

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Informed Consent process	Date Effective 11-23-04	Supercedes P&P dated 9-16-04

Tips for Developing Written Consent Forms

General guidance

Informed consent is a process, not just a form. Enough information must be presented to potential subjects to allow them to make an informed decision about whether to enroll in the study.

Format, style and reading level

Consent forms for research projects must be typed. If continuation pages are necessary, the explanation may be continued on a plain sheet of paper. Additional pages should be clearly numbered and should contain at the top of the page(s): the title of the project, the typed name of the principal investigator, and the date of the most recent draft and/or most recent revision.

In the interest of simplicity, use separate consent forms for subject subgroups (e.g. adult consent, parental permission for a child, etc.).

The explanation of the study should be written as if the investigator were speaking to the subject. *Avoid use of the first person.* It is preferable to have the explanation written in second or third person in language appropriate to the reading level of the study population.

In 1993, the National Adult Literacy Study (NALS) reported that approximately one-half of the American population is functionally illiterate or have marginal literacy skills. The NALS estimates that the “average” American reads at or below the 8th grade level. The NALS also found that people were reluctant to admit that they had reading difficulties.

The Federal regulations require that information presented in the consent form be in a language understandable (readable) by the subject or the subject’s legally authorized representative. To meet this requirement, the CHR adopted the NALS estimate as the standard reading level for all consent forms.

CHR requires that consent documents be written at no more than an 8th grade reading level, and lower if required for the population being studied. You should search the help section of your word processor to find information about using readability statistics.

Things Investigators Often Overlook

1. *Multiple enrollment warning:* If medical intervention, blood draws, and/or exposure to radiation are included in the protocol, there should be a statement that the subject should not participate in other studies while enrolled and an explanation as to why this is important (e.g. risk of intervention interactions, risk to integrity of the study)
2. *Communicable disease testing:* Based on Maryland reporting requirements, if subjects will be tested for a communicable disease, subjects and their partners, if appropriate, should be informed of the way in which their disease will be reported (i.e., with a unique identifier or by name). See [Reportable Diseases and Conditions](#).
3. *Pregnancy provisions:* If pregnancy is an exclusion criterion for enrollment, include a statement regarding what happens if a female subject should become pregnant while enrolled.
4. *Compensation not a benefit:* Compensation for time and inconvenience should not be listed as a benefit of enrollment; list these under a separate heading as “compensation”.
5. *Sensitive questions:* If sensitive questions will be asked, the general topics to be covered should be stated; e.g. sexual practices, alcohol/drug use, domestic violence.
6. *Local contact:* If this is an international study, provide local contact information (name and phone number(s)).
7. *Tissue storage for future research:* If subjects are asked to provide consent for long term storage of tissue samples for future research (unrelated to the research question covered by the original proposal), include a statement as to whether subject consent to storage is required for study enrollment and/or provide subjects with the option to refuse storage of tissue for future use (e.g. a check box). Also provide a separate [Consent to Collect Specimens for Future Research](#). See also [Storage of Biological Samples](#) and [Sample Repositories](#).
8. *Data handling:* Information on how data will be stored (e.g. in locked file cabinets, in a password-protected computer), how long data will remain linked to subject identifiers (e.g. only until data collection has been completed), and if/when data will be destroyed (e.g. when the study is completed and reported, after 5 years, etc.).
9. *Access to data:* Provide a statement describing who may have access to a subject’s study record.
10. *Length of interaction:* If an interview/survey is included, state the length of time the interview/survey is expected to last. For example, “We would like to ask you some questions about your health. This will take about 15 or 20 minutes.”
11. *Urine tests:* If urine will be tested, state the purpose of test (e.g. to detect drug use).
12. *Reasons for termination:* State the conditions, if any, for which the investigator will terminate a subject’s participation in the study.
13. *Faculty affiliation:* State the affiliation of faculty involved in study: Johns Hopkins Bloomberg School of Public Health. If this is an international study, add that JHSPH is in the USA. Also provide the affiliation for any non-JHSPH investigators..

14. *New drug*: If relevant, state that this is the first trial in which the drug being studied will be tested in humans.

Improving Understanding:

1. Know your target audience.
2. Lower the reading level.
3. Use simple language whenever possible; limit medical terms and explain those that are used. Information on the following websites can be helpful when writing consent forms:
 - Glossary of Medical Lay Terms:
<http://ovcr.ucdavis.edu/HumanSubjects/HSEDefinitions/HSGlossary.cfm>
 - Medical Dictionary: <http://www.medterms.com/Script/Main/hp.asp>
 - Glossary of Plain Non-Medical Language:
<http://www.plainlanguage.gov/library/smpl1.htm>
4. Avoid legal terminology.
5. Avoid polysyllabic words. *Examples: Use “take part in” instead of “participate;” use “needed” instead of “clinically indicated.”*
6. Write short, simple sentences of varied length.
7. Describe the procedures in a logical, organized manner.
8. Use at least a 12-point font (consider using a larger font based upon your audience.)
9. Use visual aids, charts, diagrams or pictures to describe complicated or detailed procedures.
10. Use a 50/50 blend of white space in documents and charts.
11. Be consistent in the terminology and define technical words if they cannot be replaced with simpler ones.
12. Use headers to display new information and use interactive techniques, such as leaving a space for questions, etc.
13. Test the consent form with your targeted audience.

Exculpatory language

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject’s legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Examples of exculpatory language:

1. *By agreeing to this use, you should understand that you will give up all claims to personal benefit from commercial or other use of these substances.*
2. *I voluntarily and freely donate any and all blood, urine and tissue samples to the U.S. Government and hereby relinquish all right, title and interest to said items.*
3. *By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.*
4. *I waive any possibility of compensation for injuries that I may receive as a result of participation in this research*

Examples of acceptable language:

1. *Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. We will not provide financial compensation to you should this occur.*
2. *By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.*
3. *This hospital (or JHSPH) is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.*
4. *This hospital (or JHSPH) makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.*

A Subject's View (To Be Added)