Human Research Protection Program Departmental Policy and Procedure Manual

1.2 Determining Whether an Activity is Research Involving Human Subjects

Effective Date: June 3, 2026

I. Policy Statement

a. In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any undertaking in which a UT Southwestern faculty, staff, or student (i.e., an employee or agent) conducts non-exempt human research on behalf of UT Southwestern. This policy provides information related to determining whether an activity is research involving human subjects and covered by the Federal Regulations. In general, any non-exempt activity that meets either (a) the Department of Health and Human Services (DHHS) definition of both "research" and "human subjects" or (b) the Food and Drug Administration (FDA) definitions of both "clinical investigation" and "human subjects" is considered human research and requires review and approval by the IRB.

b. Newborn Screening Blood Spots. The exception to the DHHS and FDA definitions of human subjects' research as described above are Newborn Screening Blood Spots being requested for research

1. Texas Health & Safety Code Sec. 33.018

    a. The use of de-identified blood spots requires review by Texas Department of State Health Services (DSHS) Commissioner designees and by the DSHS IRB (regardless of funding).

2. H.R. 1281 (113th): Newborn Screening Saves Lives Reauthorization Act of 2014

    a. Federally funded research using newborn dried spots is considered human subjects' research regardless of whether the biospecimens

are identifiable.

b. The IRB may not approve alterations or waivers of informed consent under 45 CFR 46.116(c) and 116(d) for federally funded research involving newborn dried blood spots.

II. Scope

a. This procedure applies to all Investigators, The Human Research Protection Program Department (HRPPD) and IRB.

b. It is the responsibility of each investigator to seek IRB approval prior to initiation of any non-exempt research involving human subjects or before conducting any clinical investigation.

c. The investigator is responsible for making a preliminary decision regarding whether his/her activities meet either (a) the Department of Health and Human Services (DHHS) definitions of both “research” and “human subjects” or (b) the FDA definitions of both “clinical investigations” and “human subjects”. The “Non-Human Research” and “Non-Regulated Research” Smartforms are available to guide the investigator in making this decision.

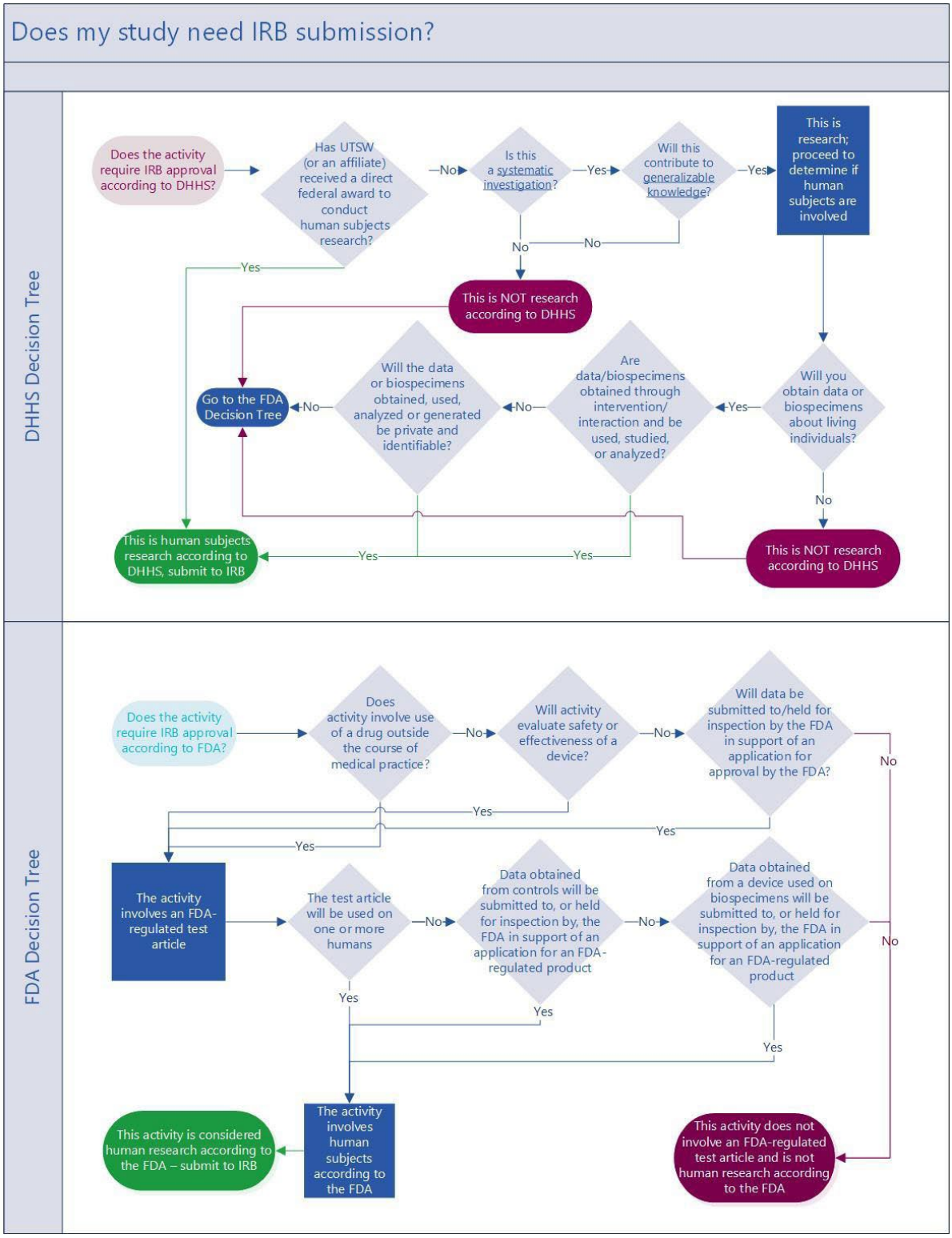
d. The investigator may contact the HRPPD staff, IRB Director Associate Vice President for Office of Research Regulatory Affairs (AVPORRA), or IRB Chair for advice on the application of the federal regulations and UT Southwestern policy.

III. Procedures for Policy Implementation

a. Non-exempt research involving human subjects conducted without IRB approval may be considered serious non-compliance in accordance with 9.3 NONCOMPLIANCE REVIEW and may jeopardize an investigator’s ability to receive IRB approval to conduct research involving human subjects in the future.

b. The following assessment is used when evaluating a particular activity to

determine whether the activity is human research:


Does my study need IRB submission?
DHHS Decision Tree
Does the activity require IRB approval according to DHHS?
Has UTSW (or an affiliate) received a direct federal award to conduct human subjects research?
No
Is this a systematic investigation?
Yes
Will this contribute to generalizable knowledge?
Yes
This is research; proceed to determine if human subjects are involved
Yes
No
No
This is NOT research according to DHHS
Will you obtain data or biospecimens about living individuals?
Yes
Are data/biospecimens obtained through intervention/ interaction and be used, studied, or analyzed?
No
Will the data or biospecimens obtained, used, analyzed or generated be private and identifiable?
No
Go to the FDA Decision Tree
No
This is human subjects research according to DHHS, submit to IRB
Yes
Yes
This is NOT research according to DHHS
FDA Decision Tree
Does the activity require IRB approval according to FDA?
Does activity involve use of a drug outside the course of medical practice?
No
Will activity evaluate safety or effectiveness of a device?
No
Will data be submitted to/held for inspection by the FDA in support of an application for approval by the FDA?
No
Yes
Yes
Yes
The activity involves an FDA-regulated test article
The test article will be used on one or more humans
No
Data obtained from controls will be submitted to, or held for inspection by, the FDA in support of an application for an FDA-regulated product
No
Data obtained from a device used on biospecimens will be submitted to, or held for inspection by, the FDA in support of an application for an FDA-regulated product
No
Yes
Yes
Yes
The activity involves human subjects according to the FDA
This activity is considered human research according to the FDA – submit to IRB
This activity does not involve an FDA-regulated test article and is not human research according to the FDA

c. Investigators will be informed of the HRPPD's determination of whether the proposed activity constitutes research involving human subjects, is non-regulated research or is non-human subjects' research (See 8.2 REPORTING POLICY AND PROCEDURE). A determination of non-human subjects research is not issued as a formal letter; rather, the determination is communicated via email through the ETHOS system.

d. The following are examples of human subject research studies that must be reviewed and approved by the UTSW IRB.

1. Masters thesis/Doctoral dissertation: graduate work which involves research on human subjects or a clinical investigation and results in a thesis or dissertation.
2. Pilot studies: pilot studies involving human subjects are considered human subject research and require IRB review.
3. Clinical research: involves research to increase scientific understanding about normal or abnormal physiology, disease states or development and research to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention. Vaccine trials, medical device or drug studies and cancer research are all types of clinical research.
4. Behavioral and Social Sciences Research: focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.
5. Epidemiological research: focuses on health outcomes, interventions, disease states and conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations.

This research may be conducted through surveillance, observation monitoring, and reporting programs. Other methods are retrospective review of medical, public health and/or other records.

6. Human genetic research: includes studies such as pedigree studies, positional cloning studies, gene transfer research, longitudinal studies to associate genetic conditions with health, health care or social outcomes and gene frequency studies.

7. Repository or Bank: includes collecting or storing human biospecimens or data for future use in research.

e. The following activities are generally not considered "research" and do not need IRB approval:

1. Case reports. Includes the use of medical information collected from a clinical activity rather than a research activity and presented on typically no more than three (3) patients. Case reports are generally done by retrospective review of the medical record and highlights a unique treatment, case or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI (a HIPAA Authorization or waiver may be required).

2. Class projects. Academic projects or student assignments involving collection of data from human subjects when the data is used solely for the purpose of teaching course content (e.g., to teach proficiency in performing certain tasks or using specific tools or methods) and not intended to be used to develop or contribute to generalizable knowledge using the information collected as part of the class project.

3. Scholarly and journalistic activities. Includes the collection and use of

information, that focus directly on the specific individuals about whom the information is collected (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship). Research involving a single individual is not generalizable knowledge (see case reports below).

4. Public Health surveillance. Includes the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Including the collection and testing of information of biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

5. Routine Quality Improvement (QI). Includes systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. QI involves deliberate actions to improve care, guided by data reflecting the effects of local care (e.g., types of practical problem solving; an evidence-based management style; the application of science of how to bring about system change; review of aggregate data at the patient/provider/unit/ organizational level to identify a clinical or management change that can be expected to improve care).

6. Medical quality assurance. This refers to activities particular to an institution's Quality Assurance (QA) program, such as those activities protected from disclosure as part of its confidential medical quality-

assurance program or other equivalent programs.

7. Program evaluation. This refers to assessments of the success of established programs in achieving objectives when the assessments are for the use of program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. [Note: Non-research evaluation is generally designed to assess or improve the program or service rather than to generate knowledge about a disease or condition.]

8. Customer satisfaction surveys. This refers to surveys of program users to obtain feedback for use by program managers. This is similar to program evaluation. The purpose of these surveys is to improve a specific service or program or develop new services or programs under the control of the individual/organization obtaining the information and not to conduct research.

9. Community outreach. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research community outreach activity is to prevent or control disease or injury and improve health, or to improve an ongoing community outreach program or service. Knowledge may be gained in any community outreach endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit patients participating in an outreach health program or a population by controlling a health problem in the population from which the information is gathered.

10. Publicly available data. research involving publicly available information (e.g., census data, labor statistics) does not constitute human research.

11. Criminal Investigations. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

12. Official Activities. Authorized operational activities (as determined by each federal agency) in support of intelligence, homeland security, defense, or other national security missions.

f. The following research is generally considered "non-human research" and do not need approval:

1. Repository research, tissue banking, and databases: research limited to obtaining deidentified stored data or biospecimens from a repository only if the investigator cannot readily ascertain the identity of the subject from whom the data or materials originated.

2. Anonymous pre-existing data sets or specimens: anonymous pre-existing data or biospecimens (anonymous materials are those with no personally identifiable information contained in either the original data or attached to the original specimen).

3. Coded pre-existing or coded prospective data or biospecimens: if

a. the private information/biospecimens were not/will not be collected specifically for the currently proposed research through an interaction or intervention with living individuals, and

b. the investigator(s) never obtains identifiable data/biospecimens because:

i. the holder of the key to decipher the code, destroys the key before the data is provided to the investigator, or

ii. the investigators and the holder of the key enter into an agreement prohibiting the

release of the key to the investigators under any circumstances, or until the individuals are deceased; or

iii. there are laws or IRB-approved written policies for a repository/data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased.

4. Research involving non-living persons. Research that utilizes information, records, or biological materials from individuals who are deceased is generally considered non-human research under federal regulations.

IV. Definitions

See Glossary of Human Research Terms

V. References

21 CFR 50: Protection of Human Subjects

45 CFR 46: Protection of Human Subjects

45 CFR 164: Security and Privacy (HIPAA Privacy Rule)

21 CFR 56: Institutional Review Boards

VI. Revision And Review History

a. Revision Date: June 2026, Author: HRPP; Description: Minor changes to format, clarified method of determination notice and added non-human research

b. Revision Date: May 2026; Author: HRPP; Description: Minor administrative updates regarding use of ETHOS and clarifications regarding non-living persons made.

c. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

d. Revision Date: January 2019; Author: HRPP; Description: Statement regarding addendum to comply with revised Common Rule

e. Revision Date: January 2019; Author: HRPP; Description: New Policy Development

f. Revision Date: J March 2012; Author: IRB Office; Description: IRB Written Procedures