DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT
POLICY AND PROCEDURE

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	EFFECTIVE: 02/19
APPROVED BY: Sohail Rao, MD, D.PHIL, President & Chief Executive Officer (Institutional Official, OHRP, DHHS)	REVIEWED/REVISED: 02/19, 02/20, 11/20, 01/21, 04/21, 05/21, 03/22

Purpose:
Informed consent is one of the primary ethical requirements underpinning research involving humans; it reflects the basic principle of respect for persons. It should always be remembered that informed consent is an ongoing process, not a single event, designed to provide potential research subjects with all of the relevant information they need to make a fully informed, autonomous decision as to whether they wish to participate in a research study.

To assist investigators and coordinators who are conducting research, information regarding the informed consent process is provided on the HRPO website. Examples and instructions are available, including guidelines for the informed consent process and sample language for the informed consent document.

Applies To:
This policy applies to the following: staff and members of the Institutional Review Board; potential research investigator; Physician staff employed by RMF and its affiliates; staff employed by DHR Health and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; staff and physicians of non-academic institutions with a current affiliation agreement with DHR Health Institute for Research & Development; Physicians with privileges to practice medicine in DHR Health, Physicians and staff employed by Starr County Memorial Hospital and its affiliates; faculty, fellows, residents, students of academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; staff and physicians of non-academic institutions with a current affiliation agreement with Starr County Memorial Hospital and its affiliates; Physicians with privileges to practice medicine in Starr County Memorial Hospital and its affiliates.

IRB Review of Informed Consent Process:
During its review of the informed consent process as described in the protocol, the IRB requires that:

- Adequate opportunity is provided to the subject or the subject's legally authorized representative to read the consent document and ask questions regarding the study before the informed consent document is signed.
- The consent process minimizes the possibility of coercion or undue influence. The consent discussion is in language understandable to the subject or the subject's legally authorized representative.
- The information communicated to the subject or the subject's legally authorized representative during the consent process does not include any exculpatory language that waives or appears to waive any legal rights that the subject may have, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for harm caused by their negligence.

In addition, the IRB requires that the consent document include all of the basic elements of consent set forth in 45 CFR 46.116 and, if applicable, 21 CFR 50.25, except those which can be waived, or altered, according to regulation. The IRB may also require that additional elements or information be given to the prospective subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of the research subject.

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Basic Elements of Informed Consent

45 CFR 46.116 (b) or 21 CFR 50.25(a) include:

- 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 that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of benefits to the subject or others that may be reasonably expected from the research;
- The disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained;
- For medical research involving more than minimal risk, an explanation as to whether or not any compensation or any medical treatments are available if injury occurs during study participation;
- The identification of an individual who can be contacted by the subject for answers to questions related to the research, research-related injury, or their rights as a research subject;
- 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 s/he is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - 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
    - 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 of Informed Consent

45 CFR 46.116 (c) or 21 CFR 50.25(b) that should be addressed, as appropriate include:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- 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 and 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;
- The approximate number of subjects involved in the study.

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

Consent Form Addendum:
When subjects need to be informed of specific changes in the risk or benefit of study participation, an addendum consent, which focuses on the new information, may be more appropriate than a modified consent document. A consent form addendum may also be used to inform enrolled subjects about significant new findings that may have a bearing on their willingness to continue participation in the study.

Waivers:
Waiver of the requirement to obtain a signed informed consent

Regulatory Requirements
Following expedited or full-board review, the IRB may waive the requirement to obtain a signed consent form for some or all subjects if it finds any of the following:

1. 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 (i.e., see 45 CFR 46.117(c)(1)(ii); 21 CFR 56.109 (c) (1)) or
2. the only record linking the subject and the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., see45 CFR 46.117(c)(1)(i))
    i. Subject to granting a waiver of the requirement to obtain a signed informed consent based on this criterion, the IRB will require the principal investigator to ask each subject whether s/he wants documentation linking him/her to the research, and the subject's wishes will govern.
3. 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. (i.e., see 45 CFR 46.117(c)(1)(iii))

The IRB will not waive the requirement to document informed consent based on criterion #2 or #3 if the research study is subject to the FDA regulations (21 CFR Parts 50, 56) governing human subject protections.

Upon granting a waiver of the requirement for obtaining a signed informed consent, the IRB reviews and approves the information that will be provided to potential subjects to obtain their verbal consent for study participation, and the procedure(s) that will be used by the investigators to document obtaining verbal consent.

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Waiver (or Alteration) Of Informed Consent:
Regulatory Requirements
The IRB requires that informed consent be sought from each prospective subject or the subject's legally authorized representative prior to participation in research activities, with the following exceptions.

1. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or
2. The IRB may waive the requirement to obtain informed consent if it finds and documents that the research activity meets the criteria for a waiver of consent as addressed under 45 CFR 46.116(f)(3) as follows:
    - The research involves no more than minimal 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;
    - Whenever appropriate, the subjects will be provided with additional pertinent information after participation; and
    - 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;
3. The IRB may also waive the requirement to obtain informed consent if it finds and documents that the research activity meets the criteria for a waiver of consent as addressed under 45 CFR 46.116 (e) This IRB does not typically receive requests of this type. If investigators wish to request this waiver, they should contact the IRB for further guidance.

The IRB does not waive the requirement to obtain informed consent if the research study is subject to the FDA regulations (21 CFR Parts 50, 56) governing human subject protections except for planned emergency research 21 CFR 50.24.

Waiver of Consent for Planned Emergency Research:
The IRB (subsequent to full-board review) may approve a research study without requiring that informed consent of all research subjects be obtained if it finds and documents that the research activity meets the criteria for an exception to the requirement to obtain informed consent for emergency research as addressed under planned emergency research regulations found at 21 CFR 50.24.

Waiver of Parental Consent for Abused or Neglected Children:
The IRB may waive the requirement for parental consent if it determines that the research study is designated for conditions or for a subject population (e.g., neglected or abused children) for which parental or guardian permission is not a reasonable requirement to protect the subjects (refer to 45 CFR 46.408(c)).

Other Considerations:
Non-English Speaking Participants
Federal regulations require that informed consent information must be presented in a language understandable to the subject and, in most situations, that informed consent be documented in writing (45 CFR 46.116 and 46.117). All required elements necessary for legally effective informed consent must be present in the consent document in the language spoken by the research subjects. Investigators should

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submit the proposed consent document in English, with a translation in the language which will be used with subjects. This process should be utilized any time a research study is actively recruiting non-English speaking participants.

Obtaining Consent:
Responsibility for Obtaining Consent
The principal investigator (PI) of the research study is ultimately accountable for assuring that all aspects of the study are at all times in compliance with applicable research regulations and IRB policies. This includes the entire informed consent process and the instruction and oversight of individuals who may be involved in this process. The IRB application must include a detailed plan for informed consent process and include the individuals who will actually be conducting the consent process.

Informed Consent Process:
Note that verbal or telephone consent is not acceptable unless the IRB has specifically waived the requirement for a signed consent form. Deferred consent (i.e., obtaining consent after the initiation of study procedures) is also prohibited.

The investigator must seek informed consent under circumstances that give the individual sufficient opportunity to consider whether to participate in the research study, and that minimize possible coercion or undue influence.

Informed consent to participate in a research study should be sought at a time separate from obtaining informed consent for procedures performed for the medical management of the patient (i.e., non-research procedures).

In the instance that the consent process cannot or may not be completed in person, the PI may obtain informed consent from prospective research participants using “TeleResearch” platform. This involves the use of video and/or audio communication followed by the use of DocuShare, Adobe Acrobat Self Sign, and/or Fax to obtain signature of the research participant.

The PI must retain the original signed informed consent document in his/her research records. A copy of the informed consent document must be provided to the subject. For hospital inpatients, a separate copy of the informed consent document should be incorporated into the patient’s medical record.

In addition to obtaining the signed, written informed consent document, it is recommended that a narrative note be written in the subject’s research records documenting the informed consent process. This documentation may depend on the risk of the study and could include information such as:

- Who was present during the informed consent discussion;
- The fact that risks were presented;
- A notation, if applicable, that significant issues of concern to the subject were addressed;
- A statement that all questions were answered to the satisfaction of the subject.

The narrative note should also indicate the date and time that the subject signed the informed consent document and be signed by individual responsible for the documentation. Noting the time of consent, in addition to the date, is especially important if any research procedures will be performed on the same day that informed consent was obtained. Note that this is a requirement for any research study involving the evaluation of a research intervention which falls under the jurisdiction of the FDA.

HIPAA Authorization:
The IRB requires that written HIPAA authorization be sought from each subject or the subject's legally authorized representative prior to participation in any research activity that involves the use of the subject's protected health information (i.e., identifiable medical record information) maintained by a covered entity (i.e., health care provider, health care plan, health care clearinghouse). HIPAA authorization must also be obtained for the placement of research data into the subject's medical record information maintained by the covered entity.

When protected health information (PHI) will be accessed, used and/or disclosed for research purposes, the research consent may include all the necessary elements under HIPAA thereby alleviating the need for a

separate HIPAA Authorization.

Regulatory Requirements:
The necessary HIPAA elements include the following:

- A specific description of PHI that will be collected for research and the purpose of collecting this information;
- A specific description of any research-derived information that will be placed in the individual's medical record;
- The person or class of persons who may use or disclose the PHI collected for research;
- The person or class of persons to whom PHI collected for research may be re-disclosed and the purpose of such re-disclosure;
- The expiration date of the authorization;
- Consequences to the individual of a refusal to sign the authorization;
- The individual's right to revoke authorization and consequences of such revocation.

Waiver of Authorization under HIPAA:
The IRB may approve a HIPAA authorization process for studies that do not include, or which alters some or all of the elements of a valid written authorization (as specified under 45 CFR 164.508(c)), or waives the requirement for written HIPAA authorization if the IRB finds and documents that the use of the subjects' protected health information meets the criteria for a waiver as addressed under 45 CFR 164.512 (i)(2)(ii). In granting an alteration or waiver of authorization under HIPAA, the IRB must determine that the alteration or waiver, in whole or in part satisfies each of the following criteria:

1. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - an adequate plan to protect the identifiers from improper use and disclosure;

- an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- an adequate written assurance that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted (i.e., under the HIPAA regulations).

2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to the use of the protected health information.

Research on Deceased Individuals:
Research involving deceased individuals is not human subjects research according to 45 CFR 46.102(e) and does not require IRB oversight unless the research involves both living and deceased individuals.

DHR Health Institute for Research and Development may grant access to and permit researchers to record the PHI of deceased individuals, held by a DHR Health facility, under the following conditions:

- if the information is de-identified by an honest broker service; or,
- if pursuant to a valid research authorization signed by the administrator or executor of the deceased individual's estate or the person who is listed as next of kin.

HIV Consent
For studies involving HIV testing a separate consent can be used by investigators to address unique issues under state law. This consent notifies subjects that their information will be handled in compliance with the State of Texas law on HIV-related confidential information, that they will be notified of the testing results and that counseling will be available to them prior to and after HIV testing.