Identification and Recruitment of Participants
Policy and Procedure

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I. Policy. Individual privacy will be protected and the confidentiality of identifiable information maintained in accordance with applicable federal regulations and institutional policies. The process of identification and recruitment of research subjects must comply with the privacy and confidentiality regulations. In addition, the identification and recruitment must not be tied to payments to employees to enroll subjects which have potential for conflict of interest and undue influence.

A. Privacy - The degree to which a researcher is allowed to use private identifiable information is limited, in part, by whether the researcher has an established relationship (either treatment or research) with the individual.

B. Confidentiality – treatment team and research team members are required to take the following safeguards to protect against the unintentional breach in confidentiality.

1. When responsible for private identifiable information, research team members must ensure the information in whatever form is protected against improper disclosure.

2. Many improper disclosures are unintentional. All research team members should avoid discussing sensitive information concerning individuals where they may be overheard or leave individual’s information, either on paper or on computer screens, where they can be seen by other patients/subjects, unauthorized health care staff or the public. Reasonable steps to ensure that confidentiality of private identifiable information should be described in protocols submitted for IRB approval.

C. Compensation for Recruitment

1. Finder’s Fees – It is not permissible to pay or receive finder’s fees.

   a) The Institutional Review Board does not approve finder’s fees for UTHSCSA investigators, physicians, nurses, or others who have treating and/or counseling relationship to a subject being referred for enrollment in a research study.

2. Bonus Payments – It is not permissible to pay or receive bonus payments.

   a) All payments for the conduct of a research project must be negotiated at the beginning of the study and not provide for additional payments to UTHSCSA employees/agents based on either number or rate of subject enrollment. Payments tied to the number or rate of subject enrollment are considered to be bonus payments and are not permissible.

3. Compensation for services rendered – it may be acceptable to pay or receive compensation for recruitment and screening related activities that are unrelated to whether the participant ultimately enrolls in or completes the research study if the activity is approved by the IRB.
a) In general, the compensation paid by UTHSCSA investigators should be limited to non-HSC individuals who are not engaged in the research. The service being rendered involves identifying potential subjects and/or asking the potential subject if he/she would be willing to talk to a researcher about a relevant study. If the potential subject is not interested, no further encouragement should occur.

b) Compensation to the person assisting in identifying potential subjects should be made whether or not the potential subject enrolls in the study.

II. Overview

A. This procedure starts when a researcher or treatment team member considers authority to use or disclose private identifiable information for identification or recruitment in a research study.

B. This procedure ends when the recruitment activity ceases.

C. Summary of responsibilities

1. Individuals engaged in research or providing healthcare are responsible for ensuring the prospective study participants' privacy is protected and the confidentiality of their data is maintained.

2. Office of the IRB staff are responsible for providing guidance (in addition to that provided by the covered entity when HIPAA applies) to investigators to identify circumstances where no additional authorization is required (may contact the OIRB to ensure a HIPAA Waiver is not applicable) and processing requests for a waiver through expedited or full IRB review.

3. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative by:

   a) Obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens; or

   b) Obtaining information through oral or written communication with the prospective subject or legally authorized representative.

4. IRB Chair, IRB Director, IRB Associate Director or designee is responsible for approving, disapproving, or require changes in to secure approval, requests for HIPAA Waivers when expedited review is applicable.

5. The IRB is responsible for approving requests for HIPAA Waivers when expedited review is not applicable.

III. Procedure

1 Applicable to research approved or transitioned to the 2018 Common Rule requirements.
A. Studies only involving record review (not involving interaction or intervention with subjects)

1. The OIRB receives the request to access private identifiable information for the purpose of identification of records eligible for inclusion in the research.

2. The IRB (or designated reviewer) may permit investigators to obtain and record identifiable private information for the purposes of conducting research by waiving the requirement for informed consent for such activities.

B. Studies involving recruitment of research subjects (involving interaction or intervention with subjects)

1. The OIRB receives the request to access private identifiable information for the purpose of identification and recruitment of subjects.

2. The IRB (or designated reviewer) will consider the degree to which private identifiable information or obtaining identifiable biospecimens can be used for identification and recruitment based upon whether the individual obtaining the information has an established relationship (either treatment or research) with the individual or where permission to obtain private information has been provided by the individual.

a) Researchers with an established relationship

(1) Research approved before the 2018 Common Rule Requirements:

i. The IRB (or designated reviewer) may permit these researchers to obtain private identifiable information to identify (by waiving the requirement for informed consent) and make initial contact (recruit) individuals who may be eligible to participate in new research.

(2) Research approved or transitioned to the 2018 Common Rule requirements:

i. The IRB (or designated reviewer) may permit these researchers to obtain information through oral or written communication with the prospective subject or legally authorized representative or obtain private identifiable information or identifiable biospecimens by accessing records or stored identifiable biospecimens to identify and make initial contact (recruit) individuals who may be eligible to participate in new research.

(3) UT Medicine is considered one clinical practice; therefore, researchers recruiting participants from other UT Medicine clinics is considered an acceptable practice. Researchers should be contacted by persons known to them, such as persons directly involved in their care. However, if this approach is impractical, UTHSCSA researchers may directly contact subjects, if permitted by applicable regulations as determined by the IRB.

b) Researchers without an established relationship:

(1) Research approved before the 2018 Common Rule Requirements:

i. The IRB (or designated reviewer) may permit these researchers to obtain and record private identifiable information for the purposes of identifying potential subjects (by waiving the requirement for informed consent).

(2) Research approved or transitioned to the 2018 Common Rule requirements:
The IRB (or designated reviewer) may permit these researchers to obtain information through oral or written communication with the prospective subject or legally authorized representative or obtain and record identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens for the purposes of identifying potential subjects.

(3) The IRB (or designated reviewer) will not permit these researchers to use private identifiable information or obtain identifiable biospecimens for the purposes of making initial contact (cold calling). In these situations, the researcher should consider alternative approaches such as:

(a) Advertisements

(b) Dear Doctor Letters

(c) Request assistance from other healthcare professionals or researchers who already have an established relationship

(d) Request assistance from the institutions who hold the private information

C. Finders Fees

1. If an investigator wishes to consult the IRB regarding the approval to use finder’s fees, the following questions must be answered as part of the protocol submission:

   a) What compensation will be offered (for example, money, textbook, dinner, movie pass)?

   b) Who will obtain consent or HIPAA authorization (if applicable) from the subject?

   c) To whom is the compensation being offered and what is the person being asked to do?

   d) Could the compensation provided be coercive or appear to be linked to successful enrollment in the study?

   e) Will the subject or their insurance be charged for any study-related activity?

   f) If a person is enrolled in the study, will there be a change in the responsibility for patient care? For example, will the study investigators now provide primary treatment for a problem?

2. The responses to the questions above must be reviewed by the IRB Chair, IRB Director, IRB Associate Director or the designated reviewer.

IV. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)