Human Research Protection Program Departmental Policy and Procedure

7.2 Device Research

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: June 5, 2026

I. Policy Statement

a. The IRB reviews projects that involve medical devices to protect the rights and welfare of human subjects involved in such research/investigations as directed by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA).

b. The IRB is responsible for evaluating the use of a device in research involving human subjects (DHHS) or a clinical investigation (FDA) to determine if prior submission to the FDA is required or if the use of the device is exempt from such prior submission to the FDA. If prior submission is required, the IRB must determine whether an Investigational Device Exemption (IDE) has been obtained.

c. It is the policy of UT Southwestern that when research is conducted to determine the safety or effectiveness of a device, the device must have an IDE issued by the FDA, unless the device 1) meets one of the four exemptions from the requirement to have an IDE or 2) meets the requirements for an abbreviated IDE

d. The FDA may initiate proceedings to ban a device if:

   i. the device presents substantial deception in the labeling or an unreasonable and substantial risk of illness or injury, and.

   ii. such deception or risk cannot be, or has not been, corrected or eliminated by labeling or a change in labeling.

II. Scope

a. This policy and procedures applies to all human subjects' research of medical

devices that constitute research involving human subjects (DHHS) or clinical investigations (FDA).

III. Procedures For Policy Implementation

a. The IRB evaluates:

   i. Whether use of the device is considered research and involves human subjects (DHHS - 45 CFR 46.101), and;

   ii. Whether a device used is considered an investigational device (unapproved device or the object of an investigation) and involves human subjects (FDA - 21 CFR 56.102)

b. If the IRB determines neither a.i. nor a.ii. above are true, the activity that includes a device may still be reviewed. If the activity is not considered to be research (non-research) or research not involving human participants under DHHS rules the activity is reviewed following guidance in the 1.2 Determining Whether An Activity Is Research Involving

c. If the activity is considered exempt research (DHHS) not constituting a clinical investigation (FDA) is reviewed following guidance in the 1.3. Exempt Review Of Research.

d. All research (DHHS) involving human participants (whether or not determined to be a clinical investigation (FDA)) is evaluated following guidance in 2.1. INITIAL REVIEW OF RESEARCH.

e. Clinical investigations are evaluated by the IRB to determine whether:

   i. Submission to the FDA is required, and if required has been completed (as indicated by documentation from the sponsor that a valid IDE has been received) or;

   ii. The use of the device is exempt from prior submission to the FDA, or;

   iii. If the use of device may be approved under abbreviated requirements.

iv. The IRB will not approve a clinical investigation using a banned device.

f. Clinical investigations with an IDE (approved under Sec. 812.30) or approved by the IRB under “Abbreviated Requirements” (21 CFR 812.2(b)) exempts the device from sections 502, 510, 514, 551, 516, 519, 520(e) and 520(f). All other sections of the FDA regulations and Federal Food, Drug and Cosmetic Act remain in effect (including Sec. 820.30 (if applicable) and 721 of the Act).

g. Review under “Abbreviated Requirements” and a nonsignificant risk determination alone does not ensure a study will meet criteria for Expedited Review. The study must be minimal risk and involve only procedures listed in one or more of the specific nine categories published in the Federal Register, further explained in 6.2 IRB Approval Of Research.

h. IDE Exemption Categories:

i. Approved/Cleared Devices

1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, and will be used or investigated in accordance with the indications in labeling in effect at that time.

2. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent (510k) to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

ii. A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:

1. Is noninvasive.

2. Does not require an invasive sampling procedure that presents significant risk.

3. Does not by design or intention introduce energy into a participant.
4. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

iii. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing:

1. Is not for the purpose of determining safety or effectiveness, and
2. Does not put participants at risk.

iv. A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

i. Abbreviated IDE Requirements:

i. The IRB may approve the study as a nonsignificant risk device study if the following are met:

1. The device does not present a potential for serious risk to the health, safety, or welfare of subjects and:
2. The device will not be used in this study as an implant, and
3. It will not be used to support or sustain human life in this study, and
4. It will not be of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health in this study

ii. The FDA considers the study to have an approved IDE if the IRB approved it as a nonsignificant risk device study. The PI (or sponsor of the study) must then comply with the abbreviated requirements under 21 CFR 812.2(b):

1. The sponsor labels the device in accordance with 21 CFR §812.5 and must bear the statement "**Caution** - Investigational Device. Limited by Federal (or United States) law to investigational use."
2. The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device was not a significant risk device, and maintains such approval.
3. The sponsor ensures that investigators participating in an investigation obtain and document informed consent from each subject under the investigator's care (under 21 CFR 50), unless documentation was waived.
4. The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations.
5. The sponsor maintains the records required under 21 CFR 812.140(b)(4) and (5) and makes the reports required under 21 CFR 812.150(b)(1) through (3) and (5) through (10).
6. The sponsor ensures that participating investigator (if different from the sponsor) maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under §812.150(a) (1), (2), (5), and (7).
7. The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

j. When a Clinical Investigation (i.e., research proposal) is received where the device has an IDE number the HRPPD documents a valid IDE has been received as evidenced by:

   i. A document from the sponsor indicating the IDE number or;

   ii. A letter from the FDA indicating the IDE number or;

   iii. Other HRPPD-approved method of validation.

k. When a Clinical Investigation (i.e., research proposal) is received where the device does not have an IDE number

   i. The HRPPD staff pre-reviewer considers the investigator's rationale for exemption as provided in the ETHOS application. Based on this review, the HRPPD staff pre-reviewer determines whether the device could be exempt from the requirements to have an IDE and forwards this recommendation to the IRB for consideration.

   ii. If the IRB agrees with the rationale for the exemption determination, the investigator will be notified of the IRB's decision (see 8.2 Reporting Policy And Procedure)

   iii. If the HRPPD staff pre-reviewer determines that the use of the device is not eligible for exemption under the categories described above, then the protocol will be examined for approval under the abbreviated IDE requirements. If the protocol is either not eligible for abbreviated IDE requirements, or not eligible for expedited review it will be assigned for review by the convened IRB. A significant/non-significant risk device determination will be made and documented in the IRB minutes.

l. Significant/Non-Significant Risk Determination

   i. A significant risk/non-significant risk (NSR) determination is typically made by the sponsor.

   ii. During the initial review of the protocol, the IRB will consider the sponsor's rationale for the device risk determination.

   iii. If the sponsor makes an initial NSR determination, and the IRB agrees with this determination, then the IRB confirms that the study will be conducted in accordance with the abbreviated IDE requirements as described above. For NSR determinations, the study may be initiated without an IDE number. This determination will be documented in the IRB minutes for Convened Review.

iv. If the IRB disagrees with the sponsor's NSR determination and determines that the device represents significant risk, then the investigator and sponsor will be informed of this decision. The IRB's significant risk device determination will be documented in the IRB minutes. For such determinations, the sponsor must submit an IDE application to the FDA before the IRB will review the study. When the application is reviewed, the IDE number

m. Use of devices to perform genomic sequencing

i. For research that involves genome sequencing or the use of genome sequencing platforms/software, investigators must certify that no genome sequencer or associated software used in the research is produced by or on behalf of an entity domiciled in, owned by, or controlled by a 'foreign adversary' as defined in 15 C.F.R. § 791.4(a). Use of prohibited equipment/software is not permitted. Protocols must also ensure genomic data generated under the research are not accessible by persons located in a foreign-adversary country.

IV. Definitions

See glossary of human research terms

V. References

a. 21 CFR 50: Protection Of Human Subjects

b. 45 CFR 46: Protection Of Human Subjects

c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56: Institutional Review Boards

e. 21 CFR 812: Investigational Device Exemptions (FDA)

f. 21 CFR 809: In Vitro Diagnostic Products For Human Use (FDA)

VI. Revision and Review History

a. Revision Date: June 2026; Author: HRPP; Description: Reference to eIRB updated to ETHOS and adding a section for use of devices to perform genomic sequencing

b. Revision Date: November 2022; Author: HRPP; Description: Removed ability for NSR determinations to be reviewed using expedited review procedures.

c. Revision Date: November 2021; Author: HRPP; Description: Defined that the IRB will not approve a study using a banned device

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

e. Revision Date: January 2019; Author: HRPP; Description: Revision to reference 2019 common rule

f. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

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