BERKELEY LAB

Human Subjects Committee Exempt Research Review Policy	Document No.	HSC-2018-008
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	Approval:	

1. PURPOSE:

1.1. This document describes the research activities involving human subjects that Lawrence Berkeley National Laboratory (LBNL) may determine to be exempt from most of the requirements of 45 CFR 46 after evaluation by the LBNL Human Subjects Committee (HSC), the criteria the HSC will use in making that determination, and the expectations that will still be applied to these studies.

1.2. NOTE: this document applies only to exempt human subjects protocols created and submitted after 1/21/2019.

2. REVISION HISTORY:

Date	Revision No.	Change	Reference Section(s)
12/2018	1.0	New SOP Drafted	Not Applicable

3. DEFINITIONS:

3.1. 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.

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

3.1.2. 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:

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

3.1.2.2. 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.

3.2. **Human subject:** a living individual about whom an investigator conducting research: (1) Obtains 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 or identifiable biospecimens. 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.

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

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

3.3. **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.

3.4. **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:

3.4.1. 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;

3.4.2. 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.

3.4.3. **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.

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

3.5. **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.

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

3.7. **Vulnerable subject:** a subject potentially vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Certain circumstances may make some subjects situationally vulnerable (e.g., college students or employees) and certain groups may be vulnerable to group harms.

3.8. **Exempt research**: Research that qualifies for exemption from the requirements of federal regulations at § __.104 or, including continuing review by the Institutional Review Board (IRB), and that meets the criteria within one or more of the eight exempt categories designated in the federal regulations.

3.9. **Benign behavioral intervention**: An intervention brief in duration, harmless, painless, not physically invasive, unlikely to have a significant adverse lasting impact, and for which there is no reason to believe the subjects will find offensive or embarrassing.

4. 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. Exempt research activities are subject to the human rights protections and ethical standards outlined in the Belmont Report even when that research is exempt from most of the requirements of the "Common Rule".

4.2. That only the HSC may determine which LBNL activities qualify for exempt status.

4.3. That before the HSC determines any human subjects research application to be exempt, it must find that the applicable criteria in § __.104 have been satisfied.

5. PERSONS AFFECTED:

5.1. 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 exempt reviews.

5.2. All Protocol Lead Investigators (PLIs) participating in, conducting, or with oversight over human subjects research that may be exempt under § __.104.

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

6. 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 exempt 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 and may not find a project to be "not human subjects research". Recommendations that the project be found "not human subjects research" will be referred back to the Chair. Additionally, the Reviewer may refer the study for the expedited review process or to the full committee for review.

6.3. **Protocol Lead Investigators (PLIs)** requesting an exempt determination shall follow this policy and the procedures outlined in 7.0 (below).

6.4. The **Compliance Specialist** who processes the initial application for exempt determination review shall make an initial assessment that the application meets the criteria for exemption and is complete enough to allow for the determination to be made and assign a designated Reviewer with no obvious conflicts of interest from among those members identified as eligible by the Chair. In making these assessments, the Compliance Specialist shall consult with the Chair and/or designated Reviewers as needed.

7. PROCEDURES:

7.1. The HSC has the following requirements of studies otherwise exempt from the Common Rule regulations, to ensure the proper representation of the institution in human subjects research, as well as to satisfy reporting requirements for new applications under DOE O 443.1C.

7.1.1. Adequate training for all personnel in the ethical conduct of research with human subjects, as defined in the Training Policy (Document #HSC-2021-001)

7.1.2. Informed Consent: While the Common Rule definition of informed consent (§__.116) is not required, it is still expected that the following elements are communicated to all participants in an appropriate way prior to participation.

7.1.2.1. The study is being conducted as a part of **Research**.

7.1.2.2. Participation is **Voluntary**.

7.1.2.3. Disclosure of funding source and institutions taking part in the research.

7.1.2.4. Contact information for someone directly responsible for the research, as well as for the HSC for any questions regarding the rights of participants.

7.1.2.5. Procedures to protect participant privacy and confidentiality

7.1.2.6. Risks & Benefits to participation

7.1.3. Risks to subject are reasonable in relation to anticipated benefits.

7.1.4. Selection of subjects is equitable.

7.1.5. Recruitment materials are accurately representative of the research

7.1.6. Compensation of subjects is appropriate, and does not exert undue influence.

7.1.7. Validation of scientific merit and rational study design.

7.1.8. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7.2. The HSC may determine the research to be exempt where the only involvement of human subjects will be in one or more of the following eight categories, and where any special requirements are met.

Use of the exemption categories for special populations:

Each exempt category below may be applied to 45 CFR 46 Subpart B (fetuses, neonates, and pregnant women) if the conditions of the exemption are met.

The exempt categories do not apply to research subject to subpart C (prisoners), unless the research is aimed at a much broader subject population that only incidentally includes prisoners.

The exemptions in 7.1, 7.4, 7.5, 7.6, 7.7, and 7.8 may be applied to research subject to Subpart D (children), if the conditions of the exemption are met, however researchers should be aware that frequently there are other regulations applicable to this population (e.g. FERPA).

7.2.1. **Research conducted in educational settings,** including research on: regular and special education instructional strategies, and the effectiveness of or comparison between educational techniques, curricula, or classroom management techniques. The research must meet <u>all</u> the following criteria:

7.2.1.1. Must be conducted in an established or commonly accepted educational setting;

7.2.1.2. Must involve normal educational practices;

7.2.1.3. Is not likely to adversely impact students' opportunities to learn required material or the students' assessment by their teachers or educators;

7.2.2. **Research involving only surveys, interviews, observation of public behavior, or educational tests.** <u>At least one</u> of the following criteria must be met:

7.2.2.1. The information obtained must be recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained, either directly or through identifiers linked to the subjects, *and*, if children are involved, the researchers may not participate in the educational test or the activity being observed. ((d)(2)(i))

7.2.2.2. Any disclosure of the subjects' responses or behavior outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation. *If* children are involved, the researchers may not participate in the educational test or the activity being observed. ((d)(2)(ii))

7.2.2.3. Information obtained is recorded by the researchers in such a manner that the identity of the subjects <u>can</u> readily be ascertained, either directly or through identifiers linked to the subjects, but there are adequate provisions to protect the subjects' privacy and maintain the confidentiality of the data, *and* the research does not involve children. ((d)(2)(iii))

7.2.3. Research involving benign behavioral interventions in conjunction with the collection of information from subjects via survey, interview, or recording (audio, visual, or both). The following criteria must apply:

7.2.3.1. Subjects must be adults;

7.2.3.2. Subjects must prospectively agree to the intervention and the collection of information;

7.2.3.3. The research may not involve deception, or, if it does, the possibility that they may be misled or deceived about the purposes or nature of the research is revealed to subjects before they prospectively agree to participate;

And <u>at least one</u> of the following:

7.2.3.4. The information obtained must be recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained, either directly or through identifiers linked to the subjects, *or*

7.2.3.5. Any disclosure of the subjects' responses or behavior outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation, *or*

7.2.3.6. Information obtained is recorded by the researchers in such a manner that the identity of the subjects <u>can</u> readily be ascertained, either directly or through identifiers linked to the subjects, but

there are adequate provisions to protect the subjects' privacy and maintain the confidentiality of the data.

7.2.4. Secondary research for which consent is not required. Secondary uses of identifiable private information or identifiable biospecimens may be exempt when at least one of the following criteria is met:

7.2.4.1. The identifiable private information or identifiable biospecimens are publicly available.

7.2.4.2. Information, which may include information about biospecimens, is recorded by the investigator in such manner that the identity of the subjects cannot readily be ascertained, either directly or through identifiers linked to the subjects.

7.2.4.3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR 160 and 45 CFR 164 (HIPAA Privacy, Security, Enforcement, and Breach Notification Rules).

The HSC will not implement exempt criteria 7.2.4.3 with version 2.0 of this SOP.

7.2.4.4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or -collected data obtained for non-research purposes where:

7.2.4.4.1. If the research generates identifiable private information that is or will be maintained on information technology that is compliant with section 208(b) of the E-government act of 2002, 44 U.S.C 3501;

7.2.4.4.2. If all the identifiable private information collected, used or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a;

7.2.4.4.3. If applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C.

The HSC will not implement exempt criteria 7.2.4.4 with version 1.0 of this SOP.

7.2.5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of agency heads, that are both:

7.2.5.1. Designed to study, evaluate, improve or otherwise examine public benefit or service programs, including

7.2.5.1.1. Procedures for obtaining benefits or service under those programs;

7.2.5.1.2. Possible changes in or alternatives to those programs or procedures;

7.2.5.1.3. Possible changes in methods or levels of payment for benefits or services under those programs.

7.2.5.2. Published on the publicly accessible list of research and demonstration programs that the Federal department or agency head conducts or supports. The research must be published on this list prior to commencing the research involving human subjects.

7.2.6. Taste and food quality evaluation and consumer acceptance studies if

7.2.6.1. Wholesome foods without additives are consumed, or

7.2.6.2. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7.2.7. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential unspecified secondary research use may be exempt if the HSC conducts a review including all consent forms under which the materials were or will be collected and makes the determinations with regard to broad consent required by § __.111(a)(8) (see also HSC SOP HSC-2010-003, Rev. 2.0, Criteria for Approval of Research).

The HSC will not implement exempt criteria 7.2.7 with version 2.0 of this SOP.

7.2.8. Research involving the use of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required: Research using identifiable private information or identifiable biospecimens for secondary research use may be exempt if the following criteria are all met:

7.2.8.1. HSC conducts a review including all consent forms under which the materials were or will be collected and makes the

determinations with regard to broad consent required by § __.111(a)(8) (see also SOP HSC-2010-003, Rev. 2.0, Criteria for Approval of Research); and

7.2.8.2. Documentation of informed consent or a waiver of documentation of consent was obtained in each case in accordance with § __.117; and

7.2.8.3. The HSC makes the determination required by § __.111(a)(7) and determines that the research to be conducted is within the scope of the broad consent reference in paragraph (d)(8)(1) of this section; and

7.2.8.4. The investigator does not include returning individual research results to subjects as part of the study plan. (This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.)

The HSC will not implement exempt criteria 7.2.8 with version 2.0 of this SOP.

Regulations:
45 CFR 46 (The Common Rule)
DOE O 443.1C
HIPAA Privacy Rule