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Subject: Types of Institutional Review Board (IRB) Review
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Types of IRB Review

Per the Human Research Protection Program (HRPP) manual policies and procedures:

HRPP 2.8.1-In conducting the review of proposed research, each IRB must obtain information in sufficient detail to make the determinations required under federal and state regulations and institutional policies. This review may be conducted administratively for projects that meet criteria for exemption from formal IRB review, through expedited procedures for projects that meet regulatory criteria, or at a convened meeting of the IRB.

There are three (3) types of review paths for an IRB application: **Exempt, Expedited, and Full Board.** The review path is determined by:

- Level of risk to subjects associated with the project;
- The type of research being conducted (e.g., an educational intervention, a survey, blood draw, etc.);
- The sensitivity of the research questions or complexity of the research design;
- The involvement of vulnerable populations as research subjects.

HRPP 2.9-Exempt Review

- The Federal regulations at 45 CFR 46.104(d) provide for eight specific categories of activities that may qualify as exempt from formal IRB review and oversight. However, categories 7 and 8, related to broad consent, have not been implemented at TTUHSC El Paso at this time;
- Human subjects research can qualify for an exemption if it is no more than minimal risk and all of the research procedures fit within one or more of the exemption categories (eCFR :: 45 CFR Part 46 (2018-07-19) -- Protection of Human Subjects);
- If a researcher has a question regarding the applicability of the federal exemption categories, s/he may contact the IRB and/or review the decision charts found at the OHRP website (Human Subject Regulations Decision Charts: 2018 Requirements | HHS.gov);
- Exemption is not determined by the TTUHSC El Paso researcher or departmental representatives; must be submitted for review and acknowledgment by a TTUHSC El Paso IRB member or designee;
- The designation must be granted prior to the research commencing. IRB acknowledgement of exempt human research may never be granted for research already in progress or completed;
- If determined to not meet the definition of research with human subjects, the determination will be 'Declined as Human Subject Research';
- The IRB Chair/designee retains the right to refer any application for expedited or full board review, even if it appears to meet the qualifications for exemption.

HRPP 2.10-Expedited Review

- Review of research that may be reviewed and approved without convening a meeting of the IRB; must be submitted for review and approval by a TTUHSC El Paso IRB member;

- Regulations at 45 CFR 46.110 [21 CFR 56.110] permit IRB review through an expedited procedure;
- Research involves no more than minimal risk; if the reviewer does not believe a minimal risk determination is acceptable, full board review is required;
- Involves procedures that are listed in one or more of the research categories (OHRP Expedited Review Categories (1998) | HHS.gov);
- If the project does not meet all criteria for expedited review and/or at the discretion of the IRB member, it will be placed on the agenda for consideration at the next convened meeting.

HRPP 2.11-Full Board Review

- Federal regulations and institutional policy require full board review for applications where the research involves more than minimal risk or it has been referred to the committee by the IRB Chair or expedited reviewer;
- Proposed human subject research that does not fall into either the exempt or expedited review categories;
- Requires a convened meeting of the IRB at which a majority of the voting membership of the IRB is present, including at least one member whose primary concerns are in non-scientific area; must receive the approval of a majority of those voting members present;
- The most rigorous level of review;
- May involve clinical procedures with drugs, devices, or biologics; innovative new medical or surgical procedures; vulnerable populations.

For additional information related to human subject research, please review the IRB Website.

Thank you,

TTUHSC El Paso Institutional Review Board