

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

Tests of Understanding

Prospective research subjects have the right to be fully informed about the research in which they are being invited to take part. Information about a study is provided before and/or during the consent process and usually includes a description of the purpose of the study, study procedures, the benefits and risks of participation, and ways in which the rights and welfare of research subjects will be protected.

Although this information is clearly described either in writing or verbally, it cannot be assumed that prospective subjects have sufficient understanding to provide fully *informed* consent, especially when the information is unfamiliar or technically complex. In such instances it is important to confirm that understanding is adequate *before* the subject agrees and the consent is signed.

Simply asking whether the subject understands is not sufficient. Rather, understanding must be confirmed by asking questions about the research that the subject answers correctly. For studies that are not technically complex, this may be done verbally using a standard set of questions. However, for studies that are complex or require understanding of a large amount of information, a written test of understanding is usually better. This not only assures a uniform process for assessing understanding, but provides a written record that becomes part of the subject's file. CHR reviews tests of understanding as part of its research review process.

A test of understanding is a tool that can strengthen the consent process. It should be based on the various elements of the consent form, and will usually cover at least the following items:

- The purpose of study
- Any treatment to be given
- The benefits of participation
- Risks of participation
- Alternatives to participating
- Provisions to ensure confidentiality
- The right to withdraw from the study
- Who pays for medical expenses
- Any questions for the researchers

Tests may be given verbally or in writing. Verbal scripts and written tests should be provided to CHR for review.

Verbal tests

Verbal tests should be based on a written script to ensure that the same process is followed with each subject. Questions should be designed to determine whether the subject *understands* key elements of the information that has been given to them. The best questions are those that are open-ended and ask “what”, “why”, “when”, “where” or “how”. For example:

- *Why were you asked to take part in this study?*
- *What treatment will you be given if you join this study?*
- *What will happen if you decide you no longer want to be in the study?*
- *Who should you contact if you have any questions?*

When a subject’s answer is unclear, follow-up questions should be asked to determine whether his or her understanding is correct.

Questions that are answered by “yes” or “no” are less helpful because they provide no information on the subject’s level of understanding and the subject may guess the correct answer. Asking a subject “Do you understand?” provides no useful information; the subject is likely to answer “yes” even when he or she does not understand.

Written tests

Written tests provide a permanent record of a subject’s understanding, but are generally less flexible in format than verbal tests, especially because it is not possible to ask follow-up questions to confirm understanding. Written tests are usually based on multiple choice or true/false questions, or on questions that can be answered in one or two words. Subjects are required to answer correctly a predetermined percent of the questions, for example 75%.

Feedback

A test of understanding, whether verbal or written, provides an important opportunity to improve a subject’s understanding of the planned research. This is done by providing the correct answer, and explaining why it is correct, when a subject has answered a question incorrectly, and by encouraging the subject to ask any questions that may have arisen while taking the test.

[*A Sample Test of Understanding*](#) is available.