Human Subjects Committee Expedited Review Policy	Document No.	HSC-2018-001
	Effective Date	
	Revision Date	July 1, 2022
	Revision No.	3.0
	Page No.	
	Approval:	July 22, 2022

1.0 PURPOSE

This procedure describes how the Human Subjects Committee (HSC) of the Lawrence Berkeley National Laboratory (LBNL) conducts expedited reviews of human subjects research protocols. The goal is to ensure the protection of the rights and welfare of human subjects involved in research conducted under the auspices of LBNL, while streamlining the review process for applicable projects.

2.0 REVISION HISTORY

Date	Revision No.	Change	Reference Section(s)
01/15/10	1.0	New Procedure Drafted	N/A
9/13/12	1.1	Reformatted	All
12/07/18	2.0	Updated to comply with RCR	All
7/1/2022	3.0	Updating/formatting, defining minor modifications eligible for expedited review	All

3. DEFINITIONS

3.1. Expedited review: a human subjects research protocol review conducted by the HSC Chair or their designee(s), rather than by a convened quorum of the HSC

3.2. Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition and do not fall under one of the exclusions at § __46.102(l)(1)-(4) constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes. Exclusions: Journalism or collection of oral histories; public health surveillance activities; collection and analysis of data for criminal justice purposes; authorized operational activities for national security purposes as determined by the Department of Energy.

3.2.1. Systematic Investigation: a study or examination involving a methodical procedure or plan.

3.2.2. Generalizable knowledge: The information is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

3.2.2.1. Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied

3.2.2.2. Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

3.3. Human subject: a living individual about whom an investigator conducting research obtains: (1) information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens or (2) Obtains, uses, studies, analyzes, or generates identifiable private information. In clinical research, a subject is someone who becomes a participant in research, either as a recipient of the test article or as a control.

3.3.1. **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.3.2. **Interaction** includes communication or interpersonal contact between investigator and subject.

3.4. The "Common Rule", also known as "Federal Policy for the Protection of Human Subjects" is the regulatory language originally published in 1991 and codified in separate regulations by 15 Federal departments. The 2018 revision of these regulations, sometimes called the Final Rule, has been adopted by 20 agencies at this time. The basis of the regulations is 45 CFR 46 for the Department of Health and Human Services, and they are found in different CFRs based on the agency (e.g. 10 CFR 745 Department of Energy). To refer to all of the regulatory versions the annotation § __ will be used with a specific section noted subsequently when applicable.

3.5. Private information is information associated with individuals or groups of individuals that could reveal details of their lives or other characteristics that could impact them. Private information includes:

3.5.1. Information that is observed or recorded about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place;

3.5.2. Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g., a medical record or a utility bill.

3.5.3. **Identifiable private information** is private information for which the identity of the subject is associated with the information or may readily be ascertained by the investigator

3.5.4. An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

3.6. Risk: The probability of discomfort, harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible risks may vary from minimal to significant.

3.7. Protocol Lead Investigator: The researcher with primary responsibility for conducting human subjects research under a specific protocol

4.0 POLICY

The policy of Berkeley Lab is:

4.1. To ensure the protection of the rights and welfare of human subjects in research conducted by, or under the supervision of, its faculty, staff, or students.

4.2. That expedited review procedures may be used for certain kinds of research involving no more than minimal risk, and for minor changes in approved research, so long as the designated reviewer(s) can make the determinations required under § __111 (or 21 CFR 56.111 for FDA-regulated research) regarding risks, potential benefits, informed consent, and safeguards for human subjects.

5.0 PERSONS AFFECTED

5.1. The Human Subjects Committee (HSC); including the Chair and those HSC members designated by the Chair and appearing on the Committee roster as eligible to perform expedited reviews

5.2. All Protocol Lead Investigators (PLIs) participating in, conducting, or with oversight over human subjects research that may be eligible for expedited review.

5.3. Compliance Specialist(s) and other HARC Office staff.

6.0 RESPONSIBLITIES

6.1. The **Chair of the HSC** shall identify those members who, in addition to themselves, may act as designated Reviewers.

6.2. Designated **Reviewer(s)** shall carry out expedited reviews according to the procedures outlined in 7.0 (below). The designated Reviewer(s) may exercise all of the authorities of the full committee except that the Reviewer(s) may not disapprove the research. Additionally, the Reviewer may refer the study to the full committee for review.

6.3. The full committee, when considering a study initially submitted for expedited review, in addition to performing their usual review, shall make a determination whether future reviews of the same study shall be by Expedited or Full Committee review.

6.4. Protocol Lead Investigators (PLIs) requesting an expedited review by the HSC shall follow this policy and the procedures outlined in 7.0 (below).

6.5. The **Compliance Specialist** who processes the initial application for expedited review shall make an initial determination that the application meets the criteria for expedited review and is complete enough to permit review, and shall assign a Designated Reviewer with no obvious conflicts of interest from among those members identified as eligible by the Chair. In making these determinations, the

Compliance Specialist shall consult with the Chair and/or Designated Reviewers as needed.

7.0 PROCEDURES:

7.1. Federal regulations at § __110 allow the HSC to review certain human subjects research on an expedited basis if the study meets specified criteria. Additionally, the standard requirements for informed consent (or its waiver or alteration) apply to all HSC expedited or full committee approvals.

7.2. The HSC may use an expedited procedure to conduct an initial or continuing review of research when;

7.2.1. the proposed research activities present no more than minimal risk to human subjects, and

7.2.2. The proposed research meets the requirements of the review categories defined in part 7.4 of this policy, or

7.2.3. Minor changes, as defined in part 7.5 below, are submitted for previously approved research during the period for which approval is authorized, or

7.2.4. Limited IRB review is a condition of exemption under § __.104 categories.

7.3. Expedited procedures shall not be used when the research is classified, or greater than minimal risk.

7.4. The HSC may review research through the expedited review procedures when the proposal falls within one of the following research categories eligible for expedited review:

7.4.1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

7.4.1.1. (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.)

7.4.1.2. (b) Research on medical devices for which

7.4.1.2.1. (i) an investigational device exemption application (21 CFR Part 812) is not required; or

7.4.1.2.2. (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

7.4.2. Research involving the (limited) collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

7.4.2.1. 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 two times per week; or

7.4.2.2. 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/kg in an 8-week period and collection may not occur more frequently than two times per week.

7.4.3. Research involving the prospective collection of biological specimens for research purposes by noninvasive means. Examples:

7.4.3.1. Hair and nail clippings in a non-disfiguring manner;

7.4.3.2. Deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction;

7.4.3.3. Permanent teeth if routine patient care indicates a need for extraction;

7.4.3.4. Excreta and external secretions (including sweat);

7.4.3.5. 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;

7.4.3.6. Placenta removed at delivery;

7.4.3.7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

7.4.3.8. 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;

7.4.3.9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and/or

7.4.3.10. Sputum collected after saline mist nebulization.

7.4.4. Research involving the 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:

7.4.4.1. 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 subjects' privacy;

7.4.4.2. Weighing or testing sensory acuity;

7.4.4.3. Magnetic resonance imaging;

7.4.4.4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; and/or

7.4.4.5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

7.4.5. **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).** Note: some research in this category may be exempt from regulations (see § __.101(d)(4)). This listing refers only to research that is not exempt.

7.4.6. **Research involving the collection of data from voice, video, digital, or image recordings made for research purposes.**

7.4.7. **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 DHHS regulations (see § __.101(d)(2) and (b)(3)). This listing refers only to research that is not exempt.

7.4.8. **Continuing review of research previously approved by the fully convened HSC as follows:**

7.4.8.1. Where 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

7.4.8.2. Where no subjects have been enrolled and no additional risks have been identified; or

7.4.8.3. Where the remaining research activities are limited to data analysis.

7.4.9. 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 HSC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

7.4.10. Continuing review of research previously approved under expedited review procedures for which LBNL has agreed to provide annual reporting to the Department of Energy.

7.5. OHRP and FDA guidance allows the IRB to use an expedited review procedure to review "minor changes in previously approved research." The IRB makes the final determination as to whether study changes qualify as "minor changes in previously approved research." Minor modifications are defined by the HSC as those changes which meet the following requirements:

7.5.1. Changes, if considered independently from the overall research, involve no significant alteration in study design or fall into one or more categories allowing exempt or expedited review, AND

7.5.2. Involve no greater than minimal risk.

7.5.3. Examples of minor modifications include personnel changes (not including PLI/co-PLI); minor procedural changes; changes that reduce risks; changes to existing procedures that add minor risks (e.g., adding a second small blood draw); changes to wording in the application, consent form, or other documents. Note that changes to research that was initially approved through exempt or expedited review will generally qualify for exempt or expedited review again, unless the change increases the overall risk level of the research to greater than minimal.

7.6. Submission of Application Materials to the HSC

Protocol Lead Investigators (PLIs) wishing to have a new study reviewed under the expedited procedure must submit their protocol through the Human/Animal Research Protocol (HARP) system. The PLI will indicate on the protocol smartform the category or categories of expedited review he/she believes apply. The protocol submitted must conform to HSC requirements and include sufficient detail for the reviewer to determine whether the study qualifies for review and approval by the expedited process. There are no deadlines for submission of an Expedited Review Application. PLIs applying for new/initial Expedited Review must submit:

7.6.1. A completed HARP application;

7.6.2. Proposed Informed Consent document(s);

7.6.3. Copies of the Company Protocol, if sponsored by a for-profit entity;

7.6.4. If research is being conducted in collaboration with an assured partner institution, evidence of Institutional Review Board (IRB) approval from the entity;

7.6.5. Surveys, questionnaires, scripts, diaries, and all other subject contact instruments, if applicable;

7.6.6. For studies involving minors in school settings, an approval letter from the School Principal or School District Office;

7.6.7. Advertisements, flyers, notices used to recruit subjects;

7.6.8. The names and qualifications of all individuals engaged in research under the protocol.

7.6.9. A statement on financial disclosures related to the human subjects research under review, and financial disclosure documentation as appropriate.

7.7. HSC Review

7.7.1. The HSC Chair and/or one or more experienced reviewers identified by the HSC Chair and assigned by the Compliance Specialist in consultation, as needed, with the Chair will review or recommend changes in research that meets expedited criteria. An experienced HSC member is a voting member or alternate voting member who has served on the HSC for at least six months or has equivalent prior experience, has received training relative to the expedited review categories, and possesses the expertise needed, if any, to review the proposed research. The Chair is able to determine eligibility.

7.7.2. The reviewer may request a second reviewer or refer the research to the full HSC Committee for further determination. The reviewer(s) may also request review of the research by an expert consultant for issues that require expertise beyond, or in addition to, that available on the HSC. Should the HSC reviewer(s) require clarifications or revisions to the proposed research, the reviewer(s) shall specify the level of review for the resulting response from the PLI. The required clarifications or revisions will be communicated to the PLI typically within one to two days after review. Instructions for resubmission to the HSC should be indicated in the HSC correspondence. Review of suggested changes may be done by the initial reviewer or by the HARC compliance staff, depending on the level of complexity. In reviewing the research, the reviewer(s) may exercise all of the authorities of the full committee except that the reviewer(s) may not disapprove the research. Disapproval is only determined by the full HSC. Additionally, the reviewer may refer the study to the full committee for review. PLIs applying for continuing review (renewal) through the expedited review process must adhere to the HSC policy on continuing review.

7.7.3. Information obtained during the review of a modification, adverse event, sponsor notification, or other pertinent information may possibly disqualify the study from being approved under an expedited status. In such cases, the study will be forwarded to the full HSC for consideration of continued approval.

7.7.4. As required by federal regulations, the full HSC is advised of applications that have been approved under the expedited review procedure. Any HSC member may then request an in-meeting discussion of any such approval. Identification of all such approvals is documented in the agendas provided to the full HSC. This documentation includes directly or through a link, but is not limited to:

7.7.4.1. Name(s) of Principal Investigator(s)

7.7.4.2. Title of the Study

7.7.4.3. Protocol File Number

7.7.4.4. Study Approval Date

7.7.4.5. Study Expiration Date

7.7.4.6. Expedited Category/Categories of Approval

7.7.4.7. HSC Reviewer

Regulations:

§ __.110

21 CFR 56.110

OHRP Guidance on Expedited Review (http://www.hhs.gov/ohrp/policy/exprev.html)