

**UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE
INSTITUTIONAL REVIEW BOARD
PRIVACY AND CONFIDENTIALITY IN HUMAN SUBJECT RESEARCH
PARTICIPATION**

I. PURPOSE

To document the policy and procedures used by University of Tennessee College of Medicine Institutional Review Board regarding the privacy interests of human subjects and confidentiality of human subject research participation.

II. SCOPE

This SOP applies to the IRB administrative staff, IRB members, and research personnel.

Personnel Responsible:

UTCOCM IRB administrative staff and members, and research personnel.

III. BACKGROUND

HHS and FDA regulations for the protection of human subjects specify that IRB approval of research is contingent on the finding that “there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.” In addition, requirements for information disclosure in the informed consent process include “a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.” Moreover, HIPAA privacy rules require the authorization of subjects for access to their protected health information in research, unless specific conditions are met for waiving these requirements.

Privacy refers to the interest of individuals in controlling the access of others to a personal domain that includes our bodies and physical space, our thoughts and feelings, characteristics of our intimate relationships, sexual orientation, religious preferences and reproductive choices. The **right of privacy** reflects the obligation of others to not intrude on this domain without our consent and the freedom of each individual to choose the time, place, and manner in which others will have access to it.

Methods for identifying, screening, interacting with, and securing research data from subjects must respect privacy rights. For example, review of medical records to identify potential subjects requires specific authorization of patients or a waiver of HIPAA privacy provisions. Screening data secured from prospective subjects found ineligible for study participation must not be retained without their approval. Non-consensual research use of medical record information about subjects or use of their individually identifiable biospecimens must not occur unless conditions for waiver of consent and waiver of the HIPAA authorization are satisfied. When private information or individually identifiable specimens are used, the information recorded about subjects should be the minimum necessary to complete the study, and access to it should be limited to the minimum number of research personnel necessary to meet study objectives. Interactions with subjects must occur in circumstances that avoid disclosing their medical conditions or the fact of their research participation to persons outside the study. Strategies for tracking non-compliant subjects must similarly avoid alerting others to the health problems of subjects or their involvement in research.

Confidentiality refers to the treatment of information that an individual has already disclosed in a relationship of trust and with the expectation that it will not be divulged to others without express permission. The duty to protect confidential information reflects the right of persons to control access to information about themselves. Unauthorized disclosure of confidential information not only violates this right, but may place individuals at risk of damage to their financial standing, employability, or reputation, as well as place them at risk of criminal or civil liability.

Methods of storing and transmitting private information and biospecimens may significantly impact the degree of protection provided for the confidentiality of data secured from research participants. Methods for maintaining the security of research data must minimize the risk of unintended disclosure of private information through the use of passwords, encryption, coding, and separation of coded materials from files linking codes to the identity of subjects. Transmission of private information about subjects between study sites must also utilize security procedures that minimize the capacity of outside parties to gain unauthorized access to individually identifiable information about subjects. Similarly, storage and transmission of biospecimens should use a coding system that separates the coded specimens from files that contain the identity of individual participants.

It is the policy of the UTCOMC IRB that clinical research studies must include procedures for assuring proper regard for the privacy of subjects and proper protection for the confidentiality of identifiable data and specimens secured from research participants, which must be outlined in the relevant sections of the Smart Wizzard Application. Provisions for protecting the privacy of subjects and the confidentiality of their data must also be addressed in all informed consent documents approved by the UTCOMC IRB.

In Accordance With:

45 CFR 46.111(a)(7-8); 21 CFR 50; 21 CFR 56.111(a)(7)

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

A. Privacy

1. UTCOMC IRB will review the relevant sections of all submissions according to the following criteria (when applicable) to determine whether the provisions for protecting the privacy interests of human subjects delineated therein are consistent with the requirements of HHS and FDA regulations for the protection of human subjects, and all other pertinent institutional, local, state and federal policies, regulations and laws:
 - a. assuring that the conditions under which persons are screened or recruited for study participation provide protections against prospective subjects being witnessed, overheard, or viewed in a manner that would intrude on their private domain;
 - b. ensuring that the conditions under which persons are invited to participate in a study provide protections against prospective subjects being witnessed, overheard, or viewed in a manner that would intrude on their private domain;
 - c. planning interventions or interactions that are part of the study so that they are performed in a manner that provides protections against subjects being witnessed, overheard, or viewed in a manner that would intrude on their private domain;
 - d. disposing of screening records in the absence of consent for retention of the information;
 - e. limiting the collection of private information to the minimum necessary to meet the objectives of the study;

- f. restricting the number of key study personnel (KSP) who have access to private information to the minimum number necessary to meet the objectives of the study;
 - g. keeping research records separate from other records, such as medical or educational records, unless the information is useful or important to the welfare of the subject, or unless it is the clinic/hospital's policy to include research consent forms in the patient medical record;
 - h. limiting methods of tracking non-compliant subjects or subjects lost to follow up to assure that their medical condition and/or participation in the research is not disclosed to persons outside the research setting, unless written permission is obtained from the subjects regarding specific methods of tracking;
 - i. prohibiting non-consensual research use of existing private information or biospecimens, except where conditions are met for exemption and/or waiver of consent; and
 - j. prohibiting secondary research use without additional consent of private information or biospecimens previously collected for research purposes, except where conditions are met for exemption and/or waiver of consent.
2. The relevant sections of all Smart Wizard applications must confirm that privacy will be respected with regard to the following issues (when applicable):
- a. the location and circumstances under which prospective subjects are approached or notified about the study, invited to participate in the study, and screened for potential participation in the study;
 - b. the location and circumstances under which research procedures will be performed;
 - c. whether or not data from participants who failed screening are retained and with what permission;
 - d. the fact that the collection of private information will be limited to the minimum necessary to meet the objectives of the study;
 - e. the fact that the number of key study personnel (KSP) who have access to private information is the minimum number necessary to meet the objectives of the study;
 - f. the fact that research records will be kept separate from other records, such as medical or educational records, unless the information is useful or important to the welfare of the subject, or unless it is the clinic/hospital's policy to include research consent forms in the patient medical record;
 - g. the ways in which non-compliant subjects or subjects lost to follow up will be tracked and whether written permission has been secured from subjects to track them; and

- h. the conditions for meeting exemption and/or a justification for waiving consent (for non-consensual research use of existing private information or biospecimens and for secondary research use without additional consent of private information or biospecimens previously collected for research purposes).
3. The UTCOMC IRB will review all informed consent documents to ensure that:
 - a. if the investigator wishes to track subjects lost to follow up, the consent form states this fact and delineates the ways in which they will be tracked/contacted, *and* the subject agrees to the aforementioned methods;
 - b. if the investigator wishes to retain subjects' contact information and health information, including screening results, in order to contact them in the future regarding participation in other studies, the consent form states this fact, *and* the subject agrees to the retention; and
 - c. if photograph or audio/videotaping will occur, that this fact is stated in the consent form.

B. Confidentiality

1. UTCOMC IRB will review the relevant sections of all submissions according to the following criteria to determine whether the provisions for and limitations on confidentiality delineated therein are consistent with the requirements of HHS and FDA regulations for the protection of human subjects, the HIPAA regulations, the Genetic Information Nondiscrimination Act, and all other pertinent institutional, local, state and federal policies, regulations and laws:
 - a. the use of identifiable private information is necessary to conduct the research;
 - b. all research personnel who will have access to identifiable private information and specimens are listed in the application and are identified as such;
 - c. a plan exists for assuring that prospective subjects do not object if identifiable private information obtained for screening purposes will be retained;
 - d. adequate provisions are made to protect the confidentiality of paper records (e.g., locked and accessible only to research personnel);
 - e. adequate provisions are made to protect the confidentiality of electronically stored research records (e.g., computer password protected and accessible only to research personnel, encryption, inter-file linkage, error inoculation, top coding, bracketing, data brokering, etc.);

- f. adequate provisions are made for maintaining the confidentiality of identifiable private information electronically transmitted either locally or externally (e.g., use of an encrypted method such as UT Vault, Xythos, a federal or industry-sponsor cleared web-based portal, etc.);
 - g. adequate provisions are made for maintaining the confidentiality of specimens stored at the local site (e.g., coding of the specimens and maintenance of a separate master list linking specimens to subjects);
 - h. adequate provisions are made for maintaining the confidentiality of identifiable specimens transmitted externally (e.g., appropriate coding of the specimens);
 - i. if the study involves a repository, subjects are accurately informed regarding the protections for confidentiality that will be observed in distributing data and/or specimens to investigators who utilize the repository;
 - j. an authorization to use protected health information, comprised of the required the informational elements specified in the HIPAA privacy regulations, is included in the consent form, unless the conditions for the use without specific authorization of the subject are satisfied;
 - k. subjects are fully informed regarding the placement of information about research participation and/or the results of procedures performed for research purposes only in the medical record;
 - l. subjects are accurately informed regarding the protections for genetic information provided by the Genetic Information Nondiscrimination Act (research involving genetic analysis only);
 - m. subjects will not be identified in any presentations or publications based on the results of the research; and
 - n. federal certificates of confidentiality are obtained when appropriate (See SOP: UTCOMC IRB Certificates of Confidentiality).
2. The relevant sections of all Initial Smart Form applications must describe:
- a. the individuals and entities that will have access to identifiable private information;
 - b. whether identifiable private information obtained for screening purposes will be retained and, if so, how it will be assured that prospective subjects do not object;
 - c. how the confidentiality of paper records containing identifiable private information will be protected;
 - d. how the confidentiality of electronic records containing identifiable private information will be protected;

- e. whether identifiable private information will be transmitted electronically (either locally or externally) and how the confidentiality of the information will be protected;
 - f. whether biological specimens from individual subjects will be maintained at the local investigative site and whether they will be labeled with a code;
 - g. whether biological specimens transmitted to an external site will be labeled with a code and whether the master key linking the names of subjects with the codes will be maintained at the local investigative site;
 - h. whether data or specimens maintained in a repository will be labeled in a manner that individual investigators to whom the materials are distributed are unable to identify individual subjects;
 - i. whether the consent form will include the HIPAA template for securing subject authorization for the use of protected health information, or whether a request is being made to use the information in a manner that a specific authorization is not required;
 - j. whether information about the subject's research participation and/or the results of procedures performed for research purposes only will be placed in the medical record; and
 - k. whether a federal Certificate of Confidentiality will be obtained (See SOP: UTCOMC IRB Certificates of Confidentiality).
3. The UTCOMC IRB will review all informed consent documents to ensure that the confidentiality section accurately explains the provisions for and limitations on confidentiality pursuant to the requirements of HHS and FDA regulations for the protection of human subjects, the HIPAA regulations, the Genetic Information Nondiscrimination Act, and all other pertinent institutional, local, state or federal policies, regulations and laws. The section on confidentiality must include the following elements:
- a. a description of the individuals and entities that will have access to identifiable private information;
 - b. a statement that the research records will be accessible only to research personnel and those entities otherwise named in the application and consent form, except as required by law;
 - c. an explanation of how the confidentiality of paper research records containing identifiable private information will be protected;
 - d. an explanation of how the confidentiality of electronic research records containing identifiable private information will be protected;
 - e. an explanation of whether identifiable private information will be transmitted electronically (either locally or externally) and how the confidentiality of the information will be protected;

- f. an explanation of whether biological specimens from individual subjects will be maintained at the local investigative site and whether they will be labeled with a code;
- g. an explanation of whether biological specimens transmitted to an external site will be labeled with a code and whether the master key linking the names of subjects with the codes will be maintained at the local investigative site;
- h. if the study involves a repository, an explanation of whether data or specimens maintained in a repository will be labeled in a manner that individual investigators to whom the materials are distributed are unable to identify individual subjects;
- i. the HIPAA template for securing subject authorization for the use of protected health information (unless conditions for use of protected health information without specific authorization are satisfied);
- j. a statement explaining whether information about the subject's research participation and/or the results of procedures performed for research purposes only will be placed in the medical record;
- k. a description of the protections for genetic information provided by the Genetic Information Nondiscrimination Act (research involving genetic analysis only);
- l. assurance that subjects will not be identified in any presentations or publications based on the results of the research; and
- m. (if applicable) a description of federal Certificates of Confidentiality and how they protect subject information from disclosure.

4. UTCOMC IRB also requires disclosure to the subject about any foreseeable circumstances under which the investigator may be required to disclose protected health information (PHI) to a third party (e.g., mandatory reporting of infectious diseases, mandatory reporting of suspected child abuse, etc.).

5. In addition, UTCOMC IRB will review questionnaires, data collection tools, surveys and other methods used in the study to collect information in order to determine the types of information that will be collected from subjects and the manner in which it will be obtained.

6. The confidentiality of research subjects shall also be maintained when any study information is kept by recorded means such as audiotapes or videotapes. The investigator is required to tell the subject how his/her identity will be or will not be disclosed in these

instances, when the tapes may be used for other broadcasts or educational purposes, and how such recorded information will be kept confidential.

7. Live case recording or broadcast (including photography) of clinical research must have prior IRB approval. In all cases, the informed consent disclosure must be modified to contain additional language regarding the taping/ broadcast, and any additional risks to the subject due to the taping / live broadcast (such as increased procedure time, increased anesthesia time, loss of confidentiality, etc.).
8. Any communications between investigators and the IRB concerning research subjects will identify the subject by study number or initials.