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 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.
VII. The UIC IRB has the authority to observe or have a third part observe the informed consent process.

PROCEDURE:

   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. Individuals communicating information to the subject or LAR during the consent process will convey that information in language understandable to the subject or representative
      4. 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;
      5. 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 on the OHRP website (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html#).
   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. For research involving more than minimal risk, 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. For more information, please refer to the UIC HSPP policies Sponsor Payment for Costs Related to Subject Injury in Industry Sponsored Clinical Trials and Standard Operating Procedure Negotiating Sponsored Research Agreements for Research Involving Human Subjects.
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. Contain the basic and, when appropriate, additional elements of consent in I.D. and E.;
   2. A statement noting the possibility that the FDA may inspect the records;
3. A statement that the results of the research will be posted on clinicaltrials.gov for the following types of clinical trials: 1) controlled, clinical investigations of drugs and biologics subject to FDA regulation, excluding Phase I trials and 2) controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, but including pediatric post-market surveillance of devices ordered under section 522 of the Federal Food, Drug and Cosmetic Act.

4. 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;

5. Inform subjects, for studies that also evaluate the effectiveness of the test article, of that purpose, but should not contain claims of effectiveness;

6. 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.”

7. For FDA regulated clinical trials, the informed consent document cannot give the subject the option of having their data removed from the study database when they withdraw from the study.
   a) If subjects who withdraw from the interventional portion of a clinical trial will be asked to allow continued follow-up of clinical outcome information, their informed consent for this limited participation must be obtained on an IRB approved consent document.
   b) When subjects withdraw and do not consent to continued follow-up, investigator must not access for purposes related to the study the subject’s medical record or other confidential records.

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. (Please refer to the UIC HSPP policy Sponsor Payment for Costs Related to Subject Injury in Industry Sponsored Clinical Trials Guidance for more information regarding the injury language.)
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, Significant Financial Interest - Disclosure and Management Plan (SFI-DMP), worked out with the COI office. The IRB reviews and approves the disclosure language in the consent document;
6. If a Certificate of Confidentiality has been obtained, the consent states the terms and limitations provided by the Certificate (Refer to UIC HSPP document Guidance for Investigators: Certificates of Confidentiality).
7. Consent informs subject of their responsibilities during the study.
8. State whether biological materials obtained as part of 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. Chicago Area IRB (CHAIRb) Consent Requirements.
   1. In addition to criteria stated within this policy, the CHAIRb Informed Consent Template and CHAIRb Informed Consent Template Instructions are utilized.
   2. The most current IRB-approved consent document and approved institutional specific language are utilized when composing each participating sites' consent document.

II. Waiver or Alteration of Consent.
   A. A waiver of consent by the IRB means the entire requirement for consent is waived, including the consent process and required disclosures. On the other hand, when an alteration in consent is granted, consent is still obtained but the process or elements of disclosure differ from what is normally required.
   B. IRB approval is required for any case where the consent process is waived or altered.
   C. 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 justify in a protocol specific manner, and the IRB must document 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.

D. Department of Defense. Refer to UIC HSPP policy, Research Involving Department of Defense Components.

E. UIC IRBs require a waiver of consent to identify potential subjects in the recruitment phase of the research if reviewing medical records for recruitment. This is not considered to be in conflict with FDA regulations.

F. Deception. The investigator must request and 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 for the alteration of consent in accordance with 45 CFR 46.116(d). The investigator also must complete the corresponding questions in Appendix J to justify the use of deception. The IRB typically requires a plan for debriefing subjects.

G. 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.

H. Refer to the UIC HSPP policy, 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.

I. 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 InvestigationalDevice Exemptions regulation at 21 CFR812.2(c)(3) and as long as subject privacy is protected by using only specimens that are not individually identifiable.

J. Documentation of concurrence that a request for waiver of informed consent or an alteration of consent meets with the applicable regulatory requirements (45 CFR 46.116(c),(d)) is required of the IRB reviewer(s). The IRB reviewer(s) utilizes the "Request for Waiver of Consent, Alteration of Consent, or Waiver of Documentation" question and justification found in the IRB application. If the IRB reviews the research at a convened meeting, the IRB documents that applicable criteria has been met in the meeting minutes. If the IRB reviews the research for expedited review, the expedited reviewer documents that the applicable criteria has been met via 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 review and approve a written description of the information that will be provided to the subjects. 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.

D. Documentation of concurrence that a request for waiver of documentation meets with the applicable regulatory requirements (45 CFR 46.117) is required of the IRB reviewer(s). The IRB reviewer(s) utilizes the "Request for Waiver of Consent, Alteration of Consent, or Waiver of Documentation" question and justification found in the IRB application. If the IRB reviews the research at a convened meeting, the IRB documents that applicable criteria has been met in the meeting minutes. If the IRB reviews the research for expedited review, the expedited reviewer documents that the applicable criteria has been met via the reviewer checklist.

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.

C. Investigator should note in the source documentation the consent process, date consent obtained and that consent was obtained prior to initiating any research procedures.

D. 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 (i.e., long form):
      a) that embodies the elements of informed consent required by 45 CFR 46.116 and 21 CFR 50.25;
b) this form may be read to the subject or the subject's legally authorized representative; and

c) the investigator must give either the subject or the representative adequate opportunity to read it before it is signed.

2. A short form written consent document:
   a) that states the elements of informed consent required by 45 CFR 46.116 and 21 CFR 50.25 have been presented orally to the subject or the subject's legally authorized representative;
   b) includes a written summary of what is to be said to the subject or the representative that includes the basic required additional elements of disclosure;
   c) a witness will be present for the entire oral presentation, not just the signing of the documents;
   d) When the subject and/or LAR do not speak English, the witness will be conversant in both English and the language of the participant;
   e) witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent;
   f) the subject or the subject's LAR must sign and date the short form;
   g) the witness must sign both the short form and a copy of the summary;
   h) the person actually obtaining the consent must sign a copy of the summary;
   i) the subject or the representative must be given a copy of the signed summary as well as a copy of the signed short form consent; and
   j) the person obtaining consent may not be the witness to the consent.

E. Non-English Speaking Subjects. Documentation of consent for non-English speaking subjects is discussed in the UIC HSPP document, Guidance: Involvement of Non-English Speaking Subjects in Research.

F. 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.

G. 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.

H. 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 1-3 must be met.

V. 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 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
### REVISION TABLE:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1, 7/17/09</td>
<td>1.0, 6/23/09</td>
<td>Added information related to Department of Defense sponsored research in the “Waiver or Alteration of Consent” section.</td>
</tr>
<tr>
<td>1.2, 5/24/10</td>
<td>1.1, 7/17/09</td>
<td>Clarified that Section IV also applies to VA Research with the note that “Sections D-G apply to VA Research.”</td>
</tr>
<tr>
<td>1.3 5/2/11</td>
<td>1.2, 5/24/10</td>
<td>Updated for revised VHA Handbook 1200.05, dated 10/15/2010. Approval updated to Human Protections Administrator.</td>
</tr>
<tr>
<td>1.4, 4/8/12</td>
<td>1.3, 5/2/11</td>
<td>Additional information added to “FDA Regulated Research” section. Addition of “Consent for Research Involving Photographs or Voice or Video Recordings” section. Various editorial and grammatical revisions.</td>
</tr>
<tr>
<td>1.5, 12/19/12</td>
<td>1.4, 4/8/12</td>
<td>Correction of the name of the Conflict of Interest form. Clarification regarding waivers of informed consent regarding identifying potential subjects.</td>
</tr>
<tr>
<td>1.6, 08/30/16</td>
<td>1.5, 12/19/12</td>
<td>Removal of VA requirements &amp; language. Addition of CHAIRb requirements. Clarification regarding waivers and alterations of consent and location of protocol-specific justification for the waivers and alterations.</td>
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