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|  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 |

Consent for Clinical Procedures and Other Services that Represent Standard of Care

Many research protocols describe procedures that represent either clinical care of the subject or standard of care or practice. In such situations, it may not be clear what disclosure and consent requirements apply. The following guidelines are intended to clarify what must be included in the consent process in general, and in the consent form in particular, for a given situation.

Guidelines

In producing these guidelines, CHR has distinguished between:

1. Clinical procedures that a research subject undergoes as part of routine clinical care and would receive if he or she were not a research subject.
2. Clinical procedures provided by the research protocol in order to ensure that research subjects receive clinical care that meets the standard of care or practice.
3. Clinical procedures provided by the research protocol that a research subject undergoes solely for research purposes, but that are standard of care or practice.

The investigator's obligation to convey information on risk associated with standard of care procedures is lower than the information required for experimental procedures. The level of information required depends on the context in which standard of care procedures are provided. In general, the information on risks associated with standard of care should not dissuade participants from accepting the benefits of standard therapies or procedures just because such procedures are being delivered in the context of a research study. This could potentially deprive subjects of possible benefits, relative to persons securing such services in a non-research setting.

Requirements for the Consent Process

1. If a procedure is done *solely for clinical care and not for research* and is the standard of care or practice, and the results from the procedure will not be used in the research, then the procedure itself is not part of the research protocol and the consent form need not describe the procedure. However, if the results of the procedure will be used in the research, then the consent process must seek permission to use the results, and the Risks section of the consent form must contain a disclosure of the possibility and consequences of breach of confidentiality of the procedure results.

2. If a procedure is *provided by the research protocol in order that the subject receives appropriate clinical care* or standard of care or practice, the consent process must contain the information on risks and benefits normally communicated to patients receiving such procedures or care in a non-research setting. This information can be provided during the consent process in either the research consent form or in a separate clinical consent form for the service or procedure, if the latter is standard practice. Of importance, in the context of these requirements, the CHR defines standard of care or practice as procedures or services that are the standard of care in either the United States or in the country where the research is being conducted.
3. If a procedure or service is done *solely for research purposes*, the consent form must contain a comprehensive description of the procedure and its risks, similar to the description of research procedures.