

 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

Waiver or Alteration of the Required Elements

Exceptions to the written consent requirement are provided in the Federal regulations. With the important exception of FDA-regulated research, CHR has the authority to:

- waive or alter some or all of the elements of the written or summary consent;
- waive the requirement to obtain a signed consent or signed short form consent for some or all of the subjects; or
- waive the requirement to obtain consent.

If a waiver or alteration of the consent requirement is requested, justification for the request must be provided with the CHR research application. When the CHR approves a procedure that waives or alters the consent requirement, it will document that the study met the requirements for the waiver or alteration. When consent is obtained without a written document, evidence of verbal disclosure must be in each participant's record.

CHR *may* approve a procedure that waives or alters some or all of the elements of informed consent, or grant a waiver for obtaining consent, under either of the following conditions:

1. For public benefit or service programs, provided that the CHR finds and documents that the research or demonstration project will be conducted by, or subject to, the approval of State or local government officials and is designed to study, evaluate or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs, and the research could not practically be carried out without the waiver or alteration. Note that public benefit programs are narrowly defined in the Federal regulations and are generally under the Social Security Act.
2. For minimal risk research, provided that CHR finds and documents that the research involves no more than minimal risk to the subjects and:
 - the waiver or alteration will not adversely affect the rights or welfare of the subjects; and
 - the research could not practicably be carried out without the waiver or alteration; and
 - when appropriate, the subjects will be provided with additional pertinent information after participation.

CHR *may* also grant a waiver from obtaining a signed consent for some or all of the subjects if it finds and documents that:

- the only record linking the subject to the research would be the consent document and the principal risk of retaining this link would be a breach of confidentiality; in this case, each subject will be asked whether he or she wants documentation linking the subject with the research and the subject's wishes will govern; or
- the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research.

The CHR may require that an investigator gives research subjects a written statement about the research, even though it has approved a waiver or alteration. Additionally, Federal, State or local laws may require that certain information be disclosed to subjects in order for consent to be legally effective, for example the process for reporting certain communicable diseases as required by State laws.

Waiving consent without the formal approval of CHR is a violation of Federal regulations and of this policy.