Title: DOCUMENTATION OF INFORMED CONSENT

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidance on documentation of prospective, legally effective informed consent from research participants or their legally authorized representative.

2.0 Policy:

It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) that informed consent is documented in writing as determined in the IRB review and approval process.

Documentation of informed consent is obtained unless alternate procedures are approved by the IRB. The IRB reviews all informed consent documents to assure the adequacy of the information contained in the consent document, and adherence to Federal regulations regarding the required elements of informed consent.

The IRB requires that informed consent be documented in a written consent form approved by the IRB prior to formal recruitment of participants and signed and dated by the participant or the participant's authorized representative. A copy shall be given to the person signing the form. Forms must be dated.

There are two options for documentation of informed consent. The IRB may approve procedures for documentation of informed consent that involve either: (1) a written consent document signed and dated by the participant. The form may be read to the participant or his or her representative, but the investigator must give the participant or representative adequate opportunity to read the form and ask questions about the research before it is signed and dated; or (2) in limited circumstances, a waiver of the signed consent form. Each of these options is described in detail below.

Option One: Written Consent Form Signed by the Participant or Legally Authorized Representative. In most circumstances, the IRB should require that informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the participant or the participant's legally authorized representative.

This consent form must embody all of the elements of informed consent required by the SU IRB, in addition to any applicable additional elements that are required by the Federal regulations. This form may be read to the participant or the participant's legally authorized representative. However, the Investigator should allow the participant or the legally authorized representative adequate opportunity to read and consider the consent document before it is signed. A copy of the document must be given to the person signing the form.

The written informed consent document should embody, in language understandable to the participant, all the required elements necessary for legally effective informed consent.

Participants who do not speak English should be presented with an informed consent document written in a language understandable to them.

Option Two: Waiver of Documentation. The IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all participants if the IRB finds and documents protocol-specific findings justifying either: (1) That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; each participant would

be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern, and the research is not subject to FDA regulation; or (2) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

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.

It is the responsibility of the IRB to determine which of the procedures described is appropriate for documenting informed consent in research applications that it reviews.

No Verbal Consent. Verbal agreement to participate in a research study is not permitted unless the documentation or process of informed consent is waived by the IRB.

Use of Other Methods to Document Informed Consent. The IRB may approve a process that allows the informed consent document to be sent to (i.e., fax, mail, email, etc.) the potential participant or the potential participant's legally authorized representative and to conduct the consent interview by telephone when the participant or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

Short form Consent. The IRB does not allow the use of the short form.

3.0 References and Reference Documents:
45 CFR 46.102
45 CFR 46.111
45 CFR 46.116 and 46.117
PHL § 2441(2)
PHL § 2445

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 All informed consent documents (full written documents, oral scripts, and assent forms) will be submitted to the IRB with the new study submission.

4.1.1.1 The SU template for informed consent will be used to draft all written informed consent documents. Appropriate templates, template language, and instructions are located on the IRB website.

4.1.1.2 Informed consent documents will be written in language that is at the appropriate reading and comprehension level for the targeted population. Generally, a sixth to eighth grade reading level is recommended for adult consent documents.

4.1.1.3 The IRB recommends that the informed consent documents apply to the following division of target populations:

4.1.1.3.1 Age 18 or older utilizing the adult informed consent document;

4.1.1.3.2 Ages 13 to 17 utilizing an assent form, which may be in the same language as the adult informed consent document;

4.1.1.3.3 Ages 7 to 12 utilizing an assent form written simply and at a comprehension level appropriate for a 7 year old; and

4.1.1.3.4 Less than 7 years of age utilizing an oral script in very simple language appropriate for children of this age group.

4.1.2 Obtaining Informed Consent.

4.1.2.1 The Investigator will provide a copy of the currently approved and IRB date-stamped informed consent documents to the participant or his or her legally authorized representative.

4.1.2.1.1 New York State authorizes legally authorized representatives (LAR) to consent to research on behalf of a human subject, however, New York State does not define who qualifies as an LAR. Under both federal and New York law, research cannot be conducted on a human subject unless informed consent is obtained from the subject or an LAR. Unlike New York law, federal regulations do define who qualifies as an LAR. An LAR is "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." In situations where human subject research is not subject to federal policies and regulations, New York law governs, which does not provide a legal definition of an LAR. Where federal law controls the definition set forth above applies.

4.1.2.1.2 Under New York law, an agent with a durable power of attorney may only be granted certain types of legal authority (i.e., buy or sell real estate, conduct banking transactions, make gifts). In New York State, an agent with a durable power of attorney may not be granted the authority to make medical decisions for an individual. In addition, a health care proxy would not have the authority to consent to the principal's participation in "non-health care procedures."

4.1.2.2 The Investigator will provide the participants or his or her legally authorized representative adequate time to read the consent, ask questions, and consider the risks and benefits to participation in the research study prior to obtaining their signature.

4.1.2.3 Assent and dissent and documentation of such are to be obtained as directed by the determination of the IRB Committee.

4.1.2.4 Participants or the participant's legally authorized representative will provide a signature and the date of signature on all informed consent documents, unless a waiver of documentation has been requested by the Investigator and approved by the IRB.

4.1.3 Consent in Other Languages.

4.1.3.1 Many SU researchers conduct research in other countries or among populations in which English is not used. Informed consent must be obtained in a language readily understood by participants. The IRB requires that investigators submit consent documents in both English and in participants' own language.

4.1.3.2 Investigators must explain how consent documents were translated and how the accuracy of the translations was evaluated. The accuracy of a translation by an investigator whose first language is the non-English translation generally will be assumed by the IRB. In research involving greater than minimal risks or especially complex research procedures, the IRB may require investigators to arrange for a translation by a person unaffiliated with the research.

4.1.3.3 The Investigator may wish to delay translation until IRB approval is granted for the English version informed consent documents to avoid extra translation costs.

4.1.3.4 The Investigator must provide the qualifications of the individual or the service that was used to translate the informed consent documents. For example, include any credentials, certifications, education, native language fluency, etc.

4.1.4 Waiver of Documentation of Informed Consent.

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

4.1.4.2 The Investigator will make a request for waiver or alteration on the "IRB Application for Expedited or Full Board Review."

4.1.4.3 When an investigator requests a waiver of consent documentation the IRB must review a written script of the information to be presented.

4.1.5 The person obtaining consent should document the consent process in the participant's research record. This may include:

4.1.5.1 How consent was obtained;

4.1.5.2 The participant's level of comprehension (did they appear to understand, did they ask questions, were they able to reiterate the main purpose of the study, procedures, risks, etc.);

4.1.5.3 The participant's decision-making capacity at the time of consent (were they alert and oriented);

4.1.5.4 The time given for the participant to consider the research and whether others were involved in the decision-making; and

4.1.5.5 Identify who was present during the consenting process.

4.1.6 Any revisions to the informed consent process or documents will be submitted to the IRB for review and approval as presented in the amendment policy and procedure.

4.1 IRB Committee Responsibilities.

4.2.1 The Investigator's plan to obtain informed consent should be assessed by the IRB Committee, the Chairperson, or his or her designee to assure the appropriate conditions are met.

4.2.1.1 The IRB should consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved);

4.2.1.2 All elements of consent as required by the Federal regulations, as well as any appropriate additional elements are incorporated into the documents;

4.2.1.3 Provisions have been made if the study is to include non-English speaking participants and the translated documents have been verified to be in a language understandable to the participant;

4.2.1.4 The IRB Reviewers must assure that provisions for health care surrogates are reviewed for appropriateness, when applicable;

4.2.1.5 The reviewers are to verify that the informed consent documents are congruent with the study protocol and IRB application. If not, the Reviewer or Committee will request revisions prior to granting final approval;

4.2.1.6 The Reviewers will assure that the written language is in lay terms with correct grammar, spelling, and punctuation for readability and understanding.

4.2.2 The IRB must review all amendments to the informed consent process or documentation. If the requested amendments increase the risk relative to benefit, the review must be conducted by the IRB Committee and a determination of the necessity of re-consenting participants must also be rendered.

4.2.3 When the research includes minors (children less than 18 years of age), the IRB must determine whether assent and dissent is required, for what ages assent and dissent is required, and how assent and dissent is to be documented.

4.2.4 Decisions to waive documentation of informed consent must be clearly documented in the Review of Research Checklist and IRB minutes.

4.3 ORIP/IRB Administrator Responsibilities.

4.3.1 Once final approval is granted by the IRB, the informed consent documents will be stamped with current "Date of IRB Approval" and the "Date of IRB Expiration."

4.3.2 Changes to the informed consent process or documents are to be completed according to

the IRB amendment policy and procedure.

4.3.3 Appropriate data base entries will be completed.

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Approved by: BR Ware 5-25-09

Ben Ware — Date
Institutional Official
Vice President for Research and the Dean of Graduate School
Syracuse University

Diane A Young 5-21-09

Diane Young, Ph.D. — Date
Chair of the Institutional Review Board
Syracuse University

5-20-09

Tracy Cromp, M.S.W. — Date
Director of Office of Research and Integrity Protections
Syracuse University