

SOP: IC 702 Version No: Effective Date: 01/01/07	EXCEPTIONS FROM GENERAL CONSENT REQUIREMENTS	Supercedes Document Dated:
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1. POLICY

The IRB recognizes that there may be exemptions to requirements for informed consent and/or documentation. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (such as written documentation). The IRB may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria.

Specific Policies

1.1 IRB Waives One or More Requirements of Informed Consent

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (see SOP IC 701), or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to 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
2. The research could not practicably be carried out without the waiver or alteration, as in prospective emergency research conducted under 21 CFR 50.24.
Or that:
 - a) The research involves no more than minimal risk to the subjects;
 - b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - c) Whenever appropriate, the subjects will be provided with additional pertinent information after participation; and
 - d) The research could not practicably be carried out without the waiver or alteration.
3. The protocol demonstrates that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;

Note: When the IRB waives the requirement for documentation under this condition, each subject must be asked whether the subject wants

documentation linking the subject with the research, and the subject's wishes will govern.

1.2 An Emergency Situation Prior to IRB Review and Approval

Obtaining informed consent shall be deemed feasible except in certain emergency situations where the investigator has adequately documents the necessary exception under the guidelines described in 21 CFR 50.23 and 45 CFR 46.116, and in SOP SC 502, section 1.3.

Time was not sufficient to obtain consent from the subject or the subject's legally authorized representative. The subject or subject's legally authorized representative may receive a written statement regarding the research.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

IRB Chairperson (or designee) is responsible for determining whether informed consent exemptions are applicable and appropriate and for follow-up with Investigators as indicated from the exemption assessment.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24

21 CFR56.109(c), 56.109(d)

45 CFR 116

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

IC 702-A Waiver of Alteration of Informed Consent - 45 CFR 46.116(d) Decision Chart

7. PROCESS OVERVIEW

Investigators requesting a Waiver of Informed Consent shall indicate this request in the application of the study. The IRB will make a decision during the regular review of the protocol whether this waiver is appropriate. If of minimal risk, the study can be expedited by the IRB Chairperson (or designee). In emergency studies, the Investigator will attempt to get Informed Consent from the subject or the subject's legally authorized representative prior to treatment. However, if time is of the essence, an attempt to obtain Informed Consent may be made after initiating the emergency treatment. Nothing in this SOP is intended to limit the authority of the physician to provide emergency medical care to the extent the physician is permitted to do so under applicable law.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator or IRB Coordinator</i>	Review submission to determine if waiver is requested. If so, indicate on the IRB Agenda that waiver is requested. Record decision in the IRB Minutes.	Waiver or Alteration of Informed Consent under 45 CFR 46.116(d) Decision Chart