FRANKLIN UNIVERSITY

EXPEDITED REVIEW

The Institutional Review Board (IRB) uses an expedited review process to review studies that meet the categories adopted by the US Department of Health and Human Services (HHS) that involve no greater than "minimal risk." Expedited review procedures allow the IRB to review and approve studies that meet the criteria in the document below without convening a meeting of the full IRB. The review may be carried out by the IRB Chair or by one or more experienced reviewers from among members of the IRB. The expedited reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111. Also, expedited reviewers ensure that the study's informed consent process and documentation meets the requirements as specified in 45 CFR 46.116, unless the IRB waives the requirements in accordance with federal regulations.

Expedited reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research. Only the convened IRB disapproves a research activity in accord with non-expedited procedures set forth in the HHS regulations.

The IRB agenda for convened meetings advises the IRB of research studies approved using expedited review procedures. Any member can review the entire file of an expedited study.

PROCEDURES

Assigning Reviewers

1. IRB staff make initial IRB reviewer assignments based on the member's familiarity with IRB issues, experience, and expertise. The expedited reviewer notifies IRB staff if he/she is not available to conduct an expedited review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. IRB staff document who served as expedited reviewer.

Submission and Screening

1. The PI makes a preliminary determination that a protocol is eligible for expedited review based on the criteria in the document found at the end of this SOP. The IRB makes the final determination regarding whether a protocol is eligible for expedited review.

2. The PI submits a completed application, which IRB staff screen for completeness and accuracy and make a preliminary determination whether the application meets the criteria for expedited review, including minimal risk, and identifies the research categories. If the application fails to meet the criteria for expedited review, IRB staff inform the PI that the study will undergo full or exempt review.

3. IRB staff follow the screening procedures outlined in the Initial Full Review SOP (e.g., waiver of informed consent or documentation requests; completion of mandatory training requirements; or need of additional expertise). See the Initial Full Review SOP for a detailed description of IRB staff procedures.

4. After screening the application, IRB staff assign a primary reviewer. The reviewer receives notification that a review has been requested. In the event an assigned reviewer has a conflict of interest or is otherwise unable to complete the review, IRB staff will re-assign the application for review.

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5. If necessary, the IRB Chair or another IRB member may serve as a second reviewer of the application. In the event the IRB Chair or other IRB member has a conflict of interest or is otherwise unable to complete the review, IRB staff will re-assign the application for review.

6. With assistance from IRB staff as needed, the reviewer documents federally mandated specific findings (e.g., Subpart B, C, D, or waiver of informed consent or documentation).

IRB Reviewers have access to the following material:

1. Expedited reviewers have access to all components of an application to the IRB. They also receive comments and recommendations from IRB staff.

2. Expedited reviewers review all information in the application in enough depth to be familiar with the protocol, to determine whether the research is eligible for expedited review, and to determine whether the research meets the regulatory criteria for approval.

REVIEW OUTCOMES

1. Expedited reviewers make the final determination as to whether research activities meet the expedited review criteria.

2. Reviewers can recommend that the activities do not fall under IRB purview.

3. Reviewers determine whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111.

4. Expedited reviewers ensure that the investigator will conduct the informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117, unless the IRB waives the requirements in accordance with federal regulations.

5. The expedited reviewers raise only controverted issues or request changes they have determined do not meet the federal criteria for approval or Franklin University IRB policies.

6. The expedited reviewers document their determinations regarding expedited eligibility, applicable expedited category(ies), and whether the research meets the federal criteria for approval.

7. Expedited reviewers make one of the following three determinations:

- APPROVED: IRB approval indicates that the IRB reviewer concluded that the research and consent forms meet the federal criteria for approval. An IRB approval vote verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. IRB staff send the investigator an approval letter.
- REVISIONS and/or ADDITIONAL INFORMATION REQUIRED: The IRB reviewer withholds approval pending submission of revisions and/or additional information. IRB staff send the investigator notification describing the revisions and/or additional information requested by the IRB expedited reviewer. The PI responds to the revisions requested by the IRB and sends the response to the IRB. IRB staff notify the expedited reviewer of the response and request further review.

- FULL REVIEW REQUIRED: The IRB expedited reviewer(s) may determine the protocol requires full review by the IRB at a convened meeting.

8. Unless the IRB determines otherwise, continuing review of research is not required when research is eligible for expedited review in accordance with 45 CFR 46.110; however, Cayuse will send an automated notice when it is the anniversary of the study's approval. These notices are sent to the PI before the one-year period after initial IRB approval (e.g., approximately 90 days, 60 days, and 30 days prior to one year). The anniversary notice is a reminder that PIs should submit renewal materials and modifications if there are changes or updates to the approved protocol.

9. The IRB Office procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters outlined in the Initial Full Review SOP apply to expedited review as well.

10. The date the expedited reviewer signs off on final approval of the study is the date the approval period starts. IRB staff document the approval period dates in the approval letter to the PI.

11. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns via a written appeal that includes justification for changing the IRB decision. The PI sends the request to the IRB Office. The appropriate reviewer or, if need be, convened IRB review the appeal. The appeal determination final.

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FEDERALLY MANDATED EXPEDITED REVIEW CRITERIA – EFFECTIVE NOVEMBER 9, 1998 – AND DEFINITION OF MINIMAL RISK GUIDANCE TO PI AND REVIEWERS

Expedited procedures can be used only to review a study if the only involvement of human subjects fits one or more of the categories specified in the federal regulations and if all of the procedures present no greater than "minimal risk."

The IRB reviewer confirms that **all of the research activities** fit in one or more of the expedited categories. If the research includes activities that do not fit in the categories, the study is not eligible for expedited review even if the research involves "minimal risk."

The US Department of Health and Human Services defines minimal risk to mean "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [45 CFR 46.102(j)].

Investigators are asked to provide a risk assessment, but it is the IRB reviewer's responsibility to determine whether the research meets the federal definition.

The IRB reviewer must consider two questions:

- Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests? OR
- Is the magnitude of the harm or discomfort greater than that encountered ordinarily in the daily life or during the performance of routine physical or psychological examinations or tests?

If the answer is "yes" to either of these questions, the research does not meet the definition of minimal risk.

FEDERAL EXPEDITED REVIEW APPLICABILITY AND CATEGORIES

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. 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.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used 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= 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.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 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 Part 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. (a) from healthy, nonpregnant 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 nondisfiguring manner; (b) deciduous teeth at 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 gumbase 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. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) 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 nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

   b. where no subjects 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 investigational device exemption where categories two (2) through eight (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.