21.0 OBTAINING AND DOCUMENTING INFORMED CONSENT and ASSENT

21.1 OBJECTIVE

To describe policies and procedures for obtaining and documenting informed consent/assent and for reviewing and requesting waiver of informed consent or waiver of documentation of informed consent for non-exempt human research.

21.2 GENERAL DESCRIPTION

21.2.1 Informed Consent/Assent Permission: Process and Documentation

A major requirement of research involving human subjects is that investigators must obtain the informed consent of prospective subjects before they include these subjects in research. Informed consent is an ongoing educational process that takes place between the investigator and prospective subject, allowing the investigator and the participant to exchange information and ask questions. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation or of the process.

The consent document is not a substitute for discussion among investigators and research subjects. To ensure an effective informed consent process, the Institutional Review Board (IRB) and investigators comply with all applicable federal regulations (e.g., 21 CFR 50, 45 CFR 46.116, 117, and 38 CFR 16.116, 117). These regulations mandate the inclusion of eight basic informed consent elements. Six additional elements may be required, depending on the nature of the research. IRB policy also specifies the information to include in the consent process. The informed consent template included in the full and expedited IRB application forms outlines the required elements of informed consent. The investigator may use a short form if approved by the IRB in accord with applicable federal requirements.

REVISION/ UPDATE TO THE COMMON RULE

21.2.2 *When reviewing research subject to the revised Common Rule, the Howard University IRB will evaluate the provisions for informed consent as described in the Howard University IRB SOPP with the below variations. Investigators conducting research subject to the revised Common Rule must adhere to these requirements.*

21.2.3 General Requirements for Informed Consent *[§ .116(a)]*

In addition to the requirements for obtaining informed consent and the consent process described in the Howard University IRB SOPP the following specific

requirements for consent, whether written or oral, apply to research subject to the revised Common Rule:

Note that these requirements are "in addition" to that specified in the old SOPP.

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR.

4. The prospective subject or the LAR 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.

Except for broad consent (See Section 21.5.16 Broad Consent [§ .116(d)]

5. Informed consent – Content

Must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

i. Generally, the beginning of an informed consent should include a ***concise*** *explanation of the following:*

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

any, that might be advantageous to the prospective subject.

However, based upon the facts of an individual protocol, the IRB may require that different (or additional) information be presented at the beginning of an informed consent to satisfy this requirement.

Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

No informed consent may include any exculpatory language through which the subject or the LAR 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.

21.3 DEFINITIONS

Assent is defined as affirmative agreement of a child or an individual with impaired consent capacity to participate in research. Mere failure to object, or absent affirmative agreement, should not be construed as assent.

Permission is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications.

In Washington, D.C., the terms *child* or *children* refer to all individuals less than 18 years of age unless the individual(s) is legally emancipated (See section *Emancipated Individuals* for details of Washington, D.C. state law). Individuals under 18 years of age who are not emancipated meet the federal definition for "child" [e.g., Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and U.S. Department of Education].

Legally Authorized Representative (LAR) is an individual who has the authority to make research participation decisions on behalf of another. In accord with state law and federal regulation, individuals who can serve as legally authorized representatives are as follows:

- Permission and/or authorization by a legally authorized representative for children: Consistent with Washington, D.C. health care decision statutes for choosing an LAR for children, the following responsible parties in the order of priority listed shall be authorized to make research participation decisions on behalf of the child: (a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the parent of the child.

- Permission and/or authorization by a legally authorized representative for individuals with impaired consent capacity: Consistent with Washington, D.C. health care decision statutes for choosing a legally authorized representative for adult subjects unable to consent, one of the following responsible parties, in the following order of priority (if no individual in a prior class is reasonably available, willing, and competent to act), is authorized to make research participation decisions on behalf of the person: (a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the attorney-in-fact named in a durable power of attorney, if the durable power of attorney specifically includes authority for the decisions to be made under the consent; (c) the spouse of the person; (d) an adult child of the person, or if the person has more than one (1) child, the majority of the adult children who are reasonably available for consultation; (e) the parents of the subject; (f) the nearest living relative, or if more than one of the same relation, a majority of the nearest living relatives.

- Consent by an LAR should involve all the same considerations that informed consent from a competent subject involves.

In Washington, D.C., a *guardian* is an individual who may serve as an LAR as defined above. These individuals meet the federal definitions for guardian.

21.3.1 Waiver of Informed Consent Process

The IRBs have the authority to approve a consent procedure that does not include or which alters some or all of the federally mandated elements of informed consent provided the approved procedure meets applicable federal regulations.

Recent FDA Changes Before Revision to the Common Rule: In July 2017, the FDA revised its waiver policy at 21 C.F.R. Sections 50.3(k) and 56.102(i) to be in agreement with that of the OHRP policy at 45 C.F.R. Section 46.116(d). The FDA defines Minimal Risk as the “probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life

or during the performance of routine physical or psychological examination or test". An IRB may waive informed consent if it finds and documents that:

- The clinical investigation involves no more than "minimal risk" to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of subjects.
- The clinical investigation could not practically be carried out without the waiver or alteration, and
- The Subjects whenever appropriate, will be provided with additional pertinent information after participation.

REVISION/ UPDATE TO THE COMMON RULE

21.3.2 Waiver or Alteration of Informed Consent [§_.116(E) And (F)]

When reviewing research subject to the revised Common Rule, the Howard University IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the revised rule and summarized below. The IRB's determination will be documented in the IRB record and communicated to the investigator as described in the Howard University IRB SOPP.

21.3.3 General Waiver or Alteration of Consent

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the Howard University IRB must determine and document that the below criteria are satisfied.

1. *The research involves no more than minimal risk to the subjects;*
2. *The research could not practicably be carried out without the requested 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. *Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.*

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Restrictions:

1. *Waivers –*
    a. *If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in 21.2.1b (General Requirements for Informed Consent [§ .116(a)]) and Section 21.5.16 (Broad Consent [§ .116(d)]), 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.*

2. *Alterations –*
    a. *An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in 21.2.1b (General Requirements for Informed Consent [§ .116(a)]).*
    b. *If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 21.5.16 (Broad Consent [§ .116(d)]).*

21.3.4 Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the Howard University IRB must determine and document that the below criteria are satisfied.

1. *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***

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

Restrictions:

1. *Waivers –*
   a. *If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in 21.2.1b (General Requirements for Informed Consent [§ .116(a)]) and Section 21.5.16 (Broad Consent [§ .116(d)]), 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.*

2. *Alterations –*
   a. *An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in 21.2.1b (General Requirements for Informed Consent [§ .116(a)]) and Section 21.5.16 (Broad Consent [§ .116(d)]).*
   b. *If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 21.5.16 (Broad Consent [§ .116(d)]).*

A summary of applicable waiver federal regulations and University requirements is as follows:

- Non-FDA regulated studies: to waive informed consent requirements, the IRB must find and document that the study meets the requirements in 45 CFR 46.116(c)(d) and 38 Part 16.116(c)(d).

- Non-FDA or DHHS funded or regulated studies involving planned emergency research: the Howard University (HU) does not accept proposals that require a waiver of informed consent for planned emergency research for non-FDA/DHHS regulated research.

- FDA regulated and/or DHHS funded planned emergency research: the IRB approves exceptions for informed consent requirements if the study meets all of the requirements specified in 21 CFR Subpart B 50.24 and/or 45 CFR 46.101(i).

- Single subject emergency use of a FDA regulated test article: the HU policy is more stringent than the FDA requirements outlined in 21 CFR 50.23. HU requires investigators to consult with the IRB Chair or the RCO before using the test article in a single subject without informed consent. The IRB may allow an exception to consultation, consistent with 21 CFR 50.23.

- Waiver of parental or guardian permission in non-FDA regulated studies: when consent of parents or guardians is not a reasonable requirement because it poses additional risk to the potential subject or the parents' interest may not adequately reflect the child's interest (e.g., neglected or abused children), the IRB may waive parental or guardian permission in accord with 45 CFR 46 Subpart D and 46.408(c) and Subpart A 46.116.

21.3.5 Waiver of Documentation of Informed Consent

Federal regulations permit an IRB to waive the documentation requirements for obtaining informed consent under special circumstances.

- FDA regulated studies: IRB may waive documentation for some or all of the subjects if the study meets the conditions listed in 21 CFR 56.109(c).

- Non-FDA regulated studies: the IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if the study meets the requirements in 45 CFR 46.117(c) and 38 CFR Part 16.117(c).

21.4 RESPONSIBILITY

Execution of SOPP: Principal Investigator (PI)/Study Personnel, Office of Regulatory Research Compliance, RCO, IRB, HU Legal Counsel.

REVISION/ UPDATE TO THE COMMON RULE

21.4.1 Elements of Consent

In addition to the elements of informed consent described in the Howard University SOPP, the following additional elements are required for research subject to the revised Common Rule. The requirements for Broad Consent are described in Section 21.5.16 (Broad Consent [§ .116(d)]).

***Basic Elements** [§ .116(b)]*

5. *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.*

***Additional Elements** (must be included when appropriate) [§ .116(c)]*

1. *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;*
2. *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;*
3. *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).*

21.5 PROCEDURES

21.5.1 Documentation of Consent [§ .117]

The revised Common Rule modifies the requirements for documentation of consent as described below. When reviewing research subject to the revised Common Rule, the Howard University IRB will apply the requirements summarized below.

Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy must be given to the person signing the ICF.

The ICF may be either of the following:

1. *A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or*

2. *A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR and that the key information required by §__.116(a)(5)(i) (See 21.2.1b (General Requirements for Informed Consent [§_.116(a)] #5.a)) was presented first to the subject, before other information, if any, was provided. When this method is used:*

    a. *The oral presentation and the short form written document should be in a language understandable to the subject; and*
    b. *There must be a witness to the oral presentation; and*
    c. *The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and*
    d. *The short form document is signed by the subject;*
    e. *The witness must sign both the short form and a copy of the summary; and*
    f. *The person actually obtaining consent must sign a copy of the summary; **and***
    g. *A copy of the summary must be given to the subject or*

representative, in addition to a copy of the short form.

Who **Approves**, **Signs** and or **Receive Copies**?			
	Written Informed Consent	**Short Form Written Informed Consent**	**Short Form Written IC Summary**
IRB	Approve	Approve	Approve
Subject or legally authorized representative	Present/copy/**sign**	Present/copy/**sign**	Present/copy
Person administering consent	Present/copy/**sign**	Present/copy	Present/copy/**sign**
Witness		Present/**sign**	Present/**sign**

21.5.2 Informed Consent Process and Documentation

- The PI submits a proposed informed consent procedure and written form with his/her IRB application prior to initiation of research, except in situations such as research proposals that meet exempt criteria (although informed consent(s) may be included). The PI indicates in the IRB application the study personnel who will participate in the informed consent process or individuals the PI will authorize to obtain informed consent on his/her behalf.

- The HU IRB has an informed consent template, available in the full and expedited review applications on the ORRC website. Investigators use this template as a guide unless the IRB grants exceptions or a waiver. The consent template contains the eight required elements, the six additional elements of informed consent, and additional IRB requirements for HU research involving human subjects. See *Additional Elements Where Appropriate* below.

- At a minimum, the proposed consent process and form include the following eight federally required elements and additional elements where appropriate:

    - Research statement: a statement that the study involves research, an explanation of the purpose of the research, an explanation of the expected duration of participation, a description of the procedures involved, and identification of any procedures which will be experimental.

    - Reasonably foreseeable risks or discomforts: a statement that describes foreseeable risks or discomforts associated with the research, the likelihood of their occurrence, and the ramifications associated with the risks (e.g., decreased blood count may result in need for a blood transfusion).

    - Reasonably expected benefits to subjects or others: a statement that describes benefits to subjects or others that may reasonably be expected from the research including no benefit, if this is applicable. Payment for participation in a research project is not considered a benefit.

    - Appropriate alternatives: a statement that describes with enough detail any alternative procedures or course of treatment that may benefit the subject. If no alternatives exist, the consent form must state that there are no

alternatives except not to participate.

- Extent of confidentiality: a statement that describes the extent to which the investigator/study personnel will maintain or not maintain confidentiality of records identifying the subject (e.g., law requires reporting child abuse, etc.) and describes how the research team will protect subjects' private records during and after the conclusion of proposed research studies. Any research that is subject to audit or inspection must identify who will have access to the subject's record (e.g., FDA, National Institutes of Health (NIH), HU, Government Accounting Office, sponsors, or contract research organizations).

- Compensation or treatment for injury: for studies with greater than minimal risk, a statement explaining any compensation and an explanation of any medical treatments available if injury occurs or where the subject may obtain further information. The IRB informed consent template contains standard statements in accordance with HU policy.

- Contact information: a statement that describes contact information details, including telephone numbers, and whom to contact for the following situations: questions about the research (e.g., investigator and other team members), questions about subjects' rights, comments, suggestions, or input (e.g., the ORRC RCO), and in the event of a research-related injury (depending on the nature of the research, the PI or a physician on the research team).

- Voluntary participation statement: a statement that describes clearly that participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- Additional elements where appropriate: The IRB requires the additional elements unless the item(s) does not apply given the nature of the research or the proposed procedures (e.g., subjects will not receive remuneration for participation).

    - Unforeseeable risks to subjects, embryos, or fetuses: a statement warning subjects that some risks are currently not known or foreseeable, when applicable;
    - Investigator-initiated termination of participation: a statement that describes the instances in which an investigator may terminate a subject's participation (e.g., subject noncompliance, subject not benefiting from research, etc.);

- Additional costs: a statement that describes any additional costs a subject may encounter such as transportation, time away from work, parking, health costs, etc.;
- Early withdrawal/procedures for termination: a statement that describes a subject's right to withdraw from the study and any procedures that may be necessary after an early withdrawal for subject's safety;
- Significant new findings: a statement that subjects will be told of any new findings which may affect willingness to continue in the research;
- Approximate number of subjects: a statement that explains the approximate number of subjects to be enrolled in the study, nationwide and locally;
- Disposition of subject's blood samples: DNA testing, cell lines, development of future products;
- Payment: a statement which includes all information concerning the amount and schedule of payment for participation.

- If the research involves vulnerable populations or sensitive issues, the investigator addresses additional regulatory and/or institutional requirements. The investigator may consult the ORRC staff for guidance. The vulnerable populations and sensitive issues include, but are not limited to:
  - Research involving the participation of children;
  - Research involving individuals with *impaired decision-capacity*;
  - Research involving HIV screening and/or AIDS research;
  - Research involving DNA banking, genetic research, or gene therapy;
  - Research involving prisoners.
  - Research involving *and economically or educationally disadvantaged persons.*

- The investigator also must address the following issues, if applicable to the proposed research:
  - DHHS/NIH-sponsored multicenter clinical trial: the investigator must include a copy of the DHHS/NIH-approved sample informed consent document in the application. The investigator must justify in writing any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document, and the IRB must approve these deletions or modifications. For trials sponsored by the National Cancer Institute, investigators must forward copies of such IRB-approved changes, with their justifications to the appropriate Cooperative Group headquarters;
  - Investigational drugs, devices, or biologics: the investigator must inform the subject in the purpose that the study includes evaluation of both safety and effectiveness of the test article and state the test article is investigational, and, if applicable, not approved by the FDA;
  - Applicable FDA regulated clinical trials: the investigator must inform the subject that the clinical trial will be entered into a national clinical trial registry data bank;

- The process of dose escalation;
- The possibility of risk for an unborn child, a man or woman's ability to procreate, or a woman's ability to conceive or carry a child will include the statement listed in the Instructions for Documentation of Informed Consent, which may be revised to meet the needs of the study;
- Additional requirements as specified in the IRB full and expedited review; applications/informed consent template.

- If the research involves genetic testing or DNA banking the PI must address, in the informed consent process and form, the applicable issues discussed in the Issues to be addressed in Obtaining Informed Consent in DNA Banking and Genetic Research document.

- If the research involves establishing a specimen/tissue repository, the PI must address, in the informed consent process and form, the applicable issues discussed in the issues to be addressed in Obtaining Informed Consent Involving Specimen Collection for Tissue/Specimen Repositories document.

- The IRB assesses the PI's description of the informed consent process to ensure that the process meets the general requirements of informed consent (i.e., consent be obtained from the subject or subject's legally authorized representative; be in language understandable to the subject; be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate and that minimize coercive influences; does not include language through which the subject is made to waive his/her legal rights or releases the investigator, sponsor, or institution from liability for negligence). The IRB uses the Criteria for IRB Approval: Reviewer Checklist in conducting this assessment.

- The IRB determines whether disclosure of any investigator conflict of interest is warranted in the informed consent process and document.

- The IRB is responsible for reviewing the proposed informed consent document(s) to ensure that all applicable federal and HU requirements are met.

- Once the IRB approves the study, ORRC staff affixes an approval stamp to every page of the approved informed consent document, the first page of which includes the approval and expiration dates. ORRC staff then forward the form to the investigator. Investigators may only enroll subjects using informed consent/assent forms which have a valid "IRB approval" stamp unless the IRB grants a waiver from the requirement for informed consent or documentation.

- If the study includes documents approved by the IRB for use in the informed consent process which are not signed by subjects under waiver of documentation, (e.g., survey cover letters, web page cover letters, telephone scripts), ORRC staff affix an approval stamp to the document which includes the

approval and expiration dates. The investigator removes the approval stamp and produces a clean copy of the approved version to post or disseminate to potential subjects.

- The investigator is responsible for ensuring that informed consent is obtained from each research subject or his/her LAR after the subject or the subject's LAR has had an adequate opportunity to read the form and prior to subject participation in any part of the study, using the process and form approved by the IRB.

- The subject or the subject's LAR and the person providing the information to the subject sign and date the informed consent document at the time of consent. Only individuals authorized (in the IRB approved protocol) to obtain informed consent sign on the line entitled "Name of [authorized] person obtaining consent from the subject."

- The investigator's signature on the informed consent document verifies that the person who explained the study and obtained informed consent is qualified and that the IRB has approved him/her to do so (may not be applicable for informed consent document for nonmedical protocols). The subject or LAR signing on the subject's behalf receives a copy of the signed form.

21.5.3 Use of the Short Form Written Consent Document

- The PI may request to use a short form written consent document stating that study personnel have presented the elements of informed consent (as required by 45 CFR 46.116) orally to the subject or the subject's LAR.

- The IRB reviews the request and may approve the short form option for documentation only if the study meets all of the requirements outlined in 45 CFR 46.117(b), and as applicable, 21 CFR 50.27(b) and/or 38 CFR 16.117(b).

- When the IRB approves use of the short form method:

    - The PI must ensure there will be a witness to the oral presentation. For participants who do not speak English, the PI must ensure the witness is conversant in both English and the language of the participant.
    - The IRB must approve a written summary of the oral content presented to the subject or the subject's LAR, which embodies the basic and appropriate elements of disclosure.
    - The subject or the subject's LAR signs the short form. For FDA-regulated research the subject or the subject's LAR signs *and* dates the short form.
    - The witness signs both the short form and a copy of the summary.
    - The person actually obtaining consent signs a copy of the summary.
    - The person obtaining consent gives a copy of the summary to the subject or the subject's LAR, in addition to a copy of the short form.

21.5.4 Howard University Research Involving Individuals with *Impaired Decision-Capacity*,

- The PI completes the IRB application, including forms, and after obtaining IRB approval implements the research in accordance with the requirements for assessing *decision-capacity*, specified in the HU *Impaired Decision-Capacity* Policy. See this policy and the IRB application for details on the procedure.

- In conducting the review, the IRB uses the recommendations for assessing *decision-capacity*, as a guide to ensure additional safeguards are in place.

21.5.5 Assent

- The PI must develop processes and forms consistent with guidance provided in the applicable parts of this policies and procedures manual.

- The PI is responsible for including in the IRB application a description of the process/ procedure for obtaining and documenting assent when research includes:
  - Children and/or;
  - Individuals with *impaired decision-capacity*.

- The IRB reviews the proposed process and, if applicable, the assent form to ensure compliance with IRB guidance and federal requirements.

21.5.6 Emancipated Individuals

- Under Washington, D.C. state law, absent a court order, there are no classes of individuals under the age of eighteen who are named as emancipated for all purposes. Consequently, if the PI would like to enroll some or all prospective subjects as emancipated, the PI consults with HU legal counsel when preparing the IRB application and prior to submitting the application to the IRB. He/she includes Legal Counsel's recommendations in the IRB application.

- Under Washington, D.C. state law, in general, individuals under the age of eighteen who are living on their own, have borne a child, or are married are viewed as emancipated and are able to consent to participate in some research studies. Legal counsel reviews the studies on a case-by-case basis to determine whether the subjects are legally emancipated. If pregnant individuals under the age of eighteen are neither married nor living on their own (i.e., living at home under the care of their parents or some other adult), they are not legally emancipated, and both parental permission and subject assent are needed.

- When conducting the study, given the variety of living situations that an individual may find him or herself living in, investigators may need to make decisions on a subject-by-subject basis regarding the applicable state statutory requirements. If

there are questions relating to whether an individual meets the state statutory requirements to be emancipated, the investigator consults HU legal counsel.

- If a child or a class of subjects is deemed to be emancipated, then 45 CFR 46 Subpart D and 21 CFR 50 Subpart D do not apply, and the subject may provide informed consent as an adult.

21.5.7 Obtaining Informed Consent outside the State of Washington, D.C.

- If the PI conducts the research outside the state of Washington, D.C. and the research involves children, an LAR, or a guardian, the investigator must follow the requirements of the state/country in which he/she will conduct the research. The PI must also determine which individuals meet the federal definitions for child/children, LAR, or guardian in the location outside the state of Washington, D.C.

- The PI identifies the state law(s) applicable to the determination of legally authorized representative and contacts HU legal counsel for review and determination prior to approval by the IRB. If the PI is unable to identify applicable state law(s), the PI contacts HU legal counsel for assistance prior to approval by the IRB.

21.5.8 Non-English Speaking Subjects

- Investigators must deliver all information regarding informed consent/assent to potential subjects or their LAR in the subject's native language(s) or one that the subject understands. The investigator must provide the IRB and prospective subjects a translated version of the consent/assent form.

- ORRC staff identifies a cultural consultant to review the study and informed consent/assent document for accuracy and cultural appropriateness. If ORRC staff is unable to identify an individual to serve as a cultural consultant, the investigator provides a cultural consultant for review of accuracy of the informed consent form and cultural appropriateness.

- ORRC staff ensures that the consultant does not have a conflict of interest (See IRB Member and Consultant Conflict of Interest SOPP).

- The IRB may use expedited review procedures in approving such documents if the IRB has already approved the English language consent/assent document, and the cultural consultant attests to the accuracy of the translation.

21.5.9 Research that Requires Monitoring of Informed Consent/Assent Process and Procedures

- The IRB determines which research requires monitoring of the informed consent/assent process and the procedure and frequency with which such monitoring will occur based on the degree of risk to subjects, the need for protection of vulnerable subjects, or concerns related to an incident of noncompliance.

- A designated IRB member(s), or other designee (as determined by the IRB) may monitor the informed consent/assent process. The monitoring may involve direct observation, interviews of subjects, surveys of subjects, or other means as deemed appropriate by the IRB for the circumstances.

21.5.10 Recordkeeping

- For studies conducted at a HU hospital or clinic, the PI places a copy of the signed consent form or, if applicable, assent form in the medical record unless the IRB waives the requirement. The PI must also keep the original signed consent/assent document in his/her research records in accord with the IRB-approved protocol.

- For studies conducted in other settings (i.e., not conducted in HU hospital/clinic), the PI keeps the original signed informed consent form and, if applicable, assent in accord with the ORRC/IRB Recordkeeping SOPP and the study procedures as approved by the IRB.

- The IRB documents its review as delineated in the applicable procedures for a particular review mechanism (e.g., initial full review, expedited review, modification review, etc.) and the ORRC/IRB Recordkeeping SOPP.

21.5.11 Waiver of Informed Consent for Non-FDA Regulated Studies

- The PI makes a preliminary decision to seek waiver of informed consent and submits a justification for the request in the IRB application.

- The IRB may waive the requirements or alter elements if it finds and documents:
  - The research involves no more than minimal risk to the subjects;
  - The research will not adversely affect the rights and welfare of subjects;
  - The investigator could not practicably conduct the research without the waiver or alteration.
  - Whenever appropriate, study personnel provide subjects additional pertinent information after participation.

- The IRB may also waive the requirement to obtain informed consent or alter some of the elements if the IRB finds and documents that:

- The research or demonstration project is to be conducted by or is subject to approval of state or local government officials and is designed to study, evaluate or examine public benefit of service programs, procedures, methods or levels of payment; AND
- The investigator could not practicably conduct the research without the waiver or alteration.

- If the IRB reviews the protocol at a convened meeting, ORRC staff document the waiver of informed consent approval in the IRB meeting minutes.

- If the protocol is eligible for expedited review, the expedited reviewer documents on the expedited review approval signature page whether the study meets each of the criteria.

21.5.12 Waiver of Informed Consent for FDA Regulated and/or DHHS Funded Planned Emergency Research

- The PI completes the IRB application following the procedures outlined in the Initial Full Review SOPP. The ORRC staff screen the application using procedures outlined in the Initial Full Review SOPP. ORRC staff sends the PI a copy of the 21 CFR 50.24 and a copy of the summary of the rule in the "Overview of Basic IRB Regulations" document. ORRC staff asks the PI to address any additional issues not included in the standard IRB application, such as plans for public disclosure in communities prior to initiation.

- At the convened meeting, the ORRC staff provide the IRB Chair or designee with a copy of 21 CFR 50.24 and/or 45 CFR 46.101(i). The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable controverted issues. The outcomes of the review are the same as those listed in the Initial Full Review SOPP. ORRC staff records the discussion in the minutes, following the procedures in the Minutes of IRB Meetings SOPP.

21.5.13 Exception from Informed Consent Requirement for Use of FDA-Regulated Test Articles in a Single Subject

- The PI must obtain informed consent, even in an emergency use situation, unless the study meets certain conditions (See Emergency Use SOPP).

21.5.14 Waiver of Parental or Guardian Permission for Research Involving Children in Non-FDA Regulated Research

- The PI makes a preliminary decision to seek waiver of parental or guardian permission for participation of children in accord with 45 CFR Subpart D 46.408 (c) or 45 CFR 46.116(c)(d). The PI includes justification for the waiver and a

description of a substituted appropriate mechanism for protecting the children who will participate in the research.

- The IRB may approve the request provided the study meets the conditions outlined in 45 CFR Subpart D 46.408(c) or 45 CFR 46.116 (c)(d).

- If the IRB reviews the research at a convened meeting, ORRC staff records the discussion on each criterion in the minutes.

- If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited review signature page whether the research meets the criteria.

21.5.15 Waiver of Documentation of Informed Consent for FDA-Regulated Research

REVISION/ UPDATE TO THE COMMON RULE

21.5.15.1 Waiver of Documentation of Informed Consent [§ .117(c)]

*The revised Common Rule **adds a third condition under which an IRB may waive the requirement for an investigator to obtain a signed informed consent form**. When reviewing research subject to the revised Common Rule, in addition to the criteria described in the Howard University SOPP, the Howard University IRB may also approve a request for a waiver of documentation of consent if it finds that:*

1. *The subjects or LARs 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.*

The IRB's determination will be documented in the IRB record and communicated to the investigator as described in the Howard University IRB SOPP.

- The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.

- The IRB may waive the documentation requirement to obtain a signed consent if the research presents no more than minimal risk and involves no procedures for which the IRB normally requires written consent.

- When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the PI will give to the subjects.

- In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.

- If the IRB reviews the request at a convened meeting, ORRC staff includes the discussion on each of the criteria in the IRB minutes.

- If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited reviewer approval signature sheet whether the research meets each of the criteria.

21.5.16 Waiver of Documentation of Informed Consent for Non-FDA Regulated Studies

- The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.

- The IRB may waive the documentation requirements to obtain a signed consent if:
  - 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. Study personnel must ask each subject whether the he/she wants documentation regarding the research; or
  - The research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required (i.e., a cover letter or a phone script).

- In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.

- When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that subjects will receive.

- If the IRB reviews the request at a convened meeting, ORRC staff includes the discussion on each of the criteria in the meeting minutes.

- If the IRB reviews the protocol using expedited procedures, the expedited reviewer documents on the expedited reviewer approval signature sheet whether the research meets each of the criteria.

REVISION TO THE COMMON RULE

21.5.17 Broad Consent [§ .116(d)]

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted under the revised Common Rule. ***Broad consent is not currently recognized in FDA regulation or guidance.***

When obtaining broad consent, the general requirements for informed consent described in 21.2.1b (General Requirements for Informed Consent [§ .116(a)]) apply except as noted. The following elements of broad consent [§ .116(d)] shall be provided to each subject or the subject's LAR:

1. *A description of any reasonably foreseeable risks or discomforts to the subject;*
2. *A description of any benefits to the subject or to others which may reasonably be expected from the research;*
3. *A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;*
4. *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;*
5. *For research involving biospecimens, 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;*
6. *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);

7. *A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;*

8. *A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;*

9. *A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);*

10. *Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;*

11. *Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and*

12. *An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.*

***Research in Which Broad Consent Would be Obtained**: Investigators must include information regarding the circumstances under which broad consent will be obtained, the proposal for tracking of responses, and the proposed consent form(s) (or oral script if a waiver of documentation of consent is sought) and any other consent materials (e.g., information sheet, audiovisual materials, etc.) in their submission to the IRB. The Howard University IRB will review the information provided with the aid of a checklist to ensure that all requirements are satisfied. The outcome of the IRB's review will be communicated to the investigator in writing following the procedures described in the Howard University IRB SOPP.*

***Research in Which Broad Consent Was Previously Obtained:** When investigators propose research involving the use of identifiable private information and/or identifiable biospecimens research for which broad consent was obtained, the investigators must include documentation of the IRB approval for the storage or maintenance of the information or specimens and a copy of the consent form and/or other materials. The Howard University IRB will review the information provided with the aid of a checklist to ensure that all requirements are satisfied. The outcome of the IRB's review will be communicated to the investigator in writing following the procedures described in the Howard University IRB SOPP.*

21.5.18 Screening, Recruiting, or Determining Eligibility [§_.116(g)]

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects for inclusion in the research. Pursuant to the revised rule, the Howard University IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective subject or the subject's LAR if either of the following conditions is met:

3. *The investigator will obtain information through oral or written communication with the prospective subject or LAR, or*
4. *The investigator will obtain identifiable private information or*

identifiable biospecimens by accessing records or stored identifiable biospecimens.

When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a subject (including the use of their identifiable private information or biospecimens) in other research activities.

21.5.19 IRB Review of Grant Applications

The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. Unless required by the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the Howard University IRB will no longer require submission of, or conduct review of, Federal grant applications or proposals when research is subject to the revised Common Rule.

21.5.20 Posting of Clinical Trial Consent Forms [§ .116(h)]

The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal department or agency. 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 website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

Federal guidance or instructions regarding the implementation of this requirement was not available at the time this SOP went into

effect. Until federal guidance or instructions are available, when Howard University is the prime awardee, Investigators should consult with the grant officer regarding how to satisfy this requirement.

21.5.21 IRB Records [§_.115]

The revised Common Rule includes additional requirements for IRB records. When Howard University Investigators are engaged in human subjects research subject to the revised Common Rule, the following records will be maintained in addition to those described in the Howard University SOPP.

1. *Institutional Records –*
    a. *For nonexempt research involving human subjects covered by the Common Rule (or exempt research for which limited IRB review takes place) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol)*
2. *IRB Records –*
    a. *The rationale for conducting continuing review of research that otherwise would not require continuing review (as described under continuing review)*
    b. *The rationale for a determination that research appearing on the expedited review list published in the Federal Register is more than minimal risk*

21.5.22 Additional SOPP Content

Howard University voluntarily extends the Common Rule or the Common Rule and subparts B, C, & D to all non-exempt human subjects research on their FWA.

Statements that research involving Newborn Dried Blood Spots is considered research involving human subjects and that waivers of consent may not be granted for the Newborn Dried Blood Spots.

21.6 REFERENCES

21 CFR 50.20
21 CFR 50.23-25
21 CFR 50.27
21 CFR 56.109 (b),(c)
45 CFR 46.101(i)
45 CFR 46.109 (b),(c)
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
34 CFR 97 [Department of Education Subpart D]