

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 3.10
Expedited Review

Policy

The expedited review process consists of a review of research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. Such designees must have demonstrated familiarity with the scope of the research as well as a sound grasp of the relevant regulations and policies. Research reviewed by the expedited review process will undergo the same careful review by its reviewer as one subjected to full review; however the reviewer of an expedited project may not disapprove the research. Only a fully convened committee can disapprove a research project. A determination may be made that full committee review is required although the criteria below is met.

Categories of Research Appropriate for Expedited Review

New Studies

The categories of research that may be reviewed by the IRB through an expedited review process include research activities that (1) present no more than minimal risk or discomfort to human subjects, and (2) involve only procedures in one or more of the categories listed below. Minimal risk is defined in 45 CFR 46.102(i) and 21 CFR 56.102(i) as "...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...." This assessment should take into account both the likelihood of harm and the severity of that harm if it occurs.

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 process when the specific circumstances of the proposed research involve no more than minimal risk or discomfort to human subjects. The categories in this list apply regardless of the age of subjects, except as noted. The categories listed pertain to both initial and continuing IRB review:

1. Research on drugs for which an investigational new drug application (21 CFR 312) is not required.
 - a) Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with 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, heel or ear stick, or venipuncture, as restricted in:
 - a) From healthy, non-pregnant adults who weigh at least 110 lbs. 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.
 - 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, 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, including:
 - a) Hair and nail clippings in a non-disfiguring 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 is accomplished in accordance with accepted 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. Note: Studies 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.
 - 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, electromyogram, 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 non-research purposes (such as medical treatment or diagnosis).
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.

The expedited review process 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. Furthermore, the expedited review process may not be used for classified research involving human subjects. The expedited review process may not be used for procedures involving collection of samples for genetic analysis, unless collected anonymously.

When an investigational device meeting Non Significant Risk (NSR) criteria is used in a study that also meets minimal risk criteria, the study may be reviewed by the expedited review process. NSR medical device research not meeting minimal risk criteria will be reviewed by the full IRB. If the IRB reviews the research, the IRB also will make the final determination to concur or not concur with the sponsor's assessment of the device's non-significant or significant risk status.

For projects that include "retrospective" review of records, "retrospective" is defined as data that exists prior to the time of the IRB application submission. The Research Plan for retrospective record review projects will include the specific dates of the records to be reviewed. An amendment may not be used to revise the project to include a later date. If a later date is being requested, a complete "NEW" application must be submitted.

Extended Approval for Studies

UC San Diego's Federal Wide Assurance allows for some flexibility in applying human subjects federal regulations to non-federally funded research. The UCSD IRB/HRPP may grant study approval of up to 3 years (1095 days) for non-exempt studies that satisfy all of the following criteria:

1. The research involves no more than minimal risk to participants.

2. The research does not have direct or indirect federal funding including federal training and program project grants.
3. The research has not been reviewed by a convened IRB at any point in time.
4. The research is not subject to FDA oversight.
5. The research does not involve prisoners or parolees.
6. The research is not directed or overseen by a federal agency that has signed on to the Common Rule.
7. The research is not seeking or obtaining a Certificate of Confidentiality.
8. The research has no contractual obligations or restrictions that preclude eligibility in this policy (e.g., the non-federal sponsor or funder of the research requires an annual review).
9. The research is not funded by the California Institute for Regenerative Medicine.
10. The research does not involve key personnel's time or university resources that are in any part funded by a federal award.
11. The UCSD IRB is not serving as the IRB of record for an institution that applies the federal regulatory standards to all research regardless of the source of funding and/or requires annual review.

If a study becomes ineligible for extended approval, such as by securing new federal funding or other changes, the PI is responsible for promptly submitting an amendment to inform the HRPP of these changes. The HRPP will issue a “new” approval letter with a shortened approval period, as appropriate.

The PI is also responsible for all post-approval submissions even when a project is granted an extended approval. These responsibilities include the following:

1. Amendment request submissions, which must be approved before implementation.
2. Protocol deviations/violation and UPRs submitted per IRB/HRPP SOPP reporting criteria.
3. Continuing Review documents submitted 45 days before the expiration date of the study, if the study is still active.
4. Study Closure documents submitted when study is complete.

Minor Changes in Approved Studies and Informed Consent Documents

In some cases the Chair or Chair's designee may use the expedited review process to approve minor changes to previously approved human research procedures or informed consent documents during the period for which approval is authorized. This is only possible if the changes do not affect the rights and welfare of study subjects, do not have the potential to increase risk to study subjects, and do not involve significant changes in study procedures. Any revision that entails any increase in risk or discomfort to the participants, or which substantively changes the study design or study procedures, must be reviewed by the full IRB at a convened meeting. Changes/revisions that involve more than minimal risk or do not fall into Expedited Review categories 1-7 noted above cannot be reviewed using the expedited procedure.

Continuing Review, Interim and Completion Reports

Continuing Review for projects initially approved under expedited procedures is conducted at the intervals not greater than 365 days from the most recent project approval unless the project has been approved for extended approval, in which case intervals will be not greater than 1095 days. Interim and Completion Reports may be reviewed using the expedited review process only if:

1. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or
2. No subjects have been enrolled and no additional risks have been identified; or
3. The remaining research activities are limited to data analysis; or
4. For research not conducted under an investigational new drug application or investigational device exemption where 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; or
5. The research initially qualified for expedited review and there have been no changes that would increase the risk.

Modifications Required to Secure Approval

Minor revisions to the informed consent and other documents and clarifications submitted in response to convened IRB review as a condition for approval may be reviewed by expedited review, if determined by the convened IRB at the time of review. The Chair, his/her designee, or the primary reviewer will review the modifications and determine whether the requirements of the IRB have been met. Approval can be issued providing the revisions, documentation or clarifications do not indicate or result in a substantive change to the study design and procedures or change the risk/benefit ratio, which would require review by a convened IRB.

Modifications in Advertisements

The Chair or Chair's designee may approve minor modifications to approved recruitment advertisements using the expedited review process.

Off-site Safety Reports, Sponsor Provided Annual Reports and Data Monitoring Committee/Data Safety Monitoring Board Reports

The Chair or Chair's designee may review off-site safety reports (including IND safety reports), sponsor provided annual reports, and data monitoring committee/data safety monitoring board reports by expedited review. These reports would typically indicate that no safety issues were found, and the study should continue without modification.

Translations

Translations of consent forms and other documents submitted for IRB approval may be reviewed by an expedited review process provided one of the following procedures are followed:

1. The IRB-approved consent form is translated by the sponsor or site and submitted to the IRB. The IRB will have a member or consultant fluent in the language of the consent review the translated document for accuracy. It must match the English version; or
2. The sponsor or investigator may submit the IRB-approved version of the consent to a certified translator or individual with sufficient expertise for translation. Written documentation attesting to the accuracy, such as the proof of certification and/or affirmation by the PI, is also required.
3. While a translator may be used to facilitate conversation with the subject, routine ad hoc translation of the consent document may not be substituted for a written translation.

Process for Conducting Expedited Review

The Chair or the Chair's designee can require full review of any research at his/her discretion, even if the research would otherwise qualify for expedited review status. The decision to actually grant expedited review status is initially made by the Chair or designee. The Chair or designee must review the full set of documents submitted by the investigator in reaching a decision during an expedited review.

If it is determined that expedited review is appropriate for a study or one of the other activities described above, and the Chair or designee wishes to use this procedure, the Chair or designee will document his/her determination of risk. The review is then performed by one or more experienced members designated by the Chair. The Chair or designee may exercise all of the authorities of the IRB, except that he/she may not disapprove the research. A research proposal may be disapproved only after review by the IRB at a convened meeting. The Chair is encouraged to use the expedited review process judiciously.

The Principal Investigator must submit the following documents to the HRPP for consideration of expedited review: application facesheets; full research plan; and informed consent documents, master plan and investigator brochure, recruitment materials, and support letters (if applicable); related grant applications or progress reports available at the time of the IRB application; subject surveys or questionnaires (if applicable), supporting documentation from sponsors; drug-related information such as package inserts (if applicable); any other information known to be relevant to the scientific merit, determination of safety, risk, and benefit of the study.

Reviewers evaluating research under the expedited process either as an initial or continuing review must determine that all applicable criteria (45 CFR 46.111) are satisfied and that the research represents one or more approvable categories of research under the expedited process. Reviewers cannot disapprove research under the expedited review process.

When the expedited review process is used for initial review, continuing review, or completion reports, the IRB members will be informed of actions taken by the IRB Chair or designee at the next convened meeting. At that time the members will have the opportunity to further review, discuss, perform full review, disapprove, or require

modifications. All review requirements and approval criteria for initial and continuing review described elsewhere in these SOPP continue to apply to research reviewed under the expedited review process.

Considerations for identifying and managing conflict of interest for expedited reviews follow the same procedures as with full IRB review. When the Chair or designee discloses any conflict of interest, the Chair or designee cannot participate in the review.

Procedures

1. IRB Administrator or designee will review new submissions requesting expedited review to determine if they qualify for expedited review; prepare and distribute summary of expedited review actions to IRB members at next convened meeting; and document discussions of actions in minutes.
2. IRB Chair or designee will confirm and approve determination that submission qualified for expedited review; make and document determination of minimal risk research; and designate an appropriate IRB member (including self) to conduct the expedited review.
3. Designated Reviewer will conduct review (including protocol, informed consent form).

Applicable Regulations

[21 CFR 56.110](#)

[45 CFR 46.110](#)

<http://www.hhs.gov/ohrp/policy/expedited98.html>