

## HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

### 4.1 IDENTIFICATION AND RECRUITMENT OF PARTICIPANTS

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD)

EFFECTIVE DATE: June 7, 2021

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#### I. POLICY STATEMENT

- A. UT Southwestern appreciates and is supportive of the importance of clinical research as a means to improving the health of UT Southwestern patients and aims to facilitate patient participation in clinical research. As such, UT Southwestern patients may be contacted for potential participation in clinical research unless they have expressly indicated their desire not to be contacted for potential participation in clinical research; to “opt-out” of such contact. Patients cared for at UT Southwestern Hospitals and Clinics have the opportunity to state their preference **not** to be included in lists of potential research participants to be contacted which was obtained by review of their electronic health record (opt-out). This does not prevent their treating providers from informing them of research opportunities ongoing in their practice. Patients may change their preference to be included or excluded from potential research participant lists at any time.
- B. The method used to contact patients for potential participation in research studies will be described in the recruitment plan. Recruitment methods used to solicit volunteers into human research must be equitable and free of bias, undue influence and coercion. Recruitment methods must respect the privacy of potential research participants. The Institutional Review Board (IRB) must review and approve the methods, materials, procedures, and tools used to recruit potential research participants before they are implemented. Regardless of whether the contact occurs by letter, telephone, email, MyChart message or any other means, it must respect the patient’s privacy and the confidentiality of their PHI. The appropriateness of one method of contact versus another will depend on the condition under study and the nature of the research, and is thus specific to each research protocol.
- C. All contact with potential research participants must be initiated by a member of the research team (principal investigator, sub-investigator, coordinator, etc.) who has the appropriate training for research recruitment, and has been approved by the IRB as part of the recruitment plan described in the IRB application.
- D. 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 participants must comply with the privacy and confidentiality regulations.
  1. 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.
  2. Confidentiality –treatment team and research team members are required to have an adequate plan to protect against the unintentional breach in confidentiality.
    - a) When responsible for private identifiable information, research team members must ensure the information is protected against improper disclosure.

- b) 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/participants, 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.
- E. The identification and recruitment must not be tied to payments to employees to enroll participants which have potential for conflict of interest and undue influence.

## **II. SCOPE**

- A. This policy and procedure applies to all human subjects' research.
- B. 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. HRRPD staff are responsible for providing guidance (in addition to that provided by the covered entity when HIPAA applies) to identify circumstances where additional permission/authorization is/is not required and processing requests for waivers through expedited or full IRB review.
  - 3. IRB Chair, or designee (as members of the IRB/Privacy Board) is responsible for approving, disapproving, or requiring changes in to secure approval of requests for HIPAA Waivers when exempt or expedited review is applicable.
  - 4. The convened IRB acts as the Privacy Board at UT Southwestern and is responsible for approving requests for HIPAA Authorization Waivers when expedited review is not applicable.

## **III. PROCEDURES FOR POLICY IMPLEMENTATION**

- 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. Studies only involving record review (not involving interaction or intervention with participants)
  - 1. The HRRPD 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 access, obtain and record identifiable private information for the purposes of conducting research by waiving the requirement for informed consent and HIPAA authorization (if involving protected health information) for such activities. See the Office of Compliance Privacy Program Policy: [7.23 Waiver or Alteration of Research Authorizations](#).
- D. Studies involving record review for recruitment of research participants (studies involving interaction or intervention with participants)

1. The HRPPD receives the request to access private identifiable information for the purpose of identification and recruitment of participants.
2. The IRB (or designated reviewer) will consider the degree to which private identifiable information 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.
3. Research with Patients who have not “opted-out” of recruitment for participation in research
  - a) Researchers with an established relationship
    - (1) The IRB (or designated reviewer) may permit these researchers to use private identifiable information to identify (by granting a partial waiver of HIPAA authorization as applicable) and make initial contact (recruit) individuals who may be eligible for a new study.
  - b) Researchers without a treatment or established research relationship:
    - (1) The IRB (or designated reviewer) may permit these researchers to access, obtain and record identifiable private information for the purposes of identifying potential participants (by granting a partial waiver of HIPAA authorization as applicable).
      - i. Investigators must obtain a partial waiver of HIPAA authorization for access, use and disclosure (as applicable) of protected health information (PHI) from the UT Southwestern IRB (as the Privacy Board). This waiver allows investigators and/or the Office of Community Engagement and Participant Recruitment and Retention personnel to review the electronic health records of all patients seen by providers in the UT Southwestern Hospitals and Clinics.
      - ii. This partial waiver applies to clinical research activities at UT Southwestern and any other institutions (affiliate and non-affiliate) engaged in the research.
      - iii. Additional waivers are not required to review the medical records of patients seen at affiliated facilities (E.g., Parkland Hospital, Children’s Health, or Texas Scottish Rite Hospital). However, the fully completed, signed HIPAA Waiver form must be available for review by any other institution where investigators wish to utilize the waiver. Each institution has the right to accept the UT Southwestern HIPAA waiver or to refuse to accept it and either grant their own, require signed authorization, or refuse participation in the study.
    - (2) The IRB (or designated reviewer) may permit these researchers to use private identifiable information for the purposes of making initial contact (cold calling). If a UT Southwestern patient is approached for participation in a research project, it is usually appropriate for their treating provider to be notified. The IRB-approved recruitment plan will state whether or not permission from the treating provider to contact a patient for research participation will be obtained **prior** to research recruitment. Based on the condition under study and the nature of the research project the IRB may require explicit approval of the treating provider for contact

with their patient(s). Alternatively, the researcher could consider (and the IRB may require) other 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) Potential Research Participants Identified Through the Use of the UTSW Volunteer Research Participant Registry

- 1) All patients seen at UT Southwestern Hospitals and Clinics who **have not** 'opted out' of the possibility to be contacted directly for potential research participation by investigators who are not their treating providers are automatically included in the Volunteer Research Participant Registry
- 2) If the IRB-approved recruitment plan includes review of PHI contained in the EHR or derivatives of the EHR such as the Clinical Data Warehouse (CDW), the investigator will contact the Office of Community Engagement and Participant Recruitment and Retention to assist in the creation of a cohort of individuals who meet specific clinical, demographic, and/or laboratory criteria and have not opted out of direct contact by investigators who are not their treating providers. This Office is responsible for updating the status of potential participants who **have** opted out of direct contact on a regular basis and will inform investigators of any changes to their recruitment lists. Contacts will be monitored at the subject level and participants will be released in a controlled manner to ensure the participants will not receive numerous recruitment calls.

4. Research involving patients who have opted-out

- a) The PHI of UT Southwestern patients who have opted out of direct contact by investigators not involved in their treatment will still be maintained in the Epic EHR, as well as IRB-approved activities such as the Clinical Data Warehouse, local specialty-specific registries, and investigator-maintained registries. Their PHI can be shared with registries outside UT Southwestern such as specialty-specific clinical registries and registries required by the Federal or State government through standard HIPAA-compliant business arrangements.
  - 1) Aggregate, de-identified counts of patients, including those who have opted out of direct contact by investigators not involved in their treatment can be obtained through tools such as SlicerDicer®, i2b2, and TriNetX. This is generally considered not human subject research and does not need prior IRB approval.
  - 2) The PHI of patients who have opted out of direct contact by investigators not involved with their treatment will still be available to investigators doing IRB-approved research on existing data (i.e., retrospective chart reviews). This data may be abstracted from the CDW and provided directly to investigators by the Academic Information Service in either identified or de-identified formats. Alternatively,

investigators can be given lists of research subjects meeting certain criteria for their own data abstraction, although there should be no contact of subjects who have opted-out.

E. Compensation for Recruitment

1. The UT Southwestern IRB must consider ethical issues and potential conflicts of interest that may arise when financial compensation (i.e., finder's fees, bonus payments) is offered to researchers or clinicians for referring or identifying participants in research. There is a possibility that such financial arrangements may result in an increased chance for the researchers or clinicians to act in a manner which is not in the best interest of the participant. Therefore, it is not permissible to pay or receive Finder's Fee payments or Bonus Payments.
2. 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 UT Southwestern investigators should be limited to non-UT Southwestern individuals who are not engaged in the research. The service being rendered involves identifying potential participants and/or asking the potential participant if he/she would be willing to talk to a researcher about a relevant study. If the potential participant is not interested, no further encouragement should occur.
  - b) Compensation to the person assisting in identifying potential participants should be made whether or not the potential participant enrolls in the study.
3. 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 UT Southwestern employees/agents based on either number or rate of participant enrollment. Payments tied to the number or rate of participant enrollment are considered to be bonus payments and are not permissible.
4. If an investigator wishes to consult the IRB regarding the approval to use compensation for recruitment services, the following questions should 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 participant?
  - 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 participant 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?

- g) The responses to the questions above must be reviewed by the IRB Chair, or designated reviewer.

**IV. DEFINITIONS**

SEE GLOSSARY OF HUMAN RESEARCH TERMS

**V. REFERENCES**

21 CFR 50 – <a href="#">PROTECTION OF HUMAN SUBJECTS</a>
45 CFR 46 – <a href="#">PROTECTION OF HUMAN SUBJECTS</a>
45 CFR 164 – <a href="#">SECURITY AND PRIVACY (HIPAA PRIVACY RULE)</a>
21 CFR 56 – <a href="#">INSTITUTIONAL REVIEW BOARDS</a>
NATIONAL INSTITUTES OF HEALTH - <a href="#">CLINICAL RESEARCH AND THE HIPAA PRIVACY RULE</a>

**VI. REVISION AND REVIEW HISTORY**

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
November 2019	HRPP	Updated to add opt-out requirements and resulting recruitment procedures
January 2019	HRPP	Revision to reference 2019 common rule
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures