Policy Name: Research Informed Consent	
Policy Owner: Research Activities and Compliance Committee	**Effective Date:** 01/30/2024
Approved By: System Performance Alignment & Innovation (SPAN)	**Last Reviewed Date:** 01/30/2024
Page 1 of 10	

1.0 Scope:

1.1 Applicable Entities:
This policy applies to:

- Texas Health Resources
- Texas Health Resources (Texas Health) member hospitals
- Texas Health Physicians Group
- Affiliated Individuals doing research on a Texas Health campus
- Excludes Texas Health Urgent Care and Texas Health joint venture entities (except those listed in the Formulation and Adoption of System-Wide Policies and Procedures in Section 4.1.6 or in Section 4.1.7)

1.2 Applicable Departments:
This policy applies to all departments.

1.3 Applicable Personnel:
Texas Health research investigators, research study staff and others engaged in research activities that are subject to Texas Health institutional oversight and oversight by a designated Texas Health Institutional Review Board (IRB) of Record

2.0 Purpose:

2.1 To establish and communicate requirements for the documentation and process for obtaining informed consent of individuals participating in research activities at Texas Health.

3.0 Policy Statements:

3.1 It is Texas Health policy that researchers may not involve a human being as a participant in research unless the investigator has obtained IRB approval for the research and, when required by the IRB, also obtains that person's legally effective informed consent.

4.0 Policy Guidance:

4.1 General Requirements for the Informed consent Process

- The informed consent process must always provide relevant information in language comprehensible to the prospective subject or representative, provide

the prospective subject or subject's representative sufficient opportunity to consider whether or not to participate, and minimize the possibility of coercion or undue influence.

- The investigator must provide the IRB with a recruitment and consent plan which details how the research study will ensure that the requirements of this policy are followed.

- The prospective subject or their Legally Authorized Representative (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 be given an opportunity to discuss that information.

- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or their 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. (Not required when conducting broad consent).

- Informed consent must present information in sufficient detail relating to the research and must also be organized and presented in a way that facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. (Not required when conducting broad consent).

- No informed consent, whether oral or written, may include exculpatory language through which the subject or their LAR is made to waive or appear to waive any of the subject's legal rights.

- A member of the research team who is knowledgeable about the consent process and the research to be conducted must obtain the informed consent.

- If a member of the study team (other than the investigator) conducts the interview and obtains consent, the investigator should formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

- Waivers or alterations to either the informed consent process or the documentation of informed consent will need to be submitted by the investigator to the IRB reviewing the research and require IRB approval.

- The use of a short form with the informed consent process is not currently approved at Texas Health.

- Research involving consent of non-English speaking individuals will require the use of an informed consent document that is translated by an approved vendor and for which the translated informed consent document is also IRB approved.

- Informed consent documents are permitted to include HIPAA/Research Authorization language within a single document as long as all required authorization elements have been included.

- An approved informed consent document will have an IRB approval stamp and a separate stamp from the Texas Health Human Research Protection Program (HRPP) office indicating Texas Health institutional release.

- The informed consent document used to obtain consent must be the most current IRB approved and Texas Health HRPP released version.

- The Principal Investigator and other members of the research team will ensure that a copy of the informed consent document is made available to the subject or their LAR.

4.2 Documentation of Informed Consent

- Unless documentation of informed consent is waived, the informed consent must be appropriately documented in accordance with, and to the extent required by, Federal Policy 45 CFR 46.117 and institutional requirements:

    a. Informed consent is documented by the use of a written consent form approved by the IRB.

    b. A written copy (paper or electronic) must be provided to the person signing the consent.

    c. Informed consent may also be documented in by including a visit note describing the consent interview and outcome in the research record.

    d. If the IRB approves a waiver of documentation of consent, the researcher must still document the consent process in the research record.

- The subject or the subject's LAR and the person providing the information to the subject sign (including in an electronic format), time and date the informed consent document at the time of consent. Only study team members authorized (in the IRB approved application) to obtain informed

consent should sign as the person obtaining consent. The IRB may waive the requirement to obtain time and/or date if this is not possible within a given consent process.

- The person authorized by the investigator to obtain the informed consent signs, times and dates the form and provides a copy of the informed consent form to the subject or the subject's LAR (as applicable).

- The Principal Investigator (PI) may request approval by the IRB to document the informed consent of the subject by receiving the signed and dated informed consent document from the subject by facsimile, email, mail or other means.

- The PI is ultimately responsible for keeping the original signed informed consent form and, in accord with the requirements specified in the THR Record Retention Policy and the study procedures as approved by the IRB.

4.3 Broad Consent

- 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 non-research purposes) is permitted under the revised Common Rule (Federal Policy for the Protection of Human Subjects, 45 CFR part 46). Currently, broad consent is not recognized in the Food and Drug Administration (FDA) regulation or guidance.

- THR does not routinely allow the use of Broad Consent. All requests to use Broad Consent must be submitted and approved by the Research Activities and Compliance Committee (RACC) on a study-by-study basis.

- The use of broad consent in research may additionally be limited or constrained by the Texas Health IRB(s) of Record. Any determination where broad consent is not allowed or limited will be either noted or communicated in accordance with the policies and procedures of the respective Texas Health IRB(s) of Record.

4.4 Required Elements of Informed Consent

- The informed consent document to be used in research will, at a minimum, list the name of the research study, the name of the principal investigator, and have the following required elements:

    a. Federally required basic elements of Informed Consent

1) 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 are experimental. Informed consent documents should also identify any procedures that are done for research purposes.

2) Reasonably Foreseeable Risks or Discomforts: A statement that describes any reasonably foreseeable risks or discomforts associated with the research, an estimate of the severity of the harms or discomforts.

3) Reasonably Expected Benefits to Subjects or Others: A statement that describes any benefits to subjects or others that may be reasonably expected from the research or no benefit (if this is applicable). Payment for participation in a research study is not considered a benefit to subjects.

4) Appropriate Alternatives: A statement that describes with enough detail any alternative procedures or course of treatment that may be advantageous to the subject (if applicable).

5) Extent of Confidentiality: A statement that describes the extent to which confidentiality of records identifying the subject will be maintained or not maintained, describes how the research team will protect subjects' private records during and after the conclusion of the research studies. Any research that is subject to audit or inspection must identify the entities that will have access to the subject's record (e.g., FDA, OHRP, National Institutes of Health (NIH), the IRB, study sponsors or their contract research organizations).

6) Compensation or Treatment for Injury: For studies with greater than minimal risk, a statement containing an explanation of any compensation and an explanation of any medical treatments available if injury occurs or where further information may be obtained.

7) Contact Information: A statement that describes contact information details, including telephone numbers, and whom to contact for the following situations:

i. questions about the research study (usually the PI, another Investigator and/or other member of the study team),

ii. concerns about the research study or questions about the subjects' rights (IRB office),

iii. complaints, comments/suggestions, or concerns, and

iv. in the event of a research-related injury (depending on the nature of the research, either the PI or a physician on the research team).

8) Voluntary Participation Statement: A clear statement 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, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9) Future Research: One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens [45 CFR 46.116(b)(9)]:

i. 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 LAR, if this might be a possibility; or

ii. 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 Federal Elements (where appropriate)

a. Unforeseeable risks to subjects, embryos, or fetuses: A statement warning subjects that some risks are currently not known or foreseeable should be included when applicable (e.g., an early

phase research study where very limited information related to risks to humans is known).

b. Investigator-initiated termination of participation: A statement that describes the instances an investigator may terminate a subject's participation (e.g., subject non-compliance, subject not benefiting from research, etc.).

c. Additional costs: A statement that describes any additional costs a subject may encounter from research participation (such as: health-related costs, etc.).

d. Early withdrawal/procedures for termination: A statement that describes a subject's right to withdraw from research and any procedures that may be necessary after an early withdrawal for subject's safety, and any possible harms that may result if the recommended withdrawal procedures are not followed (e.g., tapering a drug, etc.).

e. Significant new findings: A statement that subjects will be told of any new findings which may affect the subject's willingness to continue in the research.

f. Approximate number of subjects: A statement that explains the approximate number of subjects to be enrolled in the study.

g. Use of biospecimens for commercial use: 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.

h. Return of clinically relevant research results: A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

i. Whole genome sequencing: 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).

- Additional Institutional elements

    a. Conflict of Interest (COI) disclosure language: An institutional COI management plan for the research study may mandate COI disclosure language for inclusion in the informed consent document.

    b. Additional language regarding subject injury, indemnity, or cost: Additional language or modification to template language may be required in the informed consent document for consistency with study agreements/budgets and for compliance with other THR institutional policies

- HIPAA/Research Authorization elements. An authorization for the use or disclosure of Protected Health Information (PHI) for a research study may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

    a. Authorization Core/Required Elements

        1) A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.

        2) The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.

        3) The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.

        4) A description of each purpose of the requested use or disclosure (Researchers should note that this element must be research study specific, not for future unspecified research.)

        5) Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository.)

        6) Signature of the individual and date. (If the individual's LAR signs the Authorization, a description of the

representative's authority to act for the individual must also be provided.)

b. Authorized Required Statements

1) A statement of the individual's right to revoke Authorization and how to do so, and, if applicable, the exceptions to the right to revoke Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.

2) Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.

3) A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

4.5 Informed consent by Surrogate

- Informed consent by surrogate is addressed in Research Informed Consent by Surrogate Policy.

5.0 Definitions:

5.1 Conflict of Interest (COI) in Research - The term refers to situations in which financial or other personal considerations may compromise — or have the appearance of compromising — an investigator's professional judgment in conducting or reporting research. A COI depends on the situation and not on the actions or character of an individual investigator.

6.0 Responsible Parties:

6.1 Texas Health Research Activities and Compliance Committee (RACC)

- Has responsibility for the oversight and implementation of this policy.

7.0 External References:

7.1 "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The National Commission for the Protection of Human Subjects of

Biomedical and Behavioral Research, April 18, 1979, (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

7.2 Department of Health and Human Services (DHHS) Regulations. 45 CFR Part 46, subpart A 45 CFR Part 46 Subpart A

7.3 The DHHS human subject regulations (Subpart B); (Subpart C); and (Subpart D).

7.4 FDA regulations 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 50, Subpart D, 21 CFR Part 312, 21 CFR Part 600, and 21 CFR Part 812.

7.5 HIPPA regulations 45 CFR 164.501, 164.508, 164.512(i).

8.0 Related Documentation and/or Attachments:

8.1 Informed Consent by Surrogate - THR System Policy

8.2 Research Engagement - THR System Policy

8.3 Human Research Protection Program - THR System Policy

8.4 Research Principal Investigator Obligations - THR System Policy

8.5 Record Retention - THR System Policy

8.6 Research Record Retention - THR System Policy

8.7 Research Privacy - THR System Policy

9.0 Required Statements:

9.1 This policy represents the collaborative effort of the Texas Health system entities to determine and direct the recommended practice for the care anticipated under this policy and includes the input of clinical subject matter specialists.

As no policy or published procedure can anticipate every clinical and/or medical presentation, this policy is a guideline and is not intended as a substitute for the clinician's clinical judgment and/or experience.

9.2 Physicians on the medical staff of a Texas Health hospital practice independently and are not employees or agents of the hospital. Physicians in training in Graduate Medical Education programs are employees of the hospital/institution that hosts or sponsors their training program.