Expedited Human Subject Research Procedures

I. Introduction

These procedures supplement the Protections of Human Subjects in Research Policy (the "Policy").

Federal regulations permit the use of an expedited review procedure for Minimal Risk research that meets one or more of the OHRP expedited review categories; minor changes to research previously approved by the full board; and research for which limited IRB review is a condition of exemption.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by the full board.

II. Definitions

All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

Designated Reviewer. The IRB Chairperson or an experienced IRB member designated by the Chairperson who conducts an expedited review on behalf of the IRB.

III. Expedited Research

A. Overview of Process. Applications qualifying for expedited review are accepted and review on a rolling basis. Below is an overview of the review process.

1. PI submits protocol materials to irbsubmit@tcu.edu.

2. Research Compliance reviews the application for completeness and makes an initial assessment of whether the submission is eligible for expedited review in accordance applicable law and TCU policy and procedures.

   a. If eligible for expedited review, Research Compliance sends the submission to a Designated Reviewer. The Designated Reviewer conducts the review and has the authority to make a determination or to refer a submission for full board review for multiple purposes (e.g., clarification, expertise), including disapproval. Only the full board has the authority to disapprove a study.

      In accordance with applicable law, documentation of the review will include the specific permissible categories justifying the expedited review and, if continuing review is required, the rationale for the requirement.

   b. If not eligible for expedited review, the submission is added to the agenda of the next IRB committee meeting.

3. Notice of Approval to IRB and Institution. All protocols approved through the expedited review process in any month will be documented on that month's IRB meeting agenda or, if

no meeting occurs in that month, the agenda for the next meeting. Agendas will be retained in the IRB records for a minimum of three years or as long as required by applicable law, whichever is shorter.

B. Research Eligible for Expedited Review. Expedited review procedures may be used for initial or continuing review of research that presents no more than Minimal Risk to human subjects **and** involves only activities listed in one or more of the following categories.

The expedited review procedure may not be used, however, for classified human subjects research, or where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects (e.g. financial standing, employability, insurability, reputation, or be stigmatizing), unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(Note: The activities listed should not be deemed to be of Minimal Risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than Minimal Risk to human subjects):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. Continuing review of research previously approved by the convened IRB (a) where the research is permanently closed to the enrollment of new participants, and all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research not conducted under an investigational new drug application or an investigational device exemption where categories (2) through (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.

C. Continuing review of research previously approved by the convened IRB may be reviewed by expedited review in any of the following situations:

- the research is permanently closed to enrollment, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up;
- no participants have been enrolled and no additional risks have been identified; or
- the remaining research activities are limited to data analysis.

D. Continuing Review for Expedited Research. Minimal Risk studies eligible for expedited procedure do not require annual continuing review, unless otherwise determined by the IRB. The IRB approval letter will indicate whether continuing reviews will be required of the study. If continuing reviews are not required, Researchers will be required to complete an annual progress report instead, simply to allow the IRB to determine whether the research has been completed and hence IRB approval is no longer needed. Regardless of the type of annual documentation required (i.e. continuing review or annual progress report), researchers will receive a 90, 60, and 30 day notice prior to the reporting date.

IV. Related Research Policies and Procedures

Research Integrity Policy

Research Integrity Procedures
Protection of Human Subjects in Research Policy
Human Subjects Research Oversight and Monitoring Policy
Human Subjects Research Oversight and Monitoring Procedures
IRB Review of Human Subjects Procedures

V. Effective Date

Effective Date: January 21, 2019