

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 6
Title: Informed Consent process	Date Effective 9-16-04	Supercedes P&P dated

Preparing a Written Consent Form or a Short Form Written Summary of What Will Be Said to Subjects

Use the [CHR Consent Form Template](#) to organize the following paragraph headings. Suggested language is provided under some headings.

Title of research project:

Provide the title of the project, the name of the Principal Investigator and the CHR project number.

Introduction:

- Explain that this is a research project.

“This consent form explains the research study you are being asked to join. Please review this form carefully and ask any questions about the study before you agree to join. You may also ask questions at any time after joining the study.”

- Explain that JHSPH (and any collaborating institutions) is/are conducting the research.
- Identify the financial sponsor of the study (e.g. NIH, name of company).

Purpose of this research project

- Explain the purpose of the research project, the goal of the study and why it is important.
- Explain why and how the subject was selected for the study and inform him/her why he/she is being asked to participate in the study.

e.g. “You are being asked to be in this study because you are an injection drug user at risk of HIV infection.”

- Indicate how many total subjects will be included in study. If this is a multi-site study, state how many subjects will be enrolled at this site and at all sites.

Procedures:

- Explain who is eligible for study and who is not; i.e. the inclusion and exclusion criteria. This may have been covered with the subject during the recruitment process, but should be reiterated here.
- State the procedures to be used if the subject agrees to participate in the study. It is often helpful to provide the subject with a visit-by-visit list of what to expect while enrolled.

e.g. "At the first visit you will be asked to complete a survey and provide a blood sample, etc".

- State which procedures are experimental and will be done solely for research purposes, and which are innovative in the project.
- For studies involving clinical procedures, briefly explain the study design; describe the examinations and tests in which the subject will participate (e.g. for blood draws specify the number and the amount of blood to be drawn in household measures such a teaspoon, cup, etc; for multiple blood draws indicate the total amount to be drawn and compare to the amount routinely taken from blood donors, e.g. 1 pint or 2 cups).

Specify the approximate total duration of the subject's time to participate, approximate time required for each activity, and any plans to contact the subject more than once or for possible follow-up studies. If you plan to keep subjects names and addresses on file to facilitate recruitment for future studies (other than follow-up for this particular study) you should notify the subject of your plans and allow the subject to choose not to be notified about studies in the future if that is their wish.

If the study involves a survey, describe the type of information to be collected; specify if the questions are personal or of a sensitive nature (e.g. personal finances, psychological or emotional experiences, sexual habits, marital and/or family situations, domestic violence, alcohol or illegal drug use, etc.). If you are asking subjects to provide *personal, identifiable* information about a family member you will need to get consent from the family member. See information above about secondary subjects.

- If the study involves different treatment groups, explain how the treatments or interventions will be assigned. If treatment assignments are determined by randomization, the process should be described for subjects; i.e. by drawing a card or number, or by flipping a coin.
- If the study requires review of the subject's medical records, the subject must provide either a completed [HIPPA authorization](#) (for domestic studies) or a [Medical Records Release Form](#) (for international studies).

Risks and discomforts:

- Describe all major and minor risks (physical, psychological, social) and their anticipated frequency, for example:

*Physical risks: side effects of the intervention under study;
 bruising due to blood draws;
 exposure to radiation;
 physical discomfort involved during an MRI*

*Psychological risks: discussing personal sensitive information;
knowledge to be gained as result of genetic testing*

*Social risks: disclosure of sensitive personal information to those
outside the study (e.g. genetic test, HIV test);
disclosure of information about illegal activities to those
outside study (e.g., illicit drug use)*

- Describe other study-related burdens, such as the time required of the subject or other inconveniences.
- If the study includes medical interventions, blood draws, and/or exposure to radiation, state that the subject should not participate in other studies while enrolled and explain why (e.g. risk of intervention interactions, risk to integrity of the study, etc.).
- If relevant, indicate that the intervention or procedure may involve physical risks to the subject (or embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
- If relevant, discuss the potential for community harm (e.g. results of the study may lead to discrimination directed at a particular group or reinforce stereotypes about behavior of a particular group).

Anticipated benefits:

- State potential benefits of participation for the subject. *Do not overstate benefits - Be realistic.*

If a subject will not benefit from participation, clearly state so.

Examples of potential benefits include: access to an intervention under study that may result in direct medical benefit, access to personal medical information generated by the study, or the opportunity to discuss issues under investigation.

- State the possible general benefit for science or for other subjects with similar diseases or for the population at large, if applicable.

Alternatives to participation: *(May be omitted for observational studies, intervention studies on healthy subjects, or if an alternative treatment or service is not available outside the research.)*

- Explain realistic alternatives to participation; specifically, state what treatment will be offered or recommended if the subject declines to participate (e.g. medication under study is unavailable outside of the study, but standard of care is available off protocol).

Additional costs

- Describe any actual costs to the subject that will be repaid, such as the cost of transportation to the study site.

- Describe any financial costs that the subject and/or the subject's health insurer will be responsible for as a result of enrollment (e.g. in some cases health insurers refuse to cover costs related to enrollment in an experimental trial).

Sharing of new findings:

- Explain that any new findings reported during the study and that might affect the subject's willingness to remain in the trial, for example a new treatment for the subject's condition, will be shared immediately with the subject.

"The investigators (or doctors) will share with you any new findings that may develop while you are participating in this study and that might benefit you."

Confidentiality:

Describe the procedures for protecting the confidentiality of the information collected from the subject.

- Indicate how data will be labeled and stored. Avoid using names as much as possible (e.g. use unique identifiers to label all study materials and store the list that links unique identifiers to names separately from other study materials. Indicate how data will be stored (e.g. in locked file drawer or in a password protected computer) and how long linked data and all data will be stored (e.g. until completion of follow-up data collection or until study data have been analyzed and reported).

If you are collecting audiotapes or videotapes, indicate how and when they will be destroyed and how confidentiality will be protected in transcribed information (e.g. all names will be redacted from the transcript).

- Specify who will have access to the data. It is suggested that you include the following language in all consent forms, except where subjects are strictly anonymous (e.g. you will not be collecting names or any other personal identifiers):

"Every effort will be made to protect the confidentiality of the information provided insofar as it is legally possible".

There are limits as to what information investigators can promise to keep confidential. If relevant, subjects need to be informed that certain communicable diseases, and evidence of child abuse or evidence that the subject may harm himself or herself, or others, will be reported to appropriate authorities as required by law. See [Reportable Diseases and Conditions](#).

Subjects must be informed that information provided about, or observations of, child abuse will be reported by name.

If there is reason to suspect that the data may be of interest in a legal proceeding, the references to what is "*legally possible*" should be amplified. If a Certificate of Confidentiality has been issued to protect the data from subpoena, include this information in the consent form. See [Certificate of Confidentiality](#).

Subjects should know that in some cases study sponsors (e.g. NIH or the sponsoring company) or regulators (e.g. FDA), as well as the CHR and OHRP, will have access to information collected during the study.

Suggested language: *“Under certain conditions, people in charge of making sure that the research is done properly may review your study records. This might include people from [institution(s) e.g. NIH, sponsoring company], the JHSPH Committees on Human Research or the Federal Office for Human Research Protections and the Food and Drug Administration. All of these people are also required to keep your identity confidential.*

Payments (incentives) for participating

- If payment is given to subjects for participation it must not be coercive in amount or in the way in which it is distributed. Payment is considered an incentive; it is not a benefit. See [Payments to Research Subjects](#).
- Outline the amount, schedule and procedures for any payments, including any penalties for failure to complete the study or bonuses for completion as planned.
- If relevant, describe free medical tests that will be conducted.
- Provision of free medical care should not be viewed as a benefit to be gained from the research, but should be included as an incentive to participate.

Voluntariness:

- Explain that participation in the study is entirely voluntary.

Suggested language: *“Your participation in this research project is completely voluntary. You have the right to withdraw from the research study at any time.”*

- In some cases investigators may request that subjects who want to withdraw complete a final assessment. Subjects should be made aware that completion of a final assessment is voluntary.
- Subjects who are asked to complete surveys or interviews should be reminded that they can refuse to answer any particular questions asked and can stop the interview at any time.
- Explain that not joining the study, or withdrawing from the study at any time, will not jeopardize job or medical care already available (if applicable) (e.g. if you are enrolling patients who receive care at the clinic hosting study or if you are conducting the research with individuals employed by the host clinic).

Suggested language: *“If you decide not to be in the study, or if you drop out of the study, you will still get the same medical care at [name of institution/clinic].” AND/OR “If you decide not to be in the study, or if you drop out of the study, your decision will not affect your job at [name of employer].”*

- If pregnancy is an exclusion criterion for enrollment, describe what will happen if the subject should become pregnant while enrolled.

Involuntary termination of subject participation

- If relevant, indicate the circumstances under which the subject may be withdrawn from the study; e.g. if the study is cancelled by sponsor, if enrollment is no longer in the best medical interest of subject, or the subject fails to follow the study procedures.

Persons to contact:

- For questions about the research: List the name and telephone number of the person in charge of the study. For *international studies*, a local name and phone number should be included.

Suggested language: *“You should ask the person in charge of this study, listed below, any questions you may have about this research study. You should also ask him/her questions in the future if you do not understand something about the study.”*

- For questions regarding individual’s rights as a research subject: List the name and telephone number of the CHR and other local oversight bodies, if applicable. For *international studies*, list the local IRB and phone number as well as the CHR and its number.

Suggested language: *“If you want to talk to anyone about this research study because you feel you have not been treated fairly or have been hurt by being in the study, you should call the person in charge, [name of PI], at [phone number], or call the Johns Hopkins School of Public Health Office for Research Subjects at 1-888-262-3242/FAX (410) 502-0584. The person in charge of the study or the people in the Office for Research Subjects will answer your questions”. If relevant you may add: “and/or help you to find medical care if you are hurt during the study”.*

Compensation for injury

- Whenever a project involves a procedure that may result in an injury to the participant, the prospective subject should be advised as to the availability or non-availability of medical treatment or compensation and who will be responsible for the costs of treatment.

Suggested language: *“The Johns Hopkins School of Public Health, the Johns Hopkins Hospital and the Federal Government do not have any program to provide compensation to you if you should experience injury or other bad effects that are not the fault of the investigators.”*

- Injury is not limited to physical injury. Investigators should also consider psychological, social, legal or financial risks.
- Minimal risk and/or survey research may dispense with the compensation clause.