



<b>Human Subjects Committee Membership Policy</b>	Document No.:	HSC-2021-002
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## **A. Purpose**

This document establishes the requirements and expectations for members of the Human Subjects Committee (HSC), the Institutional Review Board for Berkeley Lab. The composition of the committee, member standards and responsibilities, and processes of member appointment are all detailed below.

## **B. Persons Affected**

Active and potential members of the HSC.

## **C. Exceptions**

None

## **D. Policy Statement**

### **1) Committee Composition**

The HSC shall be composed of up to nine members as defined in the Committee’s Charter. This includes at least one member from each of the following categories; scientific, non-scientific, and unaffiliated. For the review of FDA-covered studies, a medical physician must be a part of the discussion in a voting capacity. There is no limit on the number of alternate members.

### **2) Membership Appointment Process**

Membership shall be discussed at an HSC meeting in the Spring of each year, including upcoming vacancies, term expirations, reappointments, and identification of areas where additional expertise may be needed. Recommendations shall be forwarded to the IO, who, in consultation with Lab management, shall assist in identifying candidates to fill the committee. Unexpected vacancies shall be addressed in a similar manner when they occur.

Members of the HSC may be nominated by the HSC or recommended by members of the Laboratory community. Before submitting a candidate, the recommender shall confirm that the candidate is willing to serve. Candidates will submit resumes to and be evaluated by the HSC, considering factors noted in the Charter under **Membership**. It is not expected that nominees will have taken training relative to serving on an HSC when nominated. The HSC may request additional information from the recommender or the nominee as necessary.

The IO will make appointments, as designated by the CEO, from the pool of nominees that have been evaluated. The IO has the sole authority to add or replace a member at any time. In replacing or re-appointing a member, consideration should be given to:

- Attendance at HSC meetings
- Conduct as an HSC member
- Unresolved conflict of interest
- Completion of required training
- Completion of work assigned or requested
- Willingness to continue serving on the HSC
- Management support

The IO also has the authority to terminate a sitting member from the HSC prior to expiration of his or her term when there is “just cause.” Just cause for removal may include, but is not limited to, excessive unexcused absences, misconduct, unresolved conflict of interest, failure to complete required training, or a consistent pattern of failure to complete work as assigned or requested by the chair, vice chair, or HSC administrator.

### **3) Member Appointments**

Each member is appointed for a term of up to three years and there is no limit to the number of terms a member may serve. However, each member must be reappointed to serve each additional term. Terms will be staggered whenever possible to minimize disruption of Committee functions.

Members may be designated as regular members or alternate members. Alternate members will only vote in the absence of their designated regular members, which is defined in their appointment letter. All members may be designated by the Chair as having the experience and training necessary to review applications eligible for expedited review processes.

*Ex-officio* members are non-voting Subject Matter Experts (SME) who are not required to attend meetings regularly. Instead, these members will be called upon when specific needs arise for SME input on a protocol.

### **4) Maintaining Confidentiality**

Service on the HSC includes the review of documents that contain personal, confidential and proprietary information. Members of the HSC are responsible for maintaining all committee proceedings and documents in strict confidence. Such information may not be used for any purpose other than the HSC review and may not be disclosed to anyone outside of the HSC unless permission is granted in writing by the Institutional Official for Human Subjects Protection.

### **5) Responsibilities of Committee Members**

The following expectations apply to all voting and alternate members, including the Chair.



- Complete initial training as defined in the Training Policy, within the first 3 months following appointment;
- Attend scheduled meetings, with all members expected to attend at least 2/3 of all scheduled meetings. *\*Exception\** Leaves of absence may be granted when requested in advance, and justified.
- Notify the HSC administrator promptly when unable to attend a meeting or perform a requested review;
- Review all materials distributed with the meeting agenda prior to scheduled meetings;
- Disclose and avoid conflicts of interest that could be perceived to impact the independence of their decision making, such as:
  - Members who have any disclosable financial interests (a) that would reasonably appear to be affected by the research; or (b) in entities whose financial interests would reasonably appear to be affected by the research, must recuse themselves from committee action.
  - Members who believe existing circumstances may directly affect their objectivity may request that they be recused from committee action.
  - Members with research or managerial interests in protocols that come before the committee should recuse themselves to avoid even the appearance of a conflict. This includes situations where:
    - The member is staff on the protocol
    - The member shares joint research interests and relationships with the protocol lead investigator(s) and/or co-protocol lead(s)
    - The member supervises or is supervised by the protocol lead investigator(s) and/or co-protocol lead(s)
- Participate as primary or secondary reviewers or conduct expedited reviews when requested by the Chair, Vice chair, or HARC staff; and
- Perform other HSC-related activities when requested by the Chair, Vice Chair, or HARC staff.

### **E. Roles & Responsibilities**

<b>Role</b>	<b>Responsibility</b>
Scientific Member	Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist. Scientific members are expected to review assigned applications, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the HSC if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.



Non-scientific Member	Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. Non-scientific members are expected to provide input on matters germane to their individual knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.
Unaffiliated Member	Non-affiliated members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research from that perspective. Must not have a direct affiliation (employee, contractor, student in a fellowship, volunteer at the institution, or business related to the IRB, and must not have an immediate family member who is affiliated with the institution).
HSC Chair	In addition to scientific member responsibilities listed above, the Chairperson; <ul style="list-style-type: none"><li>• Reviews all applications presented to the HSC and communicates with other reviewers as needed so that important issues or concerns are resolved or identified prior to the convened HSC meeting</li><li>• Directs the proceedings and discussion of convened HSC meetings</li><li>• Administers convened HSC decisions with assistance from HARC</li><li>• Serves as the primary liaison and authorized signatory for all communications from the committee, including recommendations to the IO and HARP letters to researchers.</li><li>• Designates reviewers for expedited review process as mandated by 45 CFR 46</li><li>• Provides review of NHSR determination requests, and signs letters</li><li>• Gives input on HSC matters whenever necessary, particularly in the case of questions fielded by the HARC office.</li><li>• Attends the HSWG meeting with the Department of Energy HSPP</li><li>• Stays up-to-date on regulatory guidelines and IRB issues through attendance at conferences and trainings as applicable</li><li>• Ensure the maintenance of a complete membership roster as required by 45 CFR 46, in conjunction with HARC</li></ul>



Primary Reviewer	Primary reviewers are assigned a study based on their particular expertise in relation to the study. The primary review is expected to present a brief oral summary of the application at the beginning of the committee discussion and then to provide detailed comments about the protocol, and consent forms if appropriate (typically requests for additional information or revisions). The primary and secondary reviewers will recommend a committee action.
Secondary Reviewer	A secondary reviewer is also assigned as backup and to provide additional comments and sometimes to provide comments in a particular area. These sets of comments should be entered electronically in HARP, either before or after the meeting. The primary and secondary reviewers will recommend a committee action.
Institutional Official	<ul style="list-style-type: none"> <li>• Appointment of committee members and Chairs, as designated by the CEO.</li> <li>• Communicate responsibilities to members.</li> <li>• Remove members and Chairs for cause.</li> </ul>
HARC Staff	<ul style="list-style-type: none"> <li>• Completion and maintenance of all member appointment letters and roster</li> <li>• Facilitation of all member-related processes</li> <li>• A Compliance Specialist from HARC will be a voting member of the HSC, whose role is to be a SME on regulatory issues during protocol review.</li> </ul>

**F. Definitions/Acronyms**

- a. **HARC:** The Human and Animal Regulatory Committees office. Operated as a part of the EH&S division, staff are responsible for the administration of the Human Subjects Committee, Animal Welfare and Research Committee, and the Radioactive Drug Research Committee.
- b. **HSWG:** Human Subjects Working Group
- c. **HSP:** Human Subjects Protection Program
- d. **SME:** Subject Matter Expert – an individual who is asked to contribute expertise from a specific subject based on their training and experience in the field.

**G. Recordkeeping Requirements**

HARC & the HSC Chair will maintain an updated version of the committee roster at all times. The membership roster will include the following information and will be used to determine relevant expertise in making protocol assignments at convened meetings:

- Names of members;



- Earned degrees;
- Representative capacities;
- Affiliation status (whether the IRB member or an immediate family member of the IRB member is affiliated with the organization)
- Indications of experience sufficient to describe each IRB member’s chief anticipated contributions;
- Employment or other relationship between each IRB member and the organization;
- Alternate members including the primary members or class of primary members for whom each alternate can substitute.

A signed copy of each member’s appointment letter shall also be available at any time.

## H. Implementing Documents

Document Number	Document Title	Type
N/A	<a href="#">Human Subjects Committee</a>	Website
N/A	<a href="#">Human/Animal Research Protocol Management System</a>	Website
HSC-2021-001	<a href="#">Training in the Responsible Use of Human Subjects in Research</a>	Policy

## I. Contact Information

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## J. Revision History