Charter

Institutional Biosafety Committee

Western Fisheries Research Center

Seattle, WA

United States Geological Survey

Department of the Interior

Approval date: April 22 2024

Stephen Libby Digitally signed by Stephen Libby
Date: 2024.04.23 07:32:02 -07'00'

Stephen J. Libby, Ph.D., Institutional Biosafety Committee Chair

MICHAEL SCHMIDT Digitally signed by MICHAEL SCHMIDT
Date: 2024.04.23 11:26:30 -07'00'

Michael Schmidt, Center Director, and Responsible Official

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1. Overall Committee Roles and Responsibilities

The Western Fisheries Research Center (WFRC) Institutional Biosafety Committee (IBC) was formed and will operate according to the most current version of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as described in the NIH Guideline. Additionally, the WFRC has the following general roles and responsibilities:

1.1. Advising the Center Director on all matters relating to the procurement, use, storage, transportation, and disposal of biohazardous materials at WFRC, including but not limited to recombinant or synthetic nucleic acid molecules consistent with NIH Guidelines:

1.1.1. Research practices

1.1.2. Coordination with the Institutional Animal Care and Use Committee

1.1.3. Facilities

1.1.4. Waste disposal

1.1.5. Training programs

1.2. Independent review and approval authority for individual research projects that involve biohazardous materials, including but not limited to recombinant or synthetic nucleic acid molecules consistent with NIH Guidelines.

1.2.1. Recombinant or synthetic nucleic acid molecules, as defined in the most current version of the National Institutes of Health "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (the NIH Guidelines). Guidelines for research in microbiological and biomedical laboratories, also known as BMBL, can be found from Centers for Disease Control and Prevention "Biosafety in Microbiological and Biomedical Laboratories" (BMBL 6th Edition).

2. Authority

2.1. The above stated Roles and Responsibilities are derived from the following authorities:

2.1.1. WFRC Center Director, who the IBC reports to and who is responsible for approving this charter and constituting an IBC.

2.1.2. National Institutes of Health "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules".

3. Institutional Responsibilities

3.1. Under the NIH Guidelines, WFRC has an institutional responsibility to support the IBC and its activities. This includes, but is not limited to, the following:

3.1.1. Establishing an IBC

3.1.2. Ensuring that the IBC has adequate membership with necessary expertise, as defined below under Section 4.

3.1.3. Providing appropriate training for the IBC chair and members.

3.1.4. Filing an annual roster update with the NIH Office of Science Policy (OSP).

3.1.5. Establishing procedures that the IBC shall follow in its initial and continuing review of applications, proposals, and activities (accomplished under this Charter).

3.1.6. Provide administrative assistance in support of IBC activities.

4. Committee Membership

4.1. Composition: The WFRC IBC shall be composed of a minimum of 7 members. These members shall include the following:

4.1.1. A committee chair, selected from the members of the IBC.

4.1.2. Two public members representing the interests of the surrounding community with no other active affiliation with WFRC as defined in the NIH Guidelines.

4.1.3. A Biological Safety Officer (BSO) from WFRC. Currently, the IBC Chair is also functioning as the Biosafety Officer.

4.1.4. The remainder of the membership shall be composed of three (3) additional members from WFRC or, in some cases, other employees of the United States Geological Survey, Department of the Interior with relevant expertise. A veterinarian with expertise in aquatic animals will be one of these three members.

4.1.5. In total, 7 members shall serve on the Committee.

4.2. Expertise: The WFRC IBC shall include members with expertise and experience related to the types of research typically reviewed by the IBC. This shall include at a minimum: i) General molecular biology; ii) General microbiology; iii) General virology and iv) Aquatic vertebrate biology and ecology.

4.3. Appointing authority: Regular members of the WFRC IBC shall be appointed by the Center Director in consultation with the IBC Chair. The IBC Chair shall be appointed by the Center Director of WFRC.

4.4. Terms of appointment: The term of appointment for regular members of the WFRC IBC is anticipated to be three (3) years. Such appointments may be renewed at the discretion of the appointing authorities and the member. Such appointments may be terminated prior to completion of a full term at the discretion of the appointing authority, in consultation with the Center Director and IBC Chair due to lack of constructive participation, or at the request of the members. There is no minimum or maximum term of appointment for the IBC Chair, who serves at the discretion of the appointing authority.

4.5. Ad hoc consultants: Ad hoc consultants on a particular topic may be utilized to review applications. They will be called to serve as the primary or secondary reviewer for projects within their range of expertise. Ad consultants may not vote projects for which they were consulted or any other project or any other issue discussed at the convened meeting. Ad hoc consultants are listed separately on the minutes for the meeting and do not count toward the quorum.

5. Review Process

5.1. Overview: The WFRC IBC shall review applications (i.e., registration documents) in accordance with the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids" and other relevant regulations. This shall include all new applications, renewal of existing applications, and changes to existing applications All members of the IBC will receive a copy of the Biosafety Applications, Significant Change Applications, and all other relevant documents prior to meeting. See Appendix A for a flowchart depicting the over schema of the WFRC IBC review process.

5.2. Research falling under Section III-F of the NIH Guidelines: The WFRC IBC chair will review proposed research that falls under Section III-F. This research will be registered and a stored on the WFRC IBC site.

5.3. CATEGORY "A" REVIEW - Research falling under Section III-E of the NIH Guidelines, or research that does not fall under the NIH Guidelines but does involve the use of Risk Group 1 and/or Risk Group 2 infectious agents.

5.3.1. The application will first be reviewed by the IBC Chair for an initial determination. The IBC chair will recommend the IBC to convene and discuss the proposal.

5.3.2. The application shall also be reviewed at an upcoming meeting of the IBC for a final decision. Research activities may not proceed until the IBC has approved and the PI has been notified in writing.

5.3.3. If the IBC does not concur with the determination of the approving application, the IBC Chair shall work with the Principal Investigator to bring the research into compliance with the final IBC determination.

5.4. CATEGORY "B" REVIEW - Research falling under Section III-D of the NIH Guidelines.

5.4.1. The application will first be reviewed by the IBC Chair for an initial determination.

5.4.2. The Primary Reviewer/IBC Chair shall review the application and resolve any outstanding issues. The Primary Reviewer shall then present the application at a convened meeting of the IBC and recommend a final decision for the application. The Secondary Reviewer will also be consulted during the meeting.

5.4.3. 5.5.3. The application shall be reviewed and voted upon at a convened meeting of the IBC.

5.4.4. 5.4.4. The Principal Investigator will be notified of the final decision. The proposed research cannot commence until all outstanding issues are resolved and the principal investigator receives an IBC Approval letter.

5.5. CATEGORY "C" REVIEW - Research falling under sections III-A, III-B, and III-C of the NIH Guidelines; or research that involves the use of infectious agents that require containment at Biosafety Level 3 (BSL-3), regardless of whether or not they fall under the NIH Guidelines. There are no RG3 agents being used at the WFRC. Further, experiments that fall under Section III-A-C are not permitted at WFRC.

6. Meeting Policies

6.1. Meeting frequency:

6.1.1. Regularly scheduled meetings: The WFRC IBC shall have regularly scheduled meetings once a quarter or more frequently as required. These regularly scheduled meetings may be canceled in the absence of a quorum as defined under Section 7, or if the IBC Chair determines there are insufficient project reviews or other issues to warrant a convened meeting.

6.1.2. Ad hoc meetings: Ad hoc meetings of the IBC can be convened, at the discretion of the IBC Chair, to address specific and time-sensitive issues or project reviews.

6.2. Meeting announcements:

6.2.1. Members of the IBC shall be notified of regularly scheduled and ad hoc meetings of the IBC by mail. This announcement shall include the following information: date, time, location, draft agenda, and access to any available materials to be discussed or reviewed. All materials to be reviewed and considered by the IBC will be made available to the IBC members via email attachment.

6.2.2. The public shall be notified of regularly scheduled and ad hoc meetings of the WFRC IBC. This announcement shall include the following information: date, time, agenda, and weblink. The announcement for regularly scheduled meetings will be posted on the WFRC IBC website no less than one week (seven days) before the meeting, and for ad hoc meetings, no less than 24 hours before the meeting. WFRC staff will also be made aware of the IBC meeting via email, referring them to the website announcement.

6.3. Meeting location: Meetings shall be held at publicly accessible areas of the WFRC Seattle, Washington location and/or via web conference/teleconference.

6.4. Meeting attendance: Convened meetings of the IBC are open to the public, in accordance with the NIH Guidelines. Public participants may attend the meeting, but may not participate in the discussions, voting, or deliberation of any applications or documents/policies being presented during the IBC meeting. A ten-minute time window will be reserved at the end of each meeting for any public participants to address the IBC. Written comments are also welcome and submitted to the IBC chair after the meeting. All written comments submitted to the IBC by the public and any response by the IBC to them will be submitted to the NIH OSP.

6.4.1. Principal Investigators will be asked to attend to address questions during the meeting when their research is novel, especially complex, and/or if the IBC chair determines that the IBC would benefit from a full description of the proposed activities.

6.5. Voting procedures: The IBC Chair will call for a vote after the discussion of an agenda item is completed. Members vote to accept or reject a proposal by a show of hands. Members may also abstain from voting if they wish, for example, because of a conflict of interest. Items will be approved via a simple majority vote.

6.6. Meeting minutes: The topics discussed and decisions made at convened IBC meetings shall be captured in the formal meeting minutes These meeting minutes will be made available to the public upon request from the IBC chair.

6.7. Non-convened meetings: On occasion, IBC subcommittees may meet to discuss policies, procedures, or other items to develop draft recommendations on institutional policies. Because these meetings do not lead to the direct and final decision of specific applications or recommendations, they will not be generally announced to the public or the IBC membership, and their deliberations will not be open to the public. The final versions of such deliberations will be brought to a convened meeting of the IBC for discussion and approval.

7. Procedures for Defining a Quorum

7.1. For purposes of a convened meeting, a quorum of the WFRC IBC shall be defined as at least one half of the current membership, not including ad hoc consults, with a requirement of at least one-non-affiliated member.

7.2. If, during the course of the meeting, a quorum is lost, the Chair shall call the meeting to a close until such time quorum can again be established.

7.3. If, during the course of the meeting, a quorum is lot due to the ineligibility of an IBC member to vote on a particular application due to a conflict of interest, final deliberation on that application will be postponed until a quorum can be established.

8. Conflict of Interest Policy

8.1. Members of the IBC shall not participate in the primary review and approval of applications under consideration by the IBC when a conflict of interest exists. This includes, but is not limited to, conflicts of interest as defined in the NIH Guidelines(Section IV-B-2-a-(2,3,4), Institutional policy, or Washington State law. Conflicts of interest must be submitted to the IBC chair prior to the convened meeting. An IBC member with a conflict of interest on a particular application shall not vote on this particular application but may do so on other applications. The IBC chair will ask the committee members if any have a conflict of interest in the proposal(s) being presented at the beginning of the convened meeting.

8.2. Examples of conflicts of interest include the following:

8.2.1. The IBC member is currently engaged, or expects to be engaged, in the research project under review, as defined in the NIH Guidelines.

8.2.2. The IBC member has a direct financial interest in the PI or the entity funding the research proposed by the PI, as defined by WFRC and/or NIH Guidelines.

8.2.3. The IBC member and the PI of the application under consideration share a familial relationship.

8.2.4. The IBC member has other reasons to feel that he/she cannot render an independent assessment of an application.

9. Provision of Meeting Minutes to the Public

9.1. Official minutes of convened meetings of the IBC shall be made available to the public in

accordance with the NIH Guidelines. Meeting minutes will be drafted by the IBC Chair and the draft approved by the Center Director, then distributed to IBC committee members for full committee approval. Approved meeting minutes are made available to the public upon request from the IBC chair, in consultation with USGS/Department of the Interior Legal Counsel as needed. Meeting minutes will be drafted and approved in a prompt manner.

9.2. IBC minutes will be maintained in a Western Fisheries Research Center server folder with restricted access determined by the Center Director.

10. Communication of Public Comments to OSP

10.1. Public comments shall be communicated to OSP as stipulated under the NIH Guidelines Section IV-B-2-a-(7). Public comments made at the conclusion of the WFRC IBC regular business and any comments on the IBC's actions or policy decisions, will be captured and forwarded to the Office of Science Policy, NIH.

11. IBC Member Training

11.1. IBC Chair: In accordance with the NIH Guidelines and WFRC is responsible for ensuring that the IBC Chair is adequately trained. At a minimum this shall include initial training regarding the Roles and Responsibilities of the IBC under the NIH Guidelines, as well as the specific procedures included in this Charter. This will typically be provided by the IBC Chair, attendance at training conferences, or through outside consultants.

11.2. Ongoing training in both broad and specific fields related to the oversight of biohazardous research. This will typically be accomplished through ongoing education opportunities (e.g., outside meetings) on at least an annual basis.

12. Frequency of Project Reviews / Renewals

12.1. Individual research projects shall be approved for a term of no more than three (3) years from the issue date of the Biosafety Application Approval letter. After this period, the Principal Investigator of the project must submit and, when appropriate, wait for IBC approval before continuing the work. The approval of a significant change does not modify the overall project approval period.

12.1.1. The IBC may determine that a shorter approval period is warranted. This condition shall be stipulated on the IBC Biosafety Application letter as a condition of approval.

12.1.2. After approval, the IBC determines that one of the following conditions exist:

12.1.2.1. New information comes to light regarding the hazards associated with the proposed research.

12.1.2.2. Issues come to light related to compliance with laboratory containment practices or other conditions stipulated in the original approval of the application by the Principal Investigator or other individuals involved in the research.

12.1.2.3. At the discretion of the IBC Chair, in consultation with the Center Director.

13. Laboratory Inspection Policy

13.1. Laboratories engaged in research covered under Sections III-A through III-E of the NIH Guidelines, with infectious agents requiring BSL1 and BSL2 containment or ABSL1-ABSL2 containment and any laboratory working with biological materials, shall be inspected for compliance to rules and regulations yearly. This inspection will typically be carried out by IBC Chair. The inspection results shall be reported to the WFRC IBC.

14. Training Policy

14.1. Training policy: The IBC requires that laboratory staff and PI have documented training prior to the approval of the project.

14.1.1. Completion of Biosafety Training is required every three years for PIs if their research includes the use of biohazardous agents. It is also required for students, fellows, laboratory managers, research staff, and all other staff who have the potential for exposure to biohazardous agents. Additional training may be required by the USGS will be coordinated by the WFRC BSO and the Collateral Safety Duty Officer.

14.1.2. Completion of the Bloodborne Pathogens (BBP) training is required annually for PIs, students, fellows, laboratory managers, research staff and all other staff who have the potential for exposure to potentially infectious material (OPIM), as required under the OSHA Bloodborne Pathogens Rule.

15. Occupational Health Surveillance Policy

15.1. The IBC, at the time of approval of individual projects, may include as a condition of approval, that the Principal Investigator include an application-specific health surveillance program or other occupational health requirements. However, these requirements must meet the following conditions:

15.1.1. They are developed and in consultation with the USGS Occupational Safety and Health Program Requirements. These policies can be found here.

15.1.2. They are consistent with Washington and all other applicable local, state, and federal regulations.

15.1.3. They are consistent with Section IV-B-1-i of the NIH Guidelines.

16. Reporting to NIH

16.1. The IBC shall report to the NIH any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses within 30-days. Reporting will be done in consultation with the WFRC center director.

17. Lines of Reporting

17.1. As stipulated in Sections 1 and 2 of this Charter, the WFRC IBC shall have independent approval authority for individual research projects involving recombinant or synthetic nucleic acid molecules and all projects involving infectious agents at WFRC consistent with Section 1-C and 1-D of the NIH Guidelines.

17.2. IBC members shall report directly to the IBC Chair.

18. BSA Application

18.1. The BSA and BSA Change Application and Significant Change form shall serve as the primary means of collecting information used by the WFRC IBC in reviewing individual research projects.

18.2. Significant changes to these forms shall be approved by the IBC via full committee review and a simple majority vote.

Definitions

BMBL: Centers for Disease Control and Prevention “Biosafety in Microbiological and Biomedical Laboratories” (http://www.cdc.gov/biosafety/publications/)

BSO: Biosafety Officer

IBC: Institutional Biosafety Committee

Biohazardous materials: biohazardous materials are defined as but not limited to infectious agents or hazardous biologic materials that present a risk or potential risk to the health of humans, animals, or the environment. The risk can be direct through infection or indirect through damage to the environment. Biohazardous materials include certain types of recombinant DNA or RNA, organisms, and viruses infectious to humans, animals, or plants (e.g., parasites, viruses, bacteria, fungi, prions, and rickettsia), and biologically active agents (e.g., toxins, allergens, and venoms) that can cause disease in other living organisms or cause significant impact to the environment or community.

Biosafety Application (BSA): - application for proposed research.

Biosafety Application Approval Letter: a letter formally approving the proposed research.

Biosafety Annual Review Form: a short concise description of current research and if there any changes to the original scope of work.

Infectious Substance: Defined in the “Biosafety in Microbiological and Biomedical Laboratories” (http://www.cdc.gov/biosafety/publications/) and the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (the NIH Guidelines). Current definition: "An infectious substance is a material known to contain or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. Infectious substances may exist as purified and concentrated cultures but may also be present in a variety of materials, such as body fluids or tissues."

WFRC: Western Fisheries Research Center, United States Geological Survey, Department of the Interior, Seattle WA.

NIH: National Institutes of Health

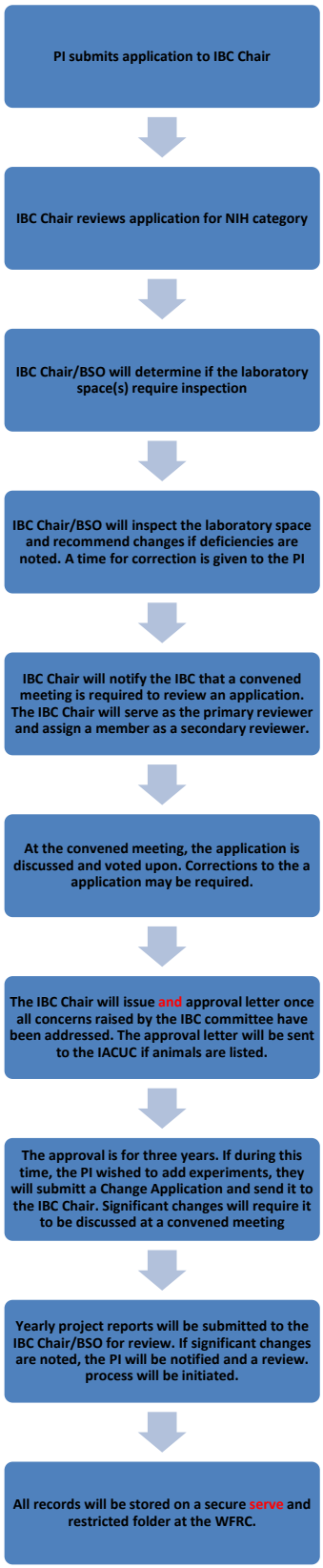
NIH Guidelines: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules; (NIH Guidelines).

Principal Investigator (PI): The Principal Investigator is an individual who is designated and given the authority by the USGS to direct a research program or project. The PI has scientific and technical direction for the research. The PI has the responsibility and authority to enforce biosafety and biosecurity regulations and policies, including the NIH Guidelines. This includes ensuring that the facilities are appropriate for the research conducted and for ensuring that personnel who will be involved with the project are trained. Any application with an assigned PI who does not fall within this definition will be considered on a case-by-case basis.

Recombinant or synthetic nucleic acids: Defined in the National Institutes of Health "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" Current definition: "In the context of the NIH Guidelines, recombinant or synthetic nucleic acids are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above."

445-2-H, Occupational Safety and Health Program Requirements: This website details the procedures and protocols for Occupational Safety and Health for the USGS.

Appendix A WFRC IBC Review Process


PI submits application to IBC Chair
IBC Chair reviews application for NIH category
IBC Chair/BSO will determine if the laboratory space(s) require inspection
IBC Chair/BSO will inspect the laboratory space and recommend changes if deficiencies are noted. A time for correction is given to the PI
IBC Chair will notify the IBC that a convened meeting is required to review an application. The IBC Chair will serve as the primary reviewer and assign a member as a secondary reviewer.
At the convened meeting, the application is discussed and voted upon. Corrections to the a application may be required.
The IBC Chair will issue and approval letter once all concerns raised by the IBC committee have been addressed. The approval letter will be sent to the IACUC if animals are listed.
The approval is for three years. If during this time, the PI wished to add experiments, they will submitt a Change Application and send it to the IBC Chair. Significant changes will require it to be discussed at a convened meeting
Yearly project reports will be submitted to the IBC Chair/BSO for review. If significant changes are noted, the PI will be notified and a review. process will be initiated.
All records will be stored on a secure serve and restricted folder at the WFRC.