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, except where a waiver of informed consent is granted by the IRB.

II. The 2018 Common Rule (45 CFR 46) or “2018 Requirements” went into effect on January 21, 2019 and affected all research, including consent documents and processes, approved on and after this date with the exception of the agencies that have not harmonized with the Common Rule.
   A. Research approved prior to January 21, 2019 will continue to comply with the requirements of the pre-2018 version of the Federal Policy for the Protection of Human Subjects (the “pre-2018 Requirements”) unless documented otherwise by the IRB on or after January 21, 2019.
   B. The following federal entities have agreed to follow the 2018 Requirements:
      1. Department of Homeland Security;
      2. Department of Agriculture;
      3. Department of Energy;
      4. National Aeronautics and Space Administration;
      5. Department of Commerce;
      7. Social Security Administration;
      8. Agency of International Development;
      9. Department of Housing and Urban Development;
     10. Department of Labor;
     11. Department of Defense;
     12. Department of Education;
     13. Department of Veterans Affairs;
     14. Environmental Protection Agency;
     15. Department of Health and Human Services;
     16. National Science Foundation; and
     17. Department of Transportation.
   C. Research involving federal entities who have not agreed to follow the 2018 Requirements (i.e., FDA, DOJ) will proceed under their most recent regulations and guidance (e.g., pre-2018 Requirements).
1. If the research falls under the purview of multiple entities with one or more entities agreeing to follow the 2018 Requirements and one or more entities who do not agree to follow the 2018 Requirements (e.g., NIH funded research testing FDA regulated products), the research will be reviewed under the pre-2018 Requirements.

III. 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 document. A waiver or alteration of informed consent must be granted by the IRB if elements of the consent process are absent.

IV. Informed consent is an ongoing process which begins with recruitment and continues throughout the subject’s participation in the study.

V. 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 a language and fashion understandable to the subject or their representative, including:
      1. Presenting key information at the beginning of the consent document, and
      2. Presenting information in sufficient detail that a reasonable person would want to know in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
   C. The consent can not include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

VI. 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.

VII. 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.

VIII. The UIC IRB has the authority to observe or have a third party observe the informed consent process as described in the Institutional Oversite policy. The UIC IRB also has the discretion of appointing an ombudsman to oversee the consent process in cases where the subject is particularly vulnerable or becomes incapacitated during the research study.
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 submission materials to ensure that:
      1. It identifies who will obtain informed consent and that consent is obtained by IRB-approved 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).
   D. Transition of consent documents to 2018 Requirements:
      1. Federally funded research approved prior to January 21, 2019 will be transitioned to the 2018 Requirements. The consent document will be revised at the time of the next continuing review.
      2. Non-federally funded research approved prior to January 21, 2019 will transition to the 2018 Requirements; however, revisions of the consent document will not be required unless otherwise determined by the IRB.
      3. Regardless of funding, initial reviews approved on or after January 21, 2019 that require a consent form must utilize the most current version of the consent form.
   E. 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(b) and/or 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 representatives of the IRB and/or UIC OPRS; representatives of the State and University responsible for ethical, regulatory, or financial oversight of research; and Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP) may have access to the consent form and research records;
   b) The consent must also indicate anyone else who may have access to the records, including, as applicable, the sponsor and funding agencies.
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.
10. Explains whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research related injury to the subject;
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; and
12. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
   a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
   b) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

F. Additional Elements of Informed Consent. The IRB determines whether one or more of the following additional elements of informed consent [45 CFR 46.116(c) and/or 21 CFR 50.25(b)] 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;
6. Approximate number of subjects involved in the research;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit [45 CFR 46.116(c)(7)];
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions [45 CFR 46.116(c)(8)]; and/or
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) [45 CFR 46.116(c)(9)].
10. For research meeting the definition of a clinical trial, the consent must include a statement that the results of the research will be posted on clinicaltrials.gov [21 CFR 50.25(c)].

G. 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.E. and F.;
2. Contain a statement noting the possibility that the FDA may inspect the records;
3. 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;
4. Inform subjects, for studies that also evaluate the effectiveness of the test article, of that purpose, but should not contain claims of effectiveness;
5. 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/device/biologic [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”;

6. 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, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records.

H. 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, human fetuses, neonates, or fetal tissue, prisoners, or research involving Department of Defense. When the research will involve UIC students or employees, the consent should include the UIC informed consent template disclosure statements for these subjects.

I. 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 and supplemental documents, guidance, and/or policies.
   2. Any deviation from the standard formatting and informed consent template language may be approved at the discretion of the IRB.
   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 granted or obtained, the consent states the terms and limitations provided by the Certificate (Refer to UIC HSPP document Guidance for Investigators: Certificates of Confidentiality).
   7. The consent document must inform subject of their responsibilities during the study.
8. The consent document must include the name, department and contact information for investigator.

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 of 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. When research involves public benefit and service programs conducted by or subject to the approval of state or local officials and involves a waiver or alteration of consent [45 CFR 46.116(e)]:
   1. The IRB may waive the requirement to obtain informed consent for research or may approve a consent procedure that omits some, or alters some or all, of the basic or additional elements of informed consent given that the IRB finds and documents that:
      a) 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:
         (1) Public benefit or service programs;
         (2) Procedures for obtaining benefits or services under those programs;
         (3) Possible changes in or alternatives to those programs or procedures; or
         (4) Possible changes in methods or levels of payment for benefits or services under those programs; and
      b) The research could not practicably be carried out without the waiver or alteration.
D. The UIC IRB may approve a waiver of consent or a consent procedure which does not include, or which alters, some or all of the basic and/or additional elements of informed consent for general research [45 CFR 46.116(f)]. 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 research could not practicably be carried out without the waiver or alteration;
   3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
   4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
   5. When appropriate, the subjects will be provided with additional pertinent information after participation.
E. Exception for screening, recruiting, or determining eligibility [45 CFR 46.116(g)]:
1. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
   a) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
   b) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

2. This exception to consent requirements for screening, recruiting, or determining eligibility does not include waiver of authorization or other HIPAA determinations. Therefore, if the research involves protected health information, determinations as to whether the research qualifies for a preparatory to research and/or a waiver/alteration of authorization must be documented.

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(f). 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. 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.

H. Per FDA Guidance, the FDA also allows waiver of informed consent for very specific scenarios:
   1. FDA-regulated minimal risk clinical investigations, when:
      a) The clinical investigation involves no more than minimal risk [as defined in 21 CFR 50.3(k) or 56.102(i)] to the subjects;
      b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
      c) The clinical investigation could not practicably be carried out without the waiver or alteration; and
      d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
   2. FDA-regulated in vitro diagnostic device investigations of leftover human specimens, when:
      a) Investigations meet the criteria for exemption from the Investigational Device Exemptions regulation at 21 CFR 812.2(c)(3);
      b) The study uses leftover specimens (e.g., remnants of specimens collected for routine clinical care or analysis that would have been discarded), specimens obtained from specimen repositories, or
leftover specimens that were previously collected for other research purposes;

c) The specimens are not individually identifiable (i.e., the identity of the subject is not known to and may not readily be ascertained by the investigator or any other individuals associated with the investigation, including the sponsor);

d) The specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor;

e) The individuals caring for the patients are different from and do not share information about the patient with those conducting the investigation; and

f) The specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information.

III. Waiver of documentation of informed consent [45 CFR 46.117(c)]

A. IRB may document a waiver of the requirement for the investigator to obtain a signed consent form if it finds any of the following:

1. 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. Each subject will be given the opportunity to say whether they want documentation linking them to the research and their wishes will govern;

2. 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

3. If the subjects are members of a distinct cultural group or community in which signing forms is not the norm, that the study presents no more than minimal risk of harm to subjects and provided there is an appropriate mechanism for documenting that informed consent was obtained.

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.

1. The IRB may require that the subjects be provided a written summary (information sheet) of the research.

2. The information sheet must include all required elements of consent unless an alteration of consent is granted by the IRB.

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 the written consent form and/or information sheet approved and stamped with the approval date or approval period (whichever is applicable) by the IRB be utilized for the consent process. Informed consent is documented via the signature and date by the subject or their legally authorized representative and the research personnel obtaining consent, except when the IRB has approved a waiver for obtaining written informed consent or a waiver of documentation of informed 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 (i.e., written or verbal), date consent was obtained, that consent was obtained prior to initiating any research procedures, that the subject was provided a copy of the consent or information sheet, and who witnessed the consent process (when applicable).

D. Except when a waiver or alteration of informed consent, or a waiver of 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/or 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.
      a) Refer to the UIC HSPP document, Guidance: Involvement of Non-English Speaking Subjects in Research for a description of the consent process when utilizing the short form.
      b) OPRS approved (but unstamped) short forms are available for utilization during enrollment of an unexpected potential subject who does not speak English. Available forms are posted on the OPRS website.
      c) Investigators who utilize short forms must follow the processes and procedures outlined on the Guidance document above, including reporting the use of the short form via a Protocol Exception form within 10 business days.

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. An
impartial third party should witness the entire consent process and sign the consent document.

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". Requirements G.1-3 above must be met.

V. **Third Party Observer/ Ombudsman**
   A. The IRB Chair, Vice Chair, or convened IRB may appoint an unbiased individual as a third party to observe the informed consent process on behalf of the IRB.
      1. The individual may monitor the process of informed consent conducted by the PI (or a member of the IRB-approved research staff delegated this role by the PI) with the prospective research participant or the participant’s legally authorized representative.
      2. The third party may collect data on the informed consent process by employing a variety of methods, including but not limited to, a physical presence (monitoring) during the consent process and/or employing written and verbal questionnaires to evaluate the effectiveness of the consent process.

   B. The IRB Chair, Vice Chair, or convened IRB may appoint an ombudsman, which is an unbiased individual to act as a subject advocate or a liaison between the PI (or delegate) and the research subject, the subject’s family, or the subject’s legally authorized representative.
      1. The IRB Chair, Vice Chair, or Convened IRB may appoint an unbiased ombudsman specializing in a vulnerable population to oversee the consent process, typically a scientist or an individual with expertise in the research area. This individual would observe the ongoing consent process and study conduct if the subject has become incapacitated during his or her research participation; or
      2. The IRB Chair, Vice Chair, or Convened IRB may also appoint an unbiased ombudsman to oversee that a subject who is particularly vulnerable receives equitable and ethical treatment throughout the course of the research study. This type of ombudsman should have
experience with the vulnerable population at issue or may also be a
group of people with an interest in the safety of human research
subjects, generally with a particular research focus. This type of
ombudsman is permitted to be an IRB member.

VI. Posting of Clinical Trials Consent Form [45 CFR 46.116(h)]
A. For each clinical trial conducted or supported by a Federal department or
agency, one IRB-approved informed consent form used to enroll subjects must
be posted by the awardee or the Federal department or agency component
conducting the trial on a publicly available Federal Web site
(http://ClinicalTrials.gov) that will be established as a repository for such
informed consent forms.
B. If the Federal department or agency supporting or conducting the clinical trial
determines that certain information should not be made publicly available on a
Federal Web site (e.g. confidential commercial information), such Federal
department or agency may permit or require redactions to the information
posted.
C. The informed consent form must be posted on the Federal Web site after the
clinical trial is closed to recruitment, and no later than 60 days after the last
study visit by any subject, as required by the protocol.

VII. 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/or
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 in the research
records (i.e., delegation log). All individuals who are delegated to conduct the
consent interview and obtain informed consent must have received the
applicable UIC Investigator training and be up to date on UIC Investigator continuing education requirements to perform these functions.

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 to 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 an amendment to the IRB for review and approval prior to implementation, with the exception of the short form.

REFERENCES:

21 CFR Part 50
45 CFR 46.109(b), 45 CFR 46.111(b), 45 CFR 46.116, 45 CFR 46.117
OHRP Exculpatory Language in Informed Consent, November 15, 1996.
FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable, Issued on April 25, 2006.
FDA Guidance on IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects, July 2017

REVISION TABLE:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
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</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</td>
</tr>
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<td>Date</td>
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<tr>
<td>2.0, 01/21/19</td>
<td>1.6, 08/30/16</td>
<td>Addition of 2018 Requirements; addition of third-party observation and ombudsman; other editorial revisions.</td>
</tr>
<tr>
<td>2.1, 10/01/19</td>
<td>2.0, 01/21/19</td>
<td>Removal of CHAIRb specific language as CHAIRb follows UIC policies and procedures. Changes to short form procedures. Addition of waiver of consent for FDA regulated research.</td>
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</table>