Title: WAIVER OF INFORMED CONSENT

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to provide guidance on obtaining a waiver of informed consent; and requesting approval for exception from informed consent in emergency research from the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:
The SU IRB does not grant waivers of informed consent in emergency situations.

Generally, the IRB must assure that provisions are made to document informed consent in writing from each research participant or the participant's legally authorized representative. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either of the following:

2.1 The principle risks are those associated with a breach of confidentiality concerning the subject's participation in the research; AND the consent document is the only record linking the subject with the research; AND each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; OR

2.2 That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Examples of studies in which the IRB may grant a waiver under this condition include naturalistic research in which the investigator interacts with participants in an informal manner (e.g., participant observation or ethnography, open-ended conversational interviewing, free-flowing focus groups) and surveys collecting information of a non-sensitive nature (the survey itself should state that completing it is voluntary and submission of the completed survey in person, by mail, or via e-mail is an indication of consent). The IRB also recognizes that in some cultures it is inappropriate or offensive to ask persons to sign a formal document involving their rights and interests and will take this into account in making determinations regarding informed consent in different cultures.

Generally, the IRB must assure that provisions are made to obtain legally effective informed consent prospectively from each research participant or the participant's legally authorized representative. The IRB may waive the requirement for the investigator to obtain the informed consent from some or all participants if it finds either of the following:

2.3 That the IRB finds and documents that:

2.3.1 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:

2.3.1.1 Public benefit or service programs;

2.3.1.2 Procedures for obtaining benefits or services under those programs;

2.3.1.3 Possible changes in or alternatives to those programs or procedures; or

2.3.1.4 Possible changes in methods or levels of payment for benefits or services under those programs; and

2.3.2 The research could not practicably be carried out without the waiver or alteration.

2.4 That the research involves no more than minimal risk to the participant; and

2.4.1 The waiver or alteration will not adversely affect the rights and welfare of the participants; and

2.4.2 The research could not practicably be carried out without the waiver or alteration; and

2.4.3 Whenever appropriate, the participants will be provided with additional pertinent information after participation.

When the IRB waives documentation of the written informed consent form, investigators must submit a script of what will be said to participants and must document participants' consent in a log or other written form (e.g., interview transcript or field notes). Such documentation of consent shall be available to the IRB for review.

Investigators desiring to not have a signed consent form must still provide participants with a consent document disclosing all the required elements necessary for informed consent. In such cases, the IRB encourages investigators to use the consent templates and remove the signature section.

Informed consent procedures, which provide for other than legally authorized and prospectively obtained consent, fail to constitute informed consent under Federal regulations for the protection of human subjects in research. Therefore, waiving informed consent using a method other than those described in this policy is a violation of IRB policy and Federal regulations and is subject to reporting to the appropriate Federal, State, and Institutional officials.

3.0 References and Reference Documents:

45 CFR 46
45 CFR 46.116
45 CFR 46.117
SOP 012, IRB Review of Human Subjects Research-Expedited
SOP 013, IRB Review of Human Subjects Research-Full Board
SOP 016, Legally Effective and Prospectively Obtained Informed Consent

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 The Investigator will assess the proposed research to determine if it meets regulatory requirements for a waiver of informed consent.

4.1.2 The Investigator will complete and submit for review the "Request for Wavier or Alteration of Consent."

4.2 IRB Committee Responsibilities.

4.2.1 The IRB Reviewers will consider the request for a wavier of informed consent and the Investigator's justification verifying and documenting that regulatory conditions are applicable to the proposed research activity.

4.2.2 If the IRB Reviewers agree with the Investigator's justification and documentation for waiver or alternation of the consent process, they will document on the Review of Research Checklist that they agreed with the Investigator's justifications.

4.2.3 If the IRB Reviewers do not agree with the Investigator's justification, but agree for other reasons that waiver or alteration of the consent process is allowable and appropriate, they must document on the Reviewer's Comment Form, their own protocol specific findings that justify the waiver or alteration of consent.

4.2.4 If the IRB reviewers do not agree that waiver or alteration of the consent process is allowable and appropriate, they will document such on the Review of Research Checklist.

4.2.5 When amendments are made to a currently approved research study, the waiver of informed consent is reassessed by the IRB Committee, Chairperson or his or her

designee, and a determination made as to whether the conditions for the waiver have been altered, necessitating the rescinding of the waiver. If this occurs, the IRB also determines whether currently enrolled participants must be re-consented by the Investigator.

4.3 ORIP/IRB Administrator Responsibilities.

4.3.1 The ORIP/IRB Administrator will forward the study and informed consent documents for review by the appropriate process (Expedited or IRB Committee review (*SOP 012* and *SOP 013*)).

4.3.2 Appropriate database entries into *InfoEd* are completed.

SOP 018: WAIVER OF INFORMED CONSENT

Approved by: BR Ware — 7-20-08

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Diane Young, Ph.D. — Date
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