there are very compelling reasons to do so, and these reasons should be explained.

- Any additional costs to the subject that may result from participation in the research

  Normally, you as the researcher should make sure that such costs do not occur. If they do, you should try and make sure that your subjects are compensated sufficiently so that they do not on net end up paying.

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

  Ideally, these procedures are minimal (again, this could be more of an issue in medical research).

- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject

  This is again mostly needed for medical research, but you should think through what a subject might want to learn about the research results. It might apply for example if you conduct any medical testing, or if you find large intervention effects of a treatment that you designed and implemented.

- The approximate number of subjects involved in the study

  This is only necessary if that information might affect how the subject feels about the study.

§46.117 DOCUMENTATION OF INFORMED CONSENT CHECKLIST

a. Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Written

The consent form may be either of the following:

1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

Done Orally

2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

In some special situations, this procedure could have advantages over the standard informed consent. Examples could be if you are consenting subjects on the street in the cold, if your subjects have trouble reading, or if they are in a rush, say, before a doctor visit. In such situations, you might consent someone into a study orally. They would only have to sign a slip of paper that says "I was explained the study procedure and all my questions were answered" or similar, without having to read additional text. The full consent text is handed to them on a separate sheet of paper.

Note that this procedure can be **helpful in situations where the subject is distrustful** of signing long documents. Even subjects who have low levels of literacy may be able to read a one-sentence consent slip, and happy to accept a written copy (without a signature from them) that explains the study in more detail.

Waiver of Requirement for Signed Form

c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

Note that this requires that no identifying data is in the data. This is typically the case for example for lab experiments, and in certain types of polls, for example exit polls at voting stations.

2. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

IRB LATITUDE TO APPROVE A CONSENT PROCEDURE THAT ALTERS OR WAIVES SOME OR ALL OF THE ELEMENTS OF CONSENT

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- C: 1.The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for

obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

- C: 2.The research could not practicably be carried out without the waiver or alteration.
- D: 1. The research involves no more than minimal risk to the subjects;
- D: 2.The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- D: 3.The research could not practicably be carried out without the waiver or alteration; and
- D: 4.Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

It is important to know what types of waivers an IRB accepts. For example, Tufts University's IRB allows a **waiver of signed consent for cultural reasons**, and this includes a distrust of authorities. Tufts IRB has previously approved a waiver of consent for research in South African townships, where subjects were extremely reluctant to sign consent forms, even if they stated to be happy to participate in the survey. This was for a study that involved electricity provision by the City of Cape Town.

SPECIAL REQUIREMENTS - 45 CFR 46 SUBPART D - ADDITIONAL DHHS PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECTS IN RESEARCH

Assent/Waiver

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.

IRBs typically require assent from children starting at around age 6 or 7 for procedures where an enumerator or other research team member directly interacts with or even touches the child, for example in order to take anthropometric measurements or conduct a medical test.

Parents

- The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405.

  Research with no greater than minimal risk, or greater than minimal risk but benefits that outweigh the risks.
- Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

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