UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT

I. PURPOSE

This document outlines the procedures for University of Tennessee Health Science Center Institutional Review Board concerning informed consent and its documentation.

II. SCOPE

This SOP applies to all IRB administrative staff, board members, and investigators.

Personnel Responsible:

IRB members and administrative staff

III. BACKGROUND

The fundamental purpose of IRB review and approval of the consent process and document is to protect the rights and welfare of human subjects. Investigators may not generally involve a human subject in clinical research without the legally effective informed consent of the subject or the subject's legally authorized representative. The informed consent disclosure must be presented in language understandable to the subject, with all required elements of information as specified in the regulations and local IRB policy. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in deciding about study participation and must have the opportunity to discuss that information. Investigators may seek consent only under circumstances that provide the subject sufficient opportunity to consider whether to participate in the study and that minimize the possibility of coercion or undue influence. In addition, no consent disclosure may contain exculpatory language through which the subject or the subject's legally authorized representative waives or appears to waive any of their legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence. The informed consent document is the written summary of the information provided to the subject in the informed consent interview, and the subject's signature on the consent form documents the prior informed and voluntary agreement of the subject to participate in the study.

UTHSC IRB is responsible for ensuring that the content of the consent disclosure includes all required elements of information, that the process for securing consent enables the prospective subject or legally authorized representative to make a

knowledgeable and voluntary decision, and that the process of securing consent is properly documented. UTHSC IRB also has the authority to audit investigators and / or observe the informed consent process to assure that consent is obtained and documented, and that records are maintained, in accordance with this standard operating procedure.

This policy is not intended to limit the authority of a physician to provide emergency medical care, to the extent that the physician is permitted to do so under any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe). The informed consent requirements of this policy are also not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American or Alaska Native tribe) which require additional information to be disclosed in order for informed consent to be legally effective.

In Accordance With:

For studies approved under both the revised and pre-2018 Common Rule:

45 CFR 46.109; 45 CFR 46.111; 45 CFR 46.116; 45 CFR 46.117;

For FDA-regulated studies:
21 CFR 11, 21 CFR 50.20, 50.25 and 50.27; 21 CFR 56.109, 56.111, and 312.62;

Applicable state and local laws.

FDA IRB Information Sheets: Guide to Informed Consent, 1998 located at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

FDA IRB Information Sheets: Frequently Asked Questions on Informed Consent Process and Informed Consent Document Content
http://www.fda.gov/oc/ohrt/IRBS/faqs.html

OHRP Guidance on Informed Consent located at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html

OHRP FAQs on Informed Consent located at
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Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. General Requirements for Informed Consent

General requirements for adequate informed consent and documentation of consent include the following:

a. Before involving a human subject in research covered by this policy, an investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless a waiver has been granted.
b. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
c. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
d. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
e. No informed consent disclosure, whether oral or written, may include any exculpatory language through which the subject or the 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.
f. Investigators are responsible for assessing the subject's capacity to consent.
g. The UTHSC IRB requires the investigator to explain the timing and circumstances under which informed consent, permission and/or adult assent will be sought in the Form 1 application. The PI must specify who has the authority to obtain informed consent. Only persons listed in section 3.0 of the application and denoted in section (415) as persons who "will obtain consent" may conduct the informed consent interview and obtain consent of prospective subjects. The PI must also specify whether or not informed consent will be secured from legally authorized representatives in some or all cases.
h. The consent process is a vital component of the investigator's ongoing relationship with the subject. Essential components of the consent process are:
    i. An ongoing, open discussion of the research study, including risks, benefits, procedures, and alternatives, appropriate to the subject and the study;
    ii. Ample opportunity for the subject to ask questions and to have them answered;
    ii. An explanation that the subject's participation is voluntary and that the subject can decline to participate;

iii. Formally obtaining the subject's consent or dissent; and
iv. Proper documentation of the consent process.

i. The process of obtaining informed consent must normally involve an informed consent interview conducted in person. Inviting the subject to read and sign the consent form is not sufficient for securing informed consent. The informed consent interview should involve disclosure of the main elements of the consent information and a determination that the subject (or legally authorized representative) adequately comprehends the information provided. The proceedings of the informed consent interview should be documented in the research record, along with including the original signed consent form (or an electronic copy of the signed original, as long as the controls delineated in 21 CFR 11.10 are in place for the closed system in which the electronic copy is stored). A written copy of the consent document must be given to the subject. Any alteration of this process must be requested as an alteration of informed consent under 45 CFR 46.116(f) (45 CFR 46.116(d) under the previous Common Rule), with a justification that establishes that the conditions for approving an alteration are satisfied.

2. **Required Informational Elements of the Main Consent Form**

UTHSC IRB will review each informed consent document and revisions to the document to assure that it contains the information required by the IRB consent form templates, including the following elements as required by federal regulations and local policy:

a. The informed consent document must begin with a concise and focused summary of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent document must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates comprehension. The summary should:
   i. Include a statement that the activity involves research;
   ii. Provide an explanation of the purposes of the research;
   iii. When applicable, that a description of the trial will be available at http://www.ClinicalTrials.gov;
   iv. Describe the main procedures involved in the study, including any that are experimental. The expected duration of the subject's participation should be explained. Any procedures being done for research purposes only should be identified.
   v. Describe in lay terms the most common (highest in frequency) physical risks of the research procedures (including drug/device administration) and the most serious physical risks (greatest in magnitude), even if the

latter rarely occur. Any serious psychological, social, or economic risks should also be described.

vi. Indicate the possible benefit for the subject and the ways in which the study has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.

vii. Disclose appropriate alternative procedures or courses of treatment (if any) that may be advantageous to the subject.

viii. State that participation is voluntary and that refusal to participate or a decision to discontinue participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.

b. A detailed description of the procedures involved in the study that:
   i. Indicates the number of subjects participating overall and locally in the study.
   ii. States the location(s) at which the research will be performed.
   iii. Describes in detail all procedures performed at each study visit.
   iv. For studies involving biospecimens, when it is possible that genetic analysis may be performed, state whether the research will (if known) or might include analyses of the genetic makeup of subjects. This might include sequencing to determine the differences between subjects in terms of disease severity, likelihood of disease progression, and so forth; sequencing of genes that may indicate a disease susceptibility heretofore unknown to the subjects; sequencing to determine pharmacogenomic phenotypes; and 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. Include an explanation of what genes are and why they may be of interest to investigators.
   v. Explains whether clinically relevant results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
   vi. Includes a statement of the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
   vii. Provides an explanation of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

c. A full explanation regarding the risks of study participation, including:
   i. A description of any reasonably foreseeable risks or discomforts for the subject, including their probability, magnitude, duration and reversibility.
   ii. A statement that particular treatments or procedures may involve risks to the subject that are currently unforeseeable.
   iii. A statement that the research may involve risks to subjects which are currently unforeseeable, that any new information that may relate to the subject's willingness to continue participation will be provided to the

subject, and that the subject may be asked to sign a new consent form if this occurs.

iv. A statement that the particular treatment or procedure may involve risks that are currently unforeseeable to an embryo or fetus, if the subject is or may become pregnant, and specific language regarding contraception (including information for male and female participants if applicable).

d. A section describing the provisions for the protection of the confidentiality of subject data. This section must also include:
   i. The HIPAA subject authorization template.
   ii. The protections afforded by the Genetic Information Non-Discrimination Act, if genetic information is being obtained or used.
   iii. The protections afforded by a Certificate of Confidentiality, if one has been obtained for the research.
   iv. For any research that involves the collection of identifiable private information or identifiable biospecimens, one of the following statements:
      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.
e. An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
f. An explanation of whom to contact for answers to pertinent questions *(include names and phone numbers)*: about the research (the principal investigator); about the subject's rights (an IRB Chairperson); and whom to contact in the event of a research-related injury (the principal investigator).
g. An explanation of whether subjects will be paid for their participation, including the amount and schedule of payments.
h. An explanation of whether profit-making activities might result from commercialization of the information and/or specimens collected during the research study (e.g., the development of a marketable diagnostic test), and whether subjects will share in any profits deriving from these activities.
i. A description of any additional costs to the subject that may result from participation in the research, including a statement that some insurance and/or other reimbursement plans may not fund or cover care that occurs in a research context.

j. A description of any conflicts of interest, as defined under University policy, that one or more individuals among the key study personnel (including their spouses, parents, or children) may have in relation to the sponsor of the research.
k. A request for the subject to permit future contact with the investigator, if applicable.
l. A statement that subjects will be provided a copy of the consent form.
m. Dated signature lines to permit verification that consent was obtained prior to participation in any study-related procedures.
n. UTHSC IRB may require additional information be given subjects when such information would enhance protection for the rights and welfare of the subjects.

3. **Formatting of the Main Consent Form Document**

Requirements for the formatting of informed consent documents include the following:

a. The consent form must normally be prepared in accord with the UTHSC IRB Main Consent Form Template available on the UTHSC IRB website at http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php.
b. Number pages 1 of 5, 2 of 5, etc.
c. Insert a line for the research subject's initials or initials of the LAR (_____) at the bottom of all pages except the signature page (where the line for initials is permitted, but not necessary).
d. Add to the bottom of each page of the consent form a "preparation date ____". (This date changes whenever a revision is made to the consent form.)
e. The document must be written in language understandable to the subjects (for most studies, this would be approximately an 8th grade readability level).
f. Consent forms must be written in the 2nd person (you).
g. If applicable, the assent discussion page should be included as the last page of the consent form if the research study includes the use of adults who do not have the capacity to consent.
h. UTHSC IRB requires the following signature lines on the informed consent document:
    i. Signature/date for the subject or subject's legally authorized representative; if a legally authorized representative is used, then a line must also be included for specifying the relationship of the legally authorized representative to the subject;
    ii. Signature/date for the person obtaining informed consent;
    iii. Signature/date for the principal, collaborating, or sub-investigator; and
    iv. Signature/date for the assent of adult subjects (if applicable).

4. **Written Documentation of Informed Consent**

a. UTHSC IRB requires the following signatures to be obtained and dated by the signatory on the informed consent document:
    i. Subject or legally authorized representative; and
    ii. The person obtaining consent who is informed and knowledgeable about the study and study requirements, and authorized in the approved application to conduct the informed consent interview; and
    iii. The principal, collaborating, or sub-investigator who attests to the best of his/her knowledge that the informed consent process has been properly conducted and completed.
b. If a subject is cognitively capable of consenting to his/her participation in the research study but cannot physically sign the consent page (for example, due to paralysis), he/she can verbally indicate that he/she consents and can designate a representative (for example, a relative, hospital patient advocate, social worker, etc.) to sign the consent line (not the LAR line) for him/her, provided the latter party is not involved in the actual conduct of the study. The representative may sign the subject's name on the consent line and then sign his/her own name beside it in parentheses. Alternatively, video and/or audiotaping of the process may be utilized with the permission of the individual and in accordance with the institution's policies. The need to alter the consent process and the actual procedures used should be explained and documented in the consent discussion notes in the research record, including a description of the identity of the person to whom the authorization has been given.
c. The person obtaining consent should sign the consent form at the time he/she obtains consent from the subject or legally authorized representative. The UTHSC IRB requires the signature of the principal, collaborating, or sub-investigator within 72 hours of the subject's entry into the study.
d. UTHSC IRB requires that the investigator place the original of the signed informed consent document (or an electronic copy of the signed original, as long as the controls delineated in 21 CFR 11.10 are in place for the closed system in which the electronic copy is stored) in the research records for the study.
e. A copy of the consent form must also be provided to the subject or the subject's legally authorized representative at the time of consent to participate in the study.
f. UTHSC IRB requires documentation in each subject's case history (e.g., source documents or case report forms) that informed consent was obtained prior to participation in the research study. In addition, if there are inclusion/exclusion criteria for the study, there should be specific documentation, such as a checklist, that the potential subject met the inclusion criteria and did not meet the exclusion criteria before a subject is consented for participation in the study or for participation in screening for the study.
g. UTHSC IRB will affix a new stamp on the approved informed consent form, and for studies that require continuing review, a date of expiration. Only the current stamped, and when applicable, unexpired, consent form may be used to secure written documentation of informed consent.

h. A copy of any approved current consent form will be kept in the IRB files for the study.
i. UTHSC IRB has the right to observe the consent process.
j. Investigators are required to report to UTHSC IRB any major deviations from or violations of the consent policies. See IRB SOP: Protocol Waivers and Deviations.

5. **Waiver or Alteration of Informed Consent**

a. General Waiver or Alteration

The UTHSC IRB may approve an alteration or waiver of informed consent under 45 CFR 46.116(f) (45 CFR 46.116(d) under the previous Common Rule) provided that the IRB finds and documents the following conditions. Satisfaction of these conditions must be established the principal investigator in the Form 1 application:

i. The research involves no more than minimal risk to the subjects;
ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
iii. The research could not practicably be carried out without the waiver or alteration;
iv. 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; and
v. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Please note that the regulations at 45 CFR 46.116(d) of the revised Common Rule state that, "If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens." This restriction on waivers of consent applies only to federally funded studies reviewed by the UTHSC IRB.

b. Waiver or Alteration of Consent for Research Involving Public Benefit Programs

The UTHSC IRB may approve an alteration or waiver of informed consent under 45 CFR 46.116(e) provided that the IRB finds and documents the following conditions. Satisfaction of these conditions must be established by the principal investigator in the Form 1 application:

i. 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:
   a) Public benefit or service programs;
   b) Procedures for obtaining benefits or services under those programs;
   c) Possible changes in or alternatives to those programs or procedures; or
   d) Possible changes in methods or levels of payment for benefits or services under those programs; and

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

c. Waiver of Consent for Screening, Recruiting, or Determining Eligibility

The UTHSC IRB may approve an alteration or waiver of informed consent under 45 CFR 46.116(g) provided that the IRB finds and documents the following conditions. Satisfaction of these conditions must be established by the principal investigator in the Form 1 application:

i. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

ii. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

6. **Waiver of the Requirement to Obtain a Signed Consent Form**

a. The UTHSC IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following:
   i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
   ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
   iii. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

b. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

7. **Consent Form Revisions**

   a. Consent form revisions for studies initially approved by the full Board will be reviewed by the full Board unless the changes satisfy criteria for expedited review.
   b. Any IRB approved revisions to the informed consent document that might relate to the subjects' willingness to continue participation in the study will necessitate the re-consent of all current subjects in the clinical study. Subjects who have completed the study may be mailed a copy of the changes to the consent document. UTHSC IRB does not require re-contacting subjects who have completed their active participation if the revisions do not involve issues pertinent to their health, safety, or well-being. UTHSC IRB does not require re-consent of subjects who are still actively participating when the revisions will not affect their willingness to continue participation in the study.
   c. UTHSC IRB will affix a new stamp on the approved informed consent form, and for studies that require continuing review, a date of expiration. Only the current stamped, and when applicable, unexpired, consent form may be used to secure written documentation of informed consent.

8. **Consent by a Legally Authorized Representative and Other Special Consent Situations**

   a. Use of Legally Authorized Representatives (LAR) for Adult Subjects:
      i. When prospective adult subjects lack adequate decision making capacity, investigators may not involve them in clinical research without the legally effective informed consent of the subject's legally authorized representative (LAR). Identification of the LAR for a subject incapable of making an autonomous decision is governed by state law. The LAR must be an adult who has exhibited special care and concern for the subject, who is familiar with the subject's personal values, who is reasonably available, and who is willing to serve. No person who is identified in a protective order or other court order that directs that person to avoid contact with the subject shall be eligible to serve as the subject's LAR. Identification of an LAR should normally be made using the following order of descending preference: conservator; guardian; attorney-in-fact; subject's spouse, unless legally separated; the subject's adult child; the subject's parent; the subject's adult sibling; any other adult relative of the subject; or any other adult who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve as LAR.
      ii. When consent has been obtained from the LAR due to the incompetence of the subject at the time of entry in a study, and the subject regains competence during study participation, then the principal investigator or

designee must secure the subject's non-objection to continued participation in the study. This process should involve an interview and review of the consent document in the same manner as required at the time of entry into a study. The subject's agreement and signature on the consent form will indicate non-objection to continued participation in the study. A written copy of the consent document must be given to the subject.

iii. If the LAR loses the legal right to consent for the subject while the subject is participating in a research study (e.g., loss of Power of Attorney for health care), a new LAR must be identified and give consent for the subject's continued participation in the study.

b. Subjects Who May Lose Ability to Consent While in the Study:

Adults who have the capacity to consent during study enrollment, but who may lose the capacity to consent at some point during study participation (due to Alzheimer's disease for instance) can name a future LAR upon study enrollment. This should be done in writing, such as on a healthcare proxy form, and be kept with the subject's research record. At the time when the investigator determines the subject has lost the capacity to continue to consent to study participation, the designated LAR should be consented. In addition, assent of the adult subject should be obtained if possible. Further, the sustained objection in word or action of the subject to continued participation should be grounds for withdrawing the subject from the study, unless the study offers a unique opportunity for direct benefit not otherwise available outside the research setting.

c. Assent By Adult Subjects Who Lack the Capacity to Give Informed Consent:

If a research study will include the use of adults who do not have the capacity to consent, assent of the adult subject should be obtained if possible and documented on the adult assent discussion page of the consent form. If the adult subject cannot sign the assent line on the assent discussion page, this should be noted on the assent discussion page and in the research record. Further, the sustained objection in word or action of the subject to continued participation should be grounds for withdrawing the subject from the study, unless the study offers a unique opportunity for direct benefit not otherwise available outside the research setting.

d. Securing Consent By Telephone:

Securing informed consent by telephone is generally not allowed; however, the UTHSC IRB may approve this procedure via an alteration of consent request

made in the electronic research application. For FDA-regulated studies, FDA guidance states that it is acceptable when necessary to send the informed consent document to the subject or legally authorized representative by facsimile and to conduct the consent interview over the telephone when the subject or legally authorized representative can read the consent form as it is discussed. Study procedures may not be initiated until the signed consent form (with the subject's/LAR's initials on each page) is returned by facsimile (or approved alternative method discussed below) to the investigative site. The consent form with the original signatures must be mailed or brought to the investigative site at the earliest opportunity. The IRB will also permit the use of alternative communication technologies in FDA-regulated studies, such as e-mail, mail, or videoconference, provided that the consent form is sent to the prospective subject or legally authorized representative prior to the consent interview, the subject or legally authorized representative can read the consent form as it is discussed, and an image of the signed consent form is returned to the investigative site prior to the initiation of study procedures.

In addition, alteration of the consent process to secure consent by telephone may sometimes be allowed for a study that is not FDA-regulated. A request to secure consent by telephone must be submitted as an alteration of informed consent in the electronic research application, with a justification that establishes that the study could not practicably be carried out without the alteration and that the rights and welfare of subjects will not be adversely affected by the alteration of the consent process.

e. Subjects Who Transfer From Other Research Sites:

   For subjects in a multi-center clinical trial who transfer to a UTHSC IRB-approved site from a different site in the trial, they must be consented with the UTHSC IRB stamped-approved consent form. Further, if a subject in a multi-center clinical trial transfers from a UTHSC IRB-approved site to a different site, and then back to the UTHSC IRB-approved site, he/she must be re-consented with the currently approved UTHSC IRB stamped consent form.

f. For **Non-English** consent procedures, see IRB SOP: UTHSC IRB Informed Consent of Non-English Speaking Subjects, Illiterate English-Speaking Subjects, and Visually-Impaired or Hearing-Impaired English Speaking Subjects.

g. For **Pediatric Assent and Parental Permission**, see IRB SOP: UTHSC IRB Review of Research – Additional Protections for Children.

h. If the study involves a **repository**, then a separate consent form must be prepared according to the UTHSC IRB consent template for repositories. See the

Repository Consent Form Template at http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php.

9. **Posting Consent Documents**

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, ClinicalTrials.gov, or in a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). It is the responsibility of the local Principal Investigator to consult with the Federal department/agency as to whether the UTHSC IRB-approved consent form should be posted, and if so, to find out on which Federal Web site it should be posted, when it should be posted, and whether the Principal Investigator or the Federal department/agency will post it. 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. 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.