5.0 Obtaining Informed Consent from Research Subjects

5.1 Policy

No investigator conducting research at Pennington Biomedical Research Center may involve a human subject in research without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative unless a waiver of consent has been approved by the IRB in accordance with section 5.10 of these procedures. Except as provided in section 5.12, informed consent must be documented by the use of a written consent form approved by the IRB (see section 5.7).

The IRB will evaluate both the consent process and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from subjects.

The following procedures describe the requirements for obtaining consent from subjects in research at Pennington Biomedical Research Center.

Regulations & Guidance: DHHS 45 CFR 46.116; FDA 21 CFR 50.20

5.2 Basic Requirements

Informed consent must be obtained by the investigator (or properly trained designee) prior to entering or enrolling a subject into an IRB approved study and/or conducting any study related procedures required by the protocol, unless consent is waived by the IRB.

If someone other than the investigator conducts the interview and obtains consent from the subject, the investigator needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study.

These informed consent requirements are not intended to preempt any applicable federal, state or local laws that require additional information to be disclosed for informed consent to be legally effective.

All consents under the purview of Pennington Biomedical Research Center IRB must be on the Pennington Biomedical Research Center consent template format located on the HRPP website. Sample or draft consent documents may be developed by a sponsor or cooperative study group; however, they must be in the Pennington Biomedical Research Center consent template.

Regulations & Guidance: FDA 21 CFR 50.20.

5.3 Securing and Documenting Informed Consent

An investigator (or properly trained designee) is required to obtain legally effective informed consent from a subject or the subject's legally authorized representative. DHHS 45 CFR 46.177; FDA 21 CFR 50.20

When informed consent is required, it must be sought prospectively, and properly documented according to legal and regulatory requirements. DHHS 45 CFR 46.117; FDA 21 CFR 50.20

The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for by the federal regulations and the IRB Office.

The informed consent process involves three key features:

- Disclosing to the prospective human subject information needed to make an informed decision
- Facilitating the understanding of what has been disclosed
- Promoting the voluntariness of the decision about whether or not to participate in the research.

Informed consent is more than just a signature on a form. It is a process of information exchange to include reading and signing the informed consent document. The informed consent process is the critical communication link between the prospective human subject and an investigator, beginning with the initial approach of an investigator and continuing through the completion of the research study. Investigators must have received the appropriate training and be knowledgeable about the study protocol in order that they may answer questions to help provide understanding to the study subject or potential study subject. The exchange of information between the investigator and study subject can occur via one or more of the following modes of communication, among others; face to face contact, mail; telephone; or fax.

5.4 Informed Consent Process

Informed consent must be obtained under the following circumstances:

- Informed consent may only be obtained from subjects who have the legal and mental capacity to give consent. For subjects without that capacity, consent must be obtained from a legally authorized representative.
- The informed consent process shall be sought under circumstances that provide the subject (or legally authorized representative) with sufficient opportunity to consider

whether or not to participate. The researcher must give either the participant or the representative adequate opportunity to read the consent document before it is signed.

- The informed consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence. Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast often occurs through an offer of an excessive or inappropriate reward or overture in order to obtain compliance.
- The informed consent information must be presented in language that is understandable to the subject (or legally authorized representative). To the extent possible, the language should be understandable by a person who is educated to 8th grade level and layman's terms shall be used in the description of the research.
- For subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the subject (or legally authorized representative). In accordance with this policy, the IRB requires that informed consent conferences include a qualified translator when the prospective subject does not understand the language of the person who is obtaining consent.
- After the written informed consent form and any other written information to be provided to participants, is read and explained to the participant or the participant's legally authorized representative, and after the participant or the participant's legally authorized representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the person administering the consent should sign and personally date the consent form.
- By signing the consent form, the person administering the consent attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the participant's legally authorized representative.
- In accordance with the American Disabilities Act, Pennington Biomedical Research Center will provide any assistance to any subject with a disability. For hearing impaired subjects, Pennington Biomedical will provide hearing impaired equipment or a translator. For subjects with a visual impairment, an impartial witness must be present during the informed consent process if the subject does not have a legally authorized representative.
- For subjects that are illiterate, an impartial witness to the subject will sign as a reader unless the subjects legally authorized representative is present.
- The informed consent process may not include any exculpatory language through which the subject is made to waive, or appear to waive any of the subject's legal rights or through which the Investigator, the Sponsor, the Institution or Pennington

employees or institutional agents are released from liability for negligence, or appear to be so released. DHHS 45 CFR 46.116; FDA 21 CFR 50.20

- The investigator is ultimately responsible for ensuring that each prospective subject is adequately informed about all aspects of the research and understands the information provided. However, the IRB office, the research investigators and the research staff all share in the responsibility of ensuring that the informed consent process is adequate.
- Federal regulations do not specify how far in advance of study entry a subject can provide consent. The amount of time required by a subject to make a decision would presumably depend upon the nature of the study, taking into consideration the degree of risk, potential benefits, alternatives, and desire to consult with family. For the sake of clarification, consents are current for 30 days but it may be prudent to review information contained in the consent document with the research subject prior to initiating any research procedures.
- Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

Regulations & Guidance: DHHS 45 CFR 46.109(b); 45 CFR 46.116, 117; FDA 21 CFR 50.25; 21 CFR 56.109(b); OHRP Guidance on Exculpatory Language in Informed Consents; FDA Information Sheets: A Guide to Informed Consents

5.5 Basic Elements of Informed Consent

To be valid, the consent process must provide the following basic elements of information to potential subjects, which includes:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental and done for research purposes; a description of any reasonably foreseeable risks or discomforts to the subject including privacy risks (legal, employment, etc.).
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- The alternative procedures or treatment that might be available to the participant, and their important potential benefits and risks.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained.
- For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research related injury, including who will pay for the treatment and whether other financial compensation is available.

- An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject.
- Contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research subject; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff.
- A statement 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.

Under the 2018 Final Rule, the basic elements have been expanded in 116(b) to include 3 *new requirements*.

- When appropriate, informed consent must include the following:
    - A statement that 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 (.116(c)(7));
    - A statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (.116(c)(8));
    - A statement about whether the research project will or might include whole genome sequencing (.116(c)(9)).

***New* Requirements to Informed Consent Process and Document** are meant to facilitate subjects' understanding of the reasons to participate (or not) in the research). It requires that key information essential to decision making receive priority by:

- Being presented first in the consent discussion; and
- Appearing at the beginning of the consent document
- Prospective subject (or LAR) must be provided with the information that a reasonable person would want to have to make an informed decision about whether to participate, and be given an opportunity to discuss that information. (.116(a)(5)(i))
- Informed consent must begin with "a concise and focused presentation 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." (§____.116(a)(5)(i)).

- This statement "must be organized and presented in a way that facilitates comprehension." (§____.116(a)(5)(i)).

The Key Information Section*:* According to the preamble of the Final Rule, a brief description of five "factors" (elements) at the beginning of an informed consent process (and consent form) would encompass the key information including a concise explanation of the following (HHS 2017, 7149-274):

(1) The fact that consent is being sought for research and that participation is voluntary
(2) The reasonably foreseeable risks or discomforts to the prospective subject
(3) The purposes of the research, expected duration of the prospective subject's participation, and procedures to be followed in the research
(4) The benefits to the prospective subject or others that may reasonably be expected from the research
(5) Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

Electronic consent is allowed if subjects are provided a written copy.

Screening, recruiting, determining eligibility. IRBs do not need to obtain informed consent in instances of obtaining information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects, under certain circumstances. (§ ____.116(g)).

For research involving collection of identifiable private information or identifiable biospecimens. In these instances, subjects should be provided with:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens; and
- The information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent, where applicable; or
- 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. (§ ____.116(b)(9)).

Regulations & Guidance: DHHS 45 CFR 46.116(a); FDA 21 CFR 50.25(a); OHRP Guidance on Exculpatory Language in Informed Consents; FDA Information Sheets: A Guide to Informed Consents; Consent Template found on the HRPP website

5.6 Additional Elements of Informed Consent to be applied, as appropriate:

Additional situational-specific elements that an informed consent should include are:

- A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. (e.g., include when the research involves procedures in which the risks to subjects are not well known).
- A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable (e.g., include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known).
- Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research (e.g., include when withdrawal from the research is associated with adverse consequences).
- Procedures for orderly termination of participation by the subject.
- A 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 (e.g., include when the research is long term and interim information is likely to be developed during the conduct of the research).
- The approximate number of subjects involved in the study (e.g., include when the research involves more than minimal risk).
- Use of a written translation of the entire IRB approved English consent form is required for subjects who do not speak English or understand English and where researchers can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (e.g., if the Investigator is targeting a non-English speaking group). The IRB must approve all translated versions of the consent form. The IRB recommends the translation is done by a certified translator, however, the IRB will consider, on a case-by-case basis, allowing other translators to perform this function with verification that the translation is an accurate and acceptable presentation of the entire English version. The IRB may have added requirements in the review process to assure the translation is accurate.
- A statement that the monitor, the auditor, the IRB, and the regulatory authority will be granted direct access to the participant's original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the participant or the participant's legally acceptable representative is authorizing such access.
- The approval of the IRB.

- For research regulated by FDA:
    - A statement that informs the subject of the possibility that FDA may inspect the records.
    - For applicable clinical trials, the following statement notifying the subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not identify you. At most, the website will include a summary of the results. You can search this website at any time.”
    - Investigational New Drug Application (IND) submitted to FDA is not required to contain a copy of the consent document. For significant risk devices, the consent document is considered to be a part of the investigational plan in the application for an Investigational Device Exemption (IDE). Any substantive changes to the document made by an IRB must be submitted to the FDA (by the sponsor) for review and approval.
    - There is a statement noting the possibility that the FDA may inspect the records that will be provided to each participant.

Regulations & Guidance: DHHS 45 CFR 46.116(b);

5.6.1 GCP Additional Elements of Informed Consent to be applied, as appropriate: When following the ICH-GCP (E6) guideline, the IRB determines that the following consent disclosures are included:

- The participant's responsibilities.
- When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- When there is no intended clinical benefit to the participant, the participant should be made aware of this.

Additional situational-specific elements that an informed consent should include are:

- The trial treatment(s) and the probability for random assignment to each treatment.
- The compensation and/or treatment available to the subject in the event of trial-related injury.
- The anticipated prorated payment, if any, to the subject for participating in the trial.
- The anticipated expenses, if any, to the subject for participating in the trial
- That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential.

- The expected duration of the subject's participation in the trial.

Regulations & Guidance: DHHS 45 CFR 46.116(b); FDA 21 CFR 50.25(b)

5.7 Documentation of Informed Consent

The IRB will ensure that the consent will be appropriately documented according to legal requirements in accordance with, and to the extent required by 45 CFR 46.117, 21 CFR 50.27, the Good Clinical Practices and to the ethical principles in the Declaration of Helsinki.

- Except as provided in section 5.10, informed consent must be documented by the use of a written consent form approved by the IRB and personally signed and dated by the subject or the subject's legally authorized representative at the time of consent.
- In addition to signing the consent document, the subject or representative should enter the date of signature on the consent document to permit verification that consent was actually obtained before the subject began participation in the study.
- If the consent is obtained on the same day as the subject's involvement in the study begins, the subject's medical records/source documentation should document that consent was obtained prior to participation in the study.
- Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the person who conducted the informed consent discussion.
- Participants or participant's legally authorized representative will be given adequate time to read the consent document before it is signed.
- If a participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.
    - After the written consent document and any other written information to be provided to participants, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the consent document, the witness should sign and personally date the consent document.
    - By signing the consent document, the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the

participant's legally acceptable representative, and that consent was freely given by the participant or the participant's legally acceptable representative.

- A copy of the signed and dated consent document will be provided to the participant or the participant's legally acceptable representative, a copy placed on all of the appropriate records, and the original signed consent document should be retained in the study records.
- To allow the use of the long form of consent documentation, the IRB will determine the following:
    - The required and appropriate additional elements of disclosure are included in the consent process
    - The consent document embodies the basic and required additional elements of disclosure.
    - The required disclosure will be provided to each participant or a legally authorized representative in accordance with legal requirements.
    - Whether additional disclosures are required for inclusion in the consent process.
    - The participant or the participant's legally authorized representative will sign the consent document
    - A copy of the consent document will be given to the person signing the consent document.
    - The researcher will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

At this time Pennington Biomedical Research Center does not permit the informed consent documentation use of a "short form".

5.8 Continued Use of Data Following Withdrawal or Termination

- When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
- A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.

- The researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.
- If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

5.8.1 FDA Regulated Studies

It is the FDA policy that participant data collected up to the time of withdrawal must remain in the data set in order for the study to be scientifically valid.

5.9 Consent Monitoring

In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, or ensure that subjects are truly giving informed consent.

Such monitoring may be particularly warranted for: high risk studies; studies that involve particularly complicated procedures or interventions; studies involving highly vulnerable populations (e.g., children); studies involving study staff with minimal risk experience in administering consent to potential study subjects, or other situations when the IRB has concerns that consent process is not being conducted appropriately.

Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular Investigator or a research project.

If the IRB determines that consent monitoring is required, the HRPP Director will develop a monitoring plan and submit it to the IRB for approval. The consent monitoring may be conducted by HRPP Director, IRB staff, IRB members or another party, either affiliated or not with the institution. The investigator will be notified of the IRB determination and the reasons for the determination. Arrangements will be made with the investigator for the monitoring of the consent process for a specified number of subjects. When observing the consent process, the monitor will determine:

- Whether the informed consent process was appropriately completed and documented;
- Whether the subject had sufficient time to consider study participation;
- Whether the consent process involved coercion or undue influence;
- Whether the information was accurate and conveyed in understandable language; and
- Whether the subject appeared to understand the information and gave their voluntary consent.

Following the monitoring, a report of the findings will be submitted to the IRB, which will determine the appropriate action to be taken.

5.10 Waiver of the Consent Process

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- The research involves no more than minimal risk tangible or intangible risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects must be provided with additional pertinent information after participation.
- If the research involves using identifiable private information or identifiable biospecimens, the research cannot practicably be carried out without using such information or biospecimens in an identifiable format.
- The IRB must determine the regulatory criteria for waivers or alterations of the consent process are met.
- The research is not regulated by the FDA.

In addition, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that 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:

- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or

- Possible changes in methods or levels of payment for benefits or services under those programs.
- The research is not FDA-regulated

Regulations & Guidance: DHHS 45 CFR 46.116(c)-(d); 117(c); FDA 21 CFR 50.23

5.10.1 FDA Waiver of the Consent Process

Waiver of informed consent for certain FDA-regulated minimal risk clinical investigations will facilitate investigators' ability to conduct studies that may contribute substantially to the development of products to diagnose or treat diseases or conditions, or address unmet medical needs. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described above.

Regulations & Guidance: FDA 21 CFR 50.25, IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects

5.11 Waiver of Parental Permission

In some cases the IRB is allowed to waive parental permission by determining the criteria for waivers or alterations is met.

- Research on Public Benefit or Service Programs
    - The IRB can waive or alter the requirements for parental permission for non-exempt research examining state or local public benefit or service programs or certain features of those programs if all of the following criteria are met:

        - 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 public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs
        - The research could not practicably be carried out without the waiver or alteration
        - The research is not FDA-regulated.

- Minimal Risk Research
    - The IRB can waive or alter the requirements for parental permission for non-exempt research that meets all of the following criteria:
        - The research involves no more than minimal risk to subjects.
        - The waiver or alteration will not adversely affect the rights and welfare of subjects.
        - The research could not practicably be carried out without the waiver or alteration.
        - Whenever appropriate, subjects will be provided with additional pertinent information after participation
        - The research is not FDA-regulated.

- Research Designed to Study Conditions in Children
    - The IRB can waive or alter the requirements for parental permission for non-exempt research designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children) when the following additional criteria are also met:
        - An appropriate mechanism is in place to protect the children
        - The waiver is not inconsistent with federal, state, or local law.
        - The research is not FDA-regulated.
- Note: IRBs may waive the requirement for obtaining parental or guardian permission as described above even if the research involves greater than minimal risk to the participants. When determining an appropriate mechanism for protecting child participants (e.g., appointment of an advocate or assent monitor), investigators and IRBs will consider the nature of the research (including any potential risks and anticipated benefits) and the children's ages, maturity, condition, and psychological/emotional states.

5.12 Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either that the:

- Only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality; Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern.
- 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. Procedures such as non-sensitive surveys, questionnaires and interviews generally do not require written consent when conducted by non-researchers.
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- For screening, recruiting, and determining eligibility, the researcher will obtain information through oral or written communication with the prospective participant or legally authorized representative, or
    - The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
- In regards to confidentiality, the oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.
- For distinct cultural groups, the oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.

When following DHHS and FDA requirements:

- Waiver of Documentation of the Consent Process: Consent normally not required outside the research context
    - The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the subject; the IRB will consider whether to require the investigator to provide subjects with a written statement regarding the research.

The IRB Chair or primary reviewer will complete a review of the request for waiver of informed consent. In addition, the IRB minutes will document required determination regarding waiver of requirements for written documentation of informed consent. The minutes also will document the protocol specific findings justifying the requirements.

Consent form for clinical trials. Each clinical trial conducted or supported by a Federal department or agency must have an approved consent form, and this form must be posted online. (§ ____.116(h)). A “clinical trial” is a “research” study in which one or more “human subjects” are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes? (§__.101(a)(2), §__.102(b)). This provision applies only to those clinical trials that are conducted or supported by a federal department or agency.

When following DHHS requirements:

- Consent form must be posted by the principal investigator of the study
    - After clinical trial is closed to recruitment, AND
    - no later than 60 days after the last study visit by any subject required by the protocol, AND
    - On a website specified by the U.S. Federal Government
- Sponsors or investigators of certain clinical trials are required by U.S. law to register their trials on and submit summary results to ClinicalTrials.gov.
- If the researcher wants to request an exception to the requirement to post the consent document and the process to redact confidential commercial information from the consent, they must follow guidance from the Federal agency.