

Informed Consent Process and Documentation

310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

Version: 1.1
Date: 09/17/2009
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 199
AAHRPP Elements: II.7.C

POLICY:

- I. The UIC IRBs require investigators to obtain prospective informed consent of each research subject or their legally authorized representative before they are included in research (including screening procedures), except where a waiver of informed consent is granted by the IRB.
- II. Investigators are responsible for incorporating the basic elements of informed consent, FDA requirements, applicable additional elements of informed consent, and UIC requirements in the informed consent. When a basic or applicable element is absent, the investigator must request a waiver or alteration of informed consent from process to the IRB.
- III. Informed consent is an ongoing process which begins with recruitment and continues throughout the subject's participation in the study.
- IV. In order to approve research involving human subjects, the UIC IRB reviews the informed consent process and documents to assure:
 - A. The required elements as defined by the Federal Regulations, VA handbook 1200.05 and UIC policy and any additional elements that are deemed appropriate by the IRB are included; and
 - B. The research is presented in an organized and easily understood fashion that allows the subjects or their representatives to make an informed and voluntary decision concerning participation.
- V. The IRB must approve the informed consent process and method of documentation, indicating whether the proposed consent process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the study.
- VI. The UIC IRB may require that information, in addition to that specifically required by applicable regulations, be given to subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects or improve subject understanding and voluntary decision-making.

PROCEDURE:

I. Informed Consent: IRB Review of the Informed Consent Process.

- A. **Submission.** Investigators submit the proposed informed consent procedures and consent document(s) with their initial and continuing review applications for IRB review and approval. This documentation is also submitted with amendments when the proposed changes alter the informed consent document or process.
- B. **IRB Documentation.** The IRB documents their review and determinations involving the consent process in the meeting minutes or, when review occurs under expedited conditions, review guides.
- C. **Consent Process.** The IRB reviews the protocol and IRB application to ensure that:
 - 1. It identifies who will obtain informed consent and that consent is obtained by research personnel with human subjects protection training;
 - 2. Modes of communication and materials are appropriate to the targeted subject population, including use of the targeted subject population's primary language and/or reading level;
 - 3. Conditions under which consent is sought provide the potential subject or their representative sufficient opportunity to consider whether or not to participate and minimize possibility of coercion or undue influence;
 - 4. Informed consent does not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence (examples of what does and does not represent exculpatory language can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm>).
- D. **Basic Elements of Consent.** The IRB verifies that the informed consent document contains the following basic elements of consent stipulated at 45 CFR 46.116(a) and 21 CFR 50.25(a):
 - 1. States that the study involves research;
 - 2. Explains the purposes of the research;
 - 3. States the expected duration of the subject's participation;
 - 4. Describes the procedures to be followed and identifies any which are experimental;
 - 5. Describes reasonably foreseeable risks or discomforts to the subject;
 - 6. Describes any benefits to the subject or to others which may reasonably be expected from the research;
 - 7. Discloses appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - 8. Describes the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - a) The consent must note the possibility that the FDA may inspect the records for FDA regulated research; and
 - b) Consent should also note others who may have access, including, as applicable, the sponsor, funding agencies, UIC OPRS, and State of Illinois auditors.

9. When applicable, explains whether any compensation and whether any medical treatments are available if any injury occurs and, if so, what they consist of, or where further information may be obtained.
 - a) UIC template consent forms contain options for language deemed acceptable for injury compensation;
 - b) Language other than one of the UIC acceptable options requires review and approval by University Counsel; and
 - c) Injury compensation language in the consent must agree with that in the Clinical Trial Agreement (CTA).
 10. Explains who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research related injury to the subject; and
 11. States that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- E. Additional Elements of Informed Consent.** The IRB determines whether one or more of the following additional elements of informed consent must be provided to subjects:
1. Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 3. Any additional costs to the subject that may result from participation in the research;
 4. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 5. Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and/or
 6. Approximate number of subjects involved in the research.
- F. FDA Regulated Research.** For all research involving a test article (i.e., investigational drug, device or biologic) regulated by the FDA, informed consent documents must, as applicable:
1. Per UIC requirements, inform subjects that a purpose of the study includes an evaluation of the safety of the test article. Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety;
 2. Inform subjects, for studies that also evaluate the effectiveness of the test article, of that purpose, but should not contain claims of effectiveness;
 3. If the research involves an investigational drug, device, biologic, or Humanitarian Use Device (HUD), states the regulatory status of the agent using explanations designed to be understood by the targeted subject population. For example, "the use of drug [insert name] in this

study is considered investigational, meaning it has not been approved by the FDA for marketing in the US for the use being tested in this research.”

- G. **Vulnerable Populations.** If the research involves groups vulnerable to coercion, the investigator must address and the IRB consider the additional consent concerns described in the UIC policies and procedures for research involving children, decisionally impaired subjects, pregnant women or fetuses, neonates, or prisoners. When the research will involve UIC students or employees, the consent should include the UIC informed consent template disclosure statements for these subjects.
- H. **UIC Specific Consent Requirements.**
1. The UIC informed consent templates provide investigators with standard formatting and language for sections (e.g., voluntary participation, other alternatives, new information, privacy and confidentiality, compensation for injury, answers to question) of the consent documents.
 2. Any deviation from the standard formatting and informed consent template language requires IRB approval.
 3. The consent document should be written in the second person (i.e., “You have been invited to participate...” or “Your participation in the research is voluntary”) to help convey the message that the subject is choosing to participate. The first person should be used only in the final section of the consent form, indicating the subject’s agreement to participate.
 4. The consent document for funded research should indicate the name of the sponsor or funding agency and that they are providing funds (or test article or other support) for the conduct of the research;
 5. Investigator discloses any conflicts of interest in the consent document following the COI disclosure agreement ([SEAM](#)) worked out with the COI office. The IRB reviews and approves the disclosure language in the consent document;
 6. If a Certificate of Confidentiality/Privacy Certificate has been obtained, consent states the terms and limitations provided by the Certificate (Refer to UIC HSPP policy and procedure [Approval Criteria: Confidentiality.](#))
 7. Consent informs subject of their responsibilities during the study.
 8. State whether biological materials obtained as part if the research will be used for commercial development and, if so, whether there are plans to compensate or allow the subject to share in the profits from this development.
 9. Provide name, department and contact information for investigator.
- I. **VA Consent Requirements.**
1. VA Form 10-1086 must be used for documenting informed consent at JBVAMC (Refer to UIC HSPP policy and procedure [Required and Additional Informed Consent Elements for VA Research](#));
 2. The IRB determines via the JBVAMC reviewer checklist and documents in the meeting minutes that the informed consent documents contain the elements required in 38 CFR 16.116, VA Handbook 1200.05, Appendix

C and listed in the JBVAMC consent template (posted the UIC OPRS website), including but not limited to the following:

- a) Statement that the Government Accounting Office (GAO) may have access to the records;
- b) Statement that in the event of a research-related injury the VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under supervision of one or more VA employees must be included. The explanation that necessary care must be provided in VA medical facilities except in limited circumstances and of the VA's authority to provide medical treatment to research subjects injured by participation in a VA research project must be included;
- c) Statement outlining what medical care will be provided in case of research-related injury pertaining to non-veteran subjects enrolled in VA-approved research;
- d) Statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project, except in accordance with 38 USC 1710(f) and 1710(g), certain veterans are required to pay co-payments for medical care and services provided by VA. Veterans receiving medical care and services from VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services; and
- e) VA required statements concerning specimen collection, storage, or use for development of a commercially valuable product or genetic testing are included when applicable.

3. Additional IRB Consent Form Review Responsibilities.

- a) The IRB assures that financial disclosure terms in the consent document, including coverage for research-related injuries and research procedures, match the clinical trial agreement.
- b) The IRB compares the investigator-submitted consent document(s) to the sponsor consent template(s) for NIH sponsored multicenter clinical trials.
- c) The information provided in the informed consent documents must be in language understandable to the participants. Technical and scientific terms should be adequately explained using lay terminology. Generic names are preferable when describing pharmaceuticals unless the brand name is more commonly known and understood. Regardless of which name is selected, it should be used consistently throughout the informed consent documents. Devices and procedures should also be described consistently throughout the documents and explained in simple language.

II. Waiver or Alteration of Consent.

- A. The UIC IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent. The investigator must show, and the IRB must document in a protocol specific manner that:
 1. The research involves no more than minimal risk to the subjects;
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. The research could not practicably be carried out without the waiver or alteration;
 4. When appropriate, the subjects will be provided with additional pertinent information after participation; and
 5. The research is not subject to FDA regulation.
- B. Department of Defense. If the research subject meets the definition of “experimental subject,” a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of “experimental subject,” the IRB may waive consent.
- C. UIC IRBs require a waiver of consent and HIPAA authorization for reviewing medical records for recruitment. This is not considered to be in conflict with FDA regulations.
- D. Deception. The investigator must obtain an alteration of the informed consent process from the IRB when deception is involved in the research. When the IRB reviews research involving deception, the minutes must document that the IRB made the findings in accordance with 45 CFR 46.116(d). The investigator also must complete the corresponding questions in Appendix J to justify to the IRB the alteration of elements of informed consent meeting the criteria in A. above (46.116(d)). The IRB typically requires a plan for debriefing subjects.
- E. Consent may also be altered or waived for certain research or demonstration projects conducted by or subject to the approval of state or local government officials that are designed to study, evaluate or otherwise examine: (i) public benefit of service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs, or (iv) possible changes in methods or levels of payment for benefits or services under those program, providing the research is not subject to FDA regulation.
- F. Refer to the UIC HSPP policy and procedure, [*Emergency Use of a Test Article*](#), for a description of when informed consent may be waived under emergency use for FDA regulated research. UIC does not currently allow planned emergency research.
- G. Per FDA Guidance, the FDA also allows waiver of informed consent for FDA-regulated in vitro diagnostic device investigations of leftover human specimens, when investigations meet the criteria for exemption from the Investigational Device Exemptions regulation at 21 CFR 812.2(c)(3) and as long as subject privacy is protected by using only specimens that are not individually identifiable.
- H. If the IRB reviews the research at a convened meeting, the determination of the waiver of informed consent is documented in the meeting minutes. If the IRB

reviews the research for expedited review, the expedited reviewer documents the determination on the reviewer checklist.

III. Waiver of documentation of informed consent.

- A. IRB may waive the requirement for the investigator to obtain a signed consent form if it finds either:
 - 1. That the study presents no more than minimal risk of harm to subjects and involve no procedures for which written consent is normally required outside of the research context, or
 - 2. That the only record linking the subject to the study is the signed informed consent and the principal risk is harm resulting from breach of confidentiality. Subjects will be given the opportunity to say whether they want documentation linking them to the research and their wishes will govern.
- B. In granting the waiver of documentation, the IRB will generally require the investigator to provide a summary of the research to potential subjects and secure oral consent. The IRB may require that the subjects be provided a written summary of the research.
- C. Waiver of requirement for documentation of informed consent is permitted for FDA regulated studies when the research presents no more than minimal risk of harm to subjects and involves procedures for which written consent is normally not required.

IV. Documentation of Informed Consent.

- A. The UIC IRB requires that informed consent is documented by use of a written consent form approved and stamped with the expiration date by the IRB, except when the IRB has approved a waiver for obtaining written informed consent. The consent is signed and dated by the subject or their legally authorized representative and the research personnel obtaining consent.
- B. The investigator provides a copy of the signed and dated informed consent document to the participant or the participant's representative and keeps the original signed informed consent document as part of the research file. In cases where photocopy equipment is unavailable, the investigator may ask the participant to sign and date two consents, one for the participant to keep and one for the research file. Investigator are strongly recommended to note in the source documentation the consent process, date consent obtained and that consent was obtained prior to initiating any research procedures.
- C. Except when a waiver for obtaining written documentation of informed consent is approved by the IRB, the UIC IRB requires that the consent form be either:
 - 1. A written consent document that embodies the elements of informed consent required by 45 CFR 46.116 and 21 CFR 50.25. This form may be read to the subject or the subject's legally authorized representative. The investigator must give either the subject or the representative adequate opportunity to read it before it is signed; or
 - 2. A short form written consent document stating that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the subject or the subject's legally authorized representative.

The IRB shall approve a written summary of what is to be said to the subject or the representative. When this method is used, a witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents. The subject or the subject's legally authorized representative must sign and date the short form. The witness must sign both the short form and a copy of the summary, and the person actually obtaining the consent must sign a copy of the summary. The subject or the representative must be given a copy of the summary as well as a copy of the short form. The person obtaining consent may not be the witness to the consent.

- D. **Non-English Speaking Subjects.** Documentation of consent for non-English speaking subjects is discussed in the UIC HSPP tip sheet, [*Involvement of Non-English Speaking Subjects in Research at the University of Illinois at Chicago.*](#)
- E. **Illiterate English-Speaking Subjects.** An individual who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document. Illinois state law allows an individual to "make their mark" instead of a signature, when necessary, and when the process is properly witnessed.
- F. **Subjects Physically Unable to Talk or Write.** An individual who can understand and comprehend spoken English, but is physically unable to talk or write, may be entered into a study if they:
 - 1. Retain the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (i.e., are competent), and
 - 2. Are able to indicate approval or disapproval to study entry.
 - 3. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.
- G. **Blind Prospective Subjects/ Prospective Subjects with Motor Difficulties.** Subjects with motor difficulties who are able to fully engage in the consent process but are unable to write their name may "make their mark." This would require a witness being present and the requirements above in 1-6 must be met.

V. VA Research.

- A. **VA Consent Document:** For studies in which subjects will be recruited from the JBVAMC or research will be conducted at the JBVAMC, use of the 10-1086 VA specific consent document is required.
 - 1. The signature and date of a witness, not otherwise involved with the study, as well as the dated signature of the individual obtaining the consent, is required on the VA 10-1086 informed consent document.
 - 2. In the event that the sponsor or IRB requires a witness to both the consenting process and to the subject's signature and the same person

serves both roles, this will be documented below the witness's signature line.

- B. For JBVAMC research, if someone other than the investigator will conduct the interview and obtain informed consent, the investigator must formally delegate this responsibility and the person so delegated must receive appropriate training to perform this activity.
- C. The person obtaining consent should document the consent process in the subject's medical record or the subject's research record. This should include at a minimum, but is not limited to:
 - 1. The name of the study.
 - 2. The person obtaining the subject's consent.
 - 3. A statement that the subject or the subject's legally authorized representative was capable of understanding the consent process.
 - a) A statement that the study was explained to the subject.
 - b) A statement that the subject was given the opportunity to ask questions.
 - 4. The PI should place an entry in the progress note when:
 - a) The subject was entered into the study.
 - b) The subject's involvement in the study was terminated.
 - 5. Once the consent document is approved by the IRB, each page of the 10-1086 is stamped indicating the date of the most recent IRB approval of the document. The approved, stamped informed consent document becomes a permanent part of the IRB Record.
 - 6. If the IRB determines that the protocol should be "flagged" in the medical record, investigators are responsible for ensuring the signed consent forms are scanned into the electronic medical record (CPRS).

VI. Informed Consent Process: Investigator Responsibilities:

- A. Informed consent is a continuous process. It starts with the initial presentation of a research activity to a prospective subject and continues until the subject ends their participation or the study closes. The Investigator must assure that an ongoing exchange of information between the research team and subjects (including persons giving consent or permission for others) are maintained throughout the course of the study.
- B. The investigator describes the informed consent process in the protocol and IRB application.
- C. The UIC IRB requires that the investigator or other study personnel who conduct the consent process present the information accurately and in a manner minimizing the possibility of coercion or undue influence.
- D. The consent process must allow prospective subjects sufficient time to consider whether to participate in the study, consult with others and have all their questions answered.
- E. The IRB may require investigators to develop a formal plan to assess and confirm that the subject understands the consent. This may include the use of a written tool, requiring a friend or family member to be present, requiring a waiting period or observation of the consent process by a representative of the IRB.

- F. Delegation of Responsibility for Obtaining Consent: If the Principal Investigator is delegating the responsibility for conducting the consent interview and obtaining informed consent to someone else on the research team, the PI must formally delegate this responsibility to this person or persons by naming them in the research application and in the research records (delegation log). The person must have received UIC IRB training and be up to date on UIC IRB continuing education requirements to perform this function.
- G. Providing Subjects with Notice of Additional Reporting Requirements. Investigators and the IRB should be aware of when the informed consent document must include a statement explaining that confidentiality might be breached due to Illinois reporting laws, including for positive HIV status, elder and child abuse, cancer, and certain infectious diseases. (Refer UIC HSPP Policy and Procedure [Ethical Standards and Legal Principles](#)).
- H. Any changes in the informed consent documents or processes after IRB approval must be submitted as a modification to the IRB for review and approval prior to implementation.

REFERENCES:

[21 CFR Part 50](#)
[38 CFR 16.116](#)
[45 CFR 46.109\(b\), 45 CFR 46.111\(b\), 45 CFR 46.116, 45 CFR 46.117, 45 CFR 46.408\(c\)](#)
[OHRP Informed Consent FAQs](#)
[OHRP Informed Consent Checklist](#)
[OHRP Informed Consent Tips](#)
[OHRP Exculpatory Language in Informed Consent, November 15, 1996.](#)
[VHA Handbook 1200.05, Appendix C](#)
[JBVAMC Consent Template](#)
[UIC Social and Behavioral Sciences Informed Consent Template](#)
[UIC Biomedical Sciences Informed Consent Template](#)

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 9/17/09	1.0, 6/23/09	Added information related to Department of Defense sponsored research in the "Waiver or Alteration of Consent" section.