1. Applicability

These procedures apply to CUNY research involving human subjects that meets the criteria for expedited review, as outlined in the federal regulations at 45 CFR 46.110.

2. Criteria for Expedited Review

2.1. Initial Review

A new human subjects research protocol may be processed on an expedited basis if the research poses no more than minimal risk[1] to subjects, as assessed by the reviewer; AND the research involves only those procedures listed in the following categories:

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 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) 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

[1] ***Minimal risk*** means that 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

(b) from other adults and children[2], 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

[2] ***Children*** means persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. 45 CFR 46.402

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).

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.

2.2. **Continuing Review**

2.2.1. **When initial review was conducted on an expedited basis**
Research that received initial review on an expedited basis may be expedited at the time of continuing review, as long as the research continues to pose minimal risk to the subjects and research procedures continue to fall within categories 1-7 listed in Section 2.1 above.

2.2.2. **When initial review was conducted by the convened IRB**
Research that received initial review by a convened IRB may be reviewed on an expedited basis at the time of continuing review if it meets one of the following criteria outlined in regulatory categories 8 or 9:

8.a. Research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and research remains active only for long-term follow-up of subjects.

8.b. No subjects have been enrolled and no additional risks have been identified.

8.c. Remaining research activities are limited to data analysis.

[**NOTE**: For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category 8 (a), (b), or (c) are satisfied for that site. However, with respect to category 8(b),

while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

9. 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.

   [**NOTE**: The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

2.3. **Modifications to IRB-Approved Protocols**

2.3.1. **When initial review was conducted on an expedited basis**

Proposed modifications to an IRB-approved protocol that ***initially underwent expedited review*** may be reviewed on an expedited basis if:

2.3.1.1. With the proposed modifications, the research would continue to pose no more than minimal risk to subjects; AND

2.3.1.2. Proposed modifications involve only those procedures listed in categories 1-7 in Section 2.1 above.

2.3.2. **When initial review was conducted by the convened IRB**

Proposed modifications to an IRB-approved protocol that received ***initial review by a convened IRB*** may be reviewed on an expedited basis if:

2.3.2.1. Proposed modifications do not pose an increased risk to subjects; AND

2.3.2.2. Proposed modifications constitute a minor change to previously approved research.

3. Exceptions and Limitations

3.1. 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 such that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

3.2. The Expedited review procedure may not be used for classified research involving human subjects.

4. Review and Reviewers

4.1. When reviewing research on an expedited basis, the designated reviewer(s) shall receive and review all documentation that would normally be submitted for a convened review, including the complete protocol, funding applications, and recruitment and consent documents.

4.2. Expedited review is conducted by the UI-IRB Chairs, Vice Chairs and members appointed to the Expedited Review Panel.

4.3. During an expedited review process, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research.

5. Possible Outcomes Of Expedited Review

5.1. **Approval.** The submission is approved, and no changes to the submission are required.

5.2. **Conditional Acceptance.** Reviewer stipulates specific clarifications or modifications to the protocol. The final approval is contingent upon the reviewer's acceptance of Principal Investigator's revisions in accordance with the reviewer's stipulations.

5.3. **Referred for Full Board Review.** The reviewer determines that the submission does not meet the criteria for expedited review, and refers it for review by the convened IRB. The reviewer may choose to request additional information from the investigator prior to review by the convened IRB.

6. Convened IRB Notification and Review

6.1. As part of the meeting agenda for UI-IRB meetings, the Board members will be notified of all expedited approvals issued since the date of the previous notification.

6.2. If a protocol eligible for expedited review is instead reviewed at a convened IRB meeting, the CUNY UI-IRB may complete the review and may approve the protocol at the meeting. The IRB shall determine that the protocol meets the criteria for expedited review, determine the appropriate category of expedited review, and document this in the minutes. All subsequent reviews, including continuing reviews and modifications may be conducted under expedited review, provided the risk level does not change and the protocol continues to meet the eligibility criteria for expedited review.

References

1. Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects

2. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*, April 18, 1979

3. US Food and Drug Administration, *Comparison of FDA and HHS Human Subject Protection Regulations*