INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

CHARTER

Institutional Biosafety Committee

University of Washington

Approval date: 12/14/18

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

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1. Overall Committee Roles and Responsibilities

The University of Washington (UW) Institutional Biosafety Committee (IBC) has the following general roles and responsibilities:

1.1. Advising the Executive Director for Health Sciences Administration and the Director of Environmental Health and Safety (EH&S) Department on all matters relating to the procurement, use, storage, transportation, and disposal of biohazardous materials at the UW. This includes, but is not limited to, the following:

1.1.1. Research practices

1.1.2. Facilities

1.1.3. Waste disposal

1.1.4. Training programs

1.2. Independent review and approval authority for individual research projects involving recombinant or synthetic nucleic acid molecules and infectious agents.

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*).

1.2.2. Infectious agents, as defined in the most current version of the Centers for Disease Control and Prevention "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) and the *NIH Guidelines*.

1.2.3. Research involving agents or toxins listed in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

2. Authority

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

2.1.1. UW Administrative Policy Statement (APS) 12.3

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

3. Institutional Responsibilities

Under the *NIH Guidelines* and the UW APS 12.3, the UW has an institutional responsibility to support the UW IBC and its activities. This includes, but is not limited to, the following:

3.1. Establishing an IBC (accomplished under APS 12.3).

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

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

3.4. Filing an annual roster update with the NIH Office of Biotechnology Activities (OBA).

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

3.6. Provide administrative assistance in support of IBC activities.

3.7. Further details related to the implementation of these responsibilities can be found in **Section A** of the IBC Operations Manual.

4. Committee Membership

4.1. Composition: The UW IBC shall be composed of a minimum of 14 members. These members shall include the following:

4.1.1. A committee chair, selected from those members of the IBC with faculty appointments.

4.1.2. A committee vice chair, to perform the duties of the chair in his or her absence.

4.1.3. At least two "public" members representing the interests of the surrounding community with no other active affiliation with the University of Washington as defined in the *NIH Guidelines*.

4.1.4. At least one member that also serves on the Institutional Animal Care and Use Committee.

4.1.5. At least one individual with expertise in animal containment principles.

4.1.6. At least one individual with expertise in plant, plant pathogen, or plant pest containment principles.

4.1.7. At least one individual who has adequate experience and training in the field of human gene transfer.

4.1.8. At least one physician.

4.1.9. A Biological Safety Officer (BSO).

4.1.10. The remainder of the membership shall be composed of faculty members or, in some cases, other employees of the University of Washington with relevant expertise.

4.2. Expertise: The UW 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; iv) Animal research; v) General plant biology; vi) Clinical gene therapy; and, vii) Public health.

4.3. Appointing authority: Regular members of the UW IBC shall be appointed by the Executive Director of Health Sciences Administration, in consultation with the Director of the Environmental Health and Safety Department and the IBC Chair. The IBC Chair and Vice Chair shall be appointed by the Executive Director of Health Sciences Administration, in consultation with the Director of the EH&S Department.

4.4. Terms of appointment: The term of appointment for regular members of the UW IBC shall be two 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 Director of the EH&S Department and the 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 and Vice Chair, who serve at the discretion of the appointing authority.

4.5 Ad hoc members: Ad hoc IBC members are appointed as described in 4.3 and 4.4. They will be called to serve as the primary or secondary reviewer for projects within their range of expertise. Ad hoc members may vote only on the specific projects for which they were consulted. Ad hoc members are listed separately on the IBC roster and do not count toward the quorum as defined in section 7.

4.6 Ad hoc reviewers: Ad hoc reviewers can be consulted on projects as determined by EH&S and the IBC chair. They may serve as subcommittee reviewers, but are not IBC members and do not vote. They do not count toward the quorum as defined in section 7.

5. Review Process

5.1. Overview: The UW IBC shall review applications (i.e., registration documents) in accordance with the *NIH Guidelines*, Centers for Disease Control and Prevention, and other relevant regulations. This shall include all new applications, renewal of existing applications, and changes to existing applications. See *Appendix A* for a flowchart depicting the overall schema of the UW IBC review process.

5.2. Research falling under section III-F of the *NIH Guidelines*: The UW IBC will not review this research, but encourages UW EH&S to recommend registration of this research with the Institution.

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*. See the Operations Manual for the full definition of Category A projects.*

5.3.1. The application will first be reviewed by EH&S for an initial determination. At the discretion of an EH&S Biosafety Officer, the application will receive preliminary approval. At this point, the proposed research can commence.

5.3.2. The application shall also be reviewed at an upcoming meeting of the IBC for a final decision.

5.3.3. If the IBC does not concur with the determination of the approving BSO, the IBC Chair shall work with the BSO and the Principal Investigator in order 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*. *See the Operations Manual for the full definition of Category B projects.*

5.4.1. The application will first be reviewed by EH&S ROS for an initial determination. In consultation with the IBC Chair, the application will then be assigned to a member of the IBC for an in-depth Primary Review. A second member will be designated as the Secondary Reviewer. The Secondary Reviewer will have sufficient knowledge of the application to present it to the IBC should the Primary Reviewer be unable to attend the meeting.

5.4.2. The Primary Reviewer, in consultation with a Biosafety Officer, 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.

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

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 a Biological Use Authorization 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. See the Operations Manual for the full definition of Category C projects.*

5.5.1. The application will first be reviewed by EH&S for an initial determination. In consultation with the IBC Chair, the application will then be assigned to a subcommittee comprised of a BSO, one or more members of the IBC, and, if needed, other ad-hoc reviewers, for an in-depth Subcommittee Review.

5.5.2. The Subcommittee Reviewers shall review the application and resolve any outstanding issues. This shall include assuring that all required approvals are in place from the NIH Office of Science Policy, the NIH Recombinant DNA Advisory Committee (RAC), and/or other governmental regulatory agencies. The Subcommittee Reviewers shall then present the application at a convened meeting of the IBC, and recommend a final decision for the application.

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

5.5.4. 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 a Biological Use Authorization letter.

5.6 **DUAL USE RESEARCH OF CONCERN (DURC) REVIEW -** Research falling under the *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*:

5.6.1. The DURC application will first be reviewed by EH&S. The DURC application will then be sent to members of the DURC Institutional Review Entity (IRE). The DURC IRE is a standing subcommittee of the IBC.

5.6.2. The DURC IRE will review the application and make an initial determination about whether the research proposal is considered DURC.

5.6.3. The DURC application and the DURC IRE's initial determination will be made available to members of the IBC, who will then review and vote upon the project at a convened IBC meeting.

5.6.4. The Principal Investigator will be notified of the final decision.

5.7. Further details related to this review process can be found in **Section B** of the IBC Operations Manual.

6. Meeting Policies

6.1. Meeting frequency:

6.1.1. Regularly scheduled meetings: The UW IBC shall have regularly scheduled meetings once a month. 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 email. This announcement shall include the following information: date, time, location, draft agenda, and access to any available materials to be discussed or reviewed.

6.2.2. The public shall be notified of regularly scheduled and *ad hoc* meetings of the UW IBC at the time points required by the institution and Washington State Open Public Meetings Act (Chapter 42.30 RCW). Regularly scheduled and ad hoc meetings of the UW IBC are announced on the publicly accessible pages of the EH&S IBC website. This announcement shall include the following information: date, time, and location. The IBC agenda will be posted on the website at least 24 hours in advance of the meeting.

6.2.3. Principal Investigators are always welcome to attend IBC meetings and will be specifically invited to attend when their research is novel or especially complex and a biosafety officer or the IBC Chair determines that the IBC would benefit from a full description of the proposed activities.

6.3. Meeting location: Meetings shall be held at publicly accessible areas of the UW main campus or, when appropriate, other branches of the UW campus.

6.4. Meeting attendance: Convened meetings of the IBC are open to the General Public, in accordance with the *NIH Guidelines* and Washington State Open Public Meetings Act (Chapter 42.30 RCW).

6.5 Voting procedures: The IBC Chair will call for a vote after the discussion of an agenda item is completed. Members vote publicly as defined in the Open Public Meetings Act. 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 as outlined in section 8. 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, in compliance with the *NIH Guidelines*. Details for the contents of the minutes can be found in Section C of the IBC Operations Manual. These meeting minutes are made available to the public.

6.7. Meeting materials: Materials to be the subject of review at a convened meeting will be made available to committee members prior to the meeting. Further details related to the distribution of materials prior to convened meetings can be found in Section D of the IBC Operations Manual.

6.8. Non-convened meetings: On occasion, IBC subcommittees may meet to discuss matters associated with the Category C project review pathway, or working groups that have been assembled 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.

7. Procedures for Defining a Quorum

7.1. For purposes of a convened meeting, a quorum of the UW IBC shall be defined as at least one half of the current membership, not including ad hoc members.

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 that a quorum can again be established.

7.3. If, during the course of the meeting, a quorum is lost 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 again be established.

8. Conflict of Interest Policy

8.1. General policy: 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*, Institutional policy, or Washington State law.

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 UW Financial Conflict of Interest Policy (Grants Information Memorandum 10) 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.

8.3. The IBC member shall disclose the conflict of interest at the following time:

8.3.1. When the IBC member is contacted to participate in the review of a project from a PI with whom the IBC member has a conflict of interest.

8.3.2. Prior to the discussion at a convened meeting of a project for which the IBC member has a conflict of interest.

8.4. An IBC member shall be recused from participating in the final decision vote on an application for which he or she has declared a conflict of interest. The IBC member shall nevertheless remain eligible to provide information related to the review of the project to the IBC.

9. Provision of Meeting Minutes to the Public

9.1. General policy: Official minutes of convened meetings of the IBC shall be made available to the public in accordance with the *NIH Guidelines* and Washington State Public Disclosure laws.

9.2. Minutes are maintained on the EH&S IBC website. Members of the public must contact the UW Office of Public Records and Open Meetings to request additional documents or information. Further details related to the content and provision of the minutes can be found in Section C of the IBC Operations Manual.

10. Communication of Public Comments to OBA

10.1. General policy: Public comments shall be communicated to OBA as stipulated under the *NIH Guidelines*.

10.2. Unsolicited oral comments received from members of the public during the course of convened IBC meetings shall be captured in the meeting minutes and from there communicated to OBA.

10.3. Unsolicited written comments addressed to the IBC from members of the public shall be directly communicated to OBA.

11. IBC Member Training

11.1. IBC Chair: In accordance with the *NIH Guidelines*, the Institution (UW) is responsible for assuring that the IBC Chair is adequately trained. At a minimum this shall include:

11.1.1. Initial training regarding the Roles and Responsibilities of the IBC under the *NIH Guidelines*, as well as the specific procedures included in this *Charter* and the IBC Operations Manual. This will typically be provided by the outgoing IBC Chair and EH&S staff members, attendance at training conferences, or through outside consultants.

11.1.2. 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.

11.2. IBC members: In accordance with the *NIH Guidelines*, the Institution (UW) is also responsible for assuring that the IBC members are adequately trained. At a minimum this shall include:

11.2.1. Initial training by the IBC Chair regarding the Roles and Responsibilities of the IBC under the *NIH Guidelines*, as well as the specific procedures included in this *Charter* and the IBC Operations Manual.

11.2.2. Completion of the online UW Biosafety Training, Bloodborne Pathogens for Researchers Training, and Dual Use Research of Concern Training every three years.

11.2.3. Completion of the Washington Open Public Meetings Act training every four years as required by RCW 42.30.

11.2.4. Periodic training in both broad and specific fields related to the oversight of biohazardous research. This will typically be accomplished through ongoing educational presentations at convened IBC meetings, or on an *ad hoc* basis.

12. Frequency of Project Reviews / Renewals

12.1. General policy: In general, individual research projects shall be approved for a term of no more then 39 months (3 years and 3 months) from the issue date of the Biological Use Authorization (BUA) 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.

12.2. Atypical approval periods: The frequency of project reviews / renewals may be changed under the following conditions:

12.2.1. At the time of approval, the IBC may determine that a shorter approval period is warranted. This condition shall be stipulated on the BUA letter as a condition of approval.

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

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

12.2.2.2. Issues come to light regarding the accuracy of the original BUA application for the proposed research.

12.2.2.3. 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.

12.2.2.4. At the discretion of the IBC Chair, in consultation with EH&S managers.

13. Laboratory Inspection Policy

13.1. General policy: In general, laboratories used for research covered under Sections III-A through III-E of the *NIH Guidelines*, or with infectious agents requiring BSL1 containment or higher, shall be inspected for compliance with applicable rules and regulations at least every three years. This inspection will typically be carried out by BSOs in conjunction with new or renewed BUA applications. The inspection results shall be reported to the UW IBC.

13.2. Although laboratory inspections are typically performed by BSOs, members of the IBC may also participate in this process. This shall be at the discretion of the IBC Chair, or at the request of individual members of the IBC, or at the request of EH&S.

13.3. For a description of inspection standards, and policies regarding more frequent inspections, see **Section E** of the IBC Operations Manual.

14. Training Policy

14.1. General policy: In general, the IBC requires training as a condition of approval for principal investigators and other laboratory staff.

14.1.1. Completion of EH&S 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.

14.1.2. Completion of the EH&S 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 human source material or other potentially infectious material (OPIM), as required under the Washington State Bloodborne Pathogens Rule.

14.1.3. Completion of the EH&S Dual Use Research of Concern (DURC) training is required every three years for principal investigators and other laboratory personnel (e.g., graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting research involving any of the agents included in the US Government Policy for Institutional Oversight of Life Sciences DURC.

15. Occupational Health Surveillance Policy

15.1. General policy: 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 in consultation with an EH&S occupational health nurse.

15.1.2. They are consistent with the Washington Industrial Safety and Health Act (WISHA), 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 Serious Adverse Events in Human Gene Therapy Trials to NIH

16.1. General policy: Serious adverse events in clinical trials involving the delivery of products containing recombinant or synthetic nucleic acid molecules shall be reported to NIH by the Principal Investigator as stipulated in the *NIH Guidelines*.

16.2. This policy shall apply to all clinical trials as defined under Appendix M of the *NIH Guidelines*, as well as vaccine trials that are exempt from Appendix M but involve direct administration of recombinant or synthetic nucleic acid molecules to human research participants.

16.3. Further details related to this reporting policy can be found in Section F of the IBC Operations Manual.

17. Reporting to NIH

17.1. General policy: The IBC, through EH&S, shall report to NIH any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses, as stipulated in the *NIH Guidelines*.

17.2. Further details related to this reporting policy can be found in Section G of the IBC Operations Manual.

18. Lines of Reporting

18.1. As stipulated in sections 1 and 2 of this *Charter*, the UW IBC shall have independent approval authority for individual research projects involving recombinant or synthetic nucleic acid molecules and infectious agents.

18.2. In all other matters, the IBC Chair shall report directly to the Executive Director of Health Sciences Administration.

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

19. Biological Use Authorization Application

19.1. The BUA application, BUA Change application, and clinical trial BUA application shall serve as the primary means of collecting information used by the UW IBC in reviewing individual research projects.

19.2. Further information related to BUA applications can be found in Section I of the IBC Operations Manual. The most current version of the BUA application and BUA Change application are included in the appendices of the IBC Operations Manual.

19.3 Significant changes to these forms shall be approved by the IBC by simple majority vote.

20. Definitions

APS: University of Washington Administrative Policy Statement (http://www.washington.edu/admin/rules//APS/12.03.html)

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

BSO: Biosafety Officer

BUA: Biological Use Authorization - application and letter formally approving proposed research (Section I of the IBC Operations Manual, and http://www.ehs.washington.edu/biological/biological-research-approval).

DURC: Dual Use Research of Concern

EH&S: Environmental Health and Safety Department

IBC: Institutional Biosafety Committee

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*; https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html). 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."

NIH: National Institutes of Health

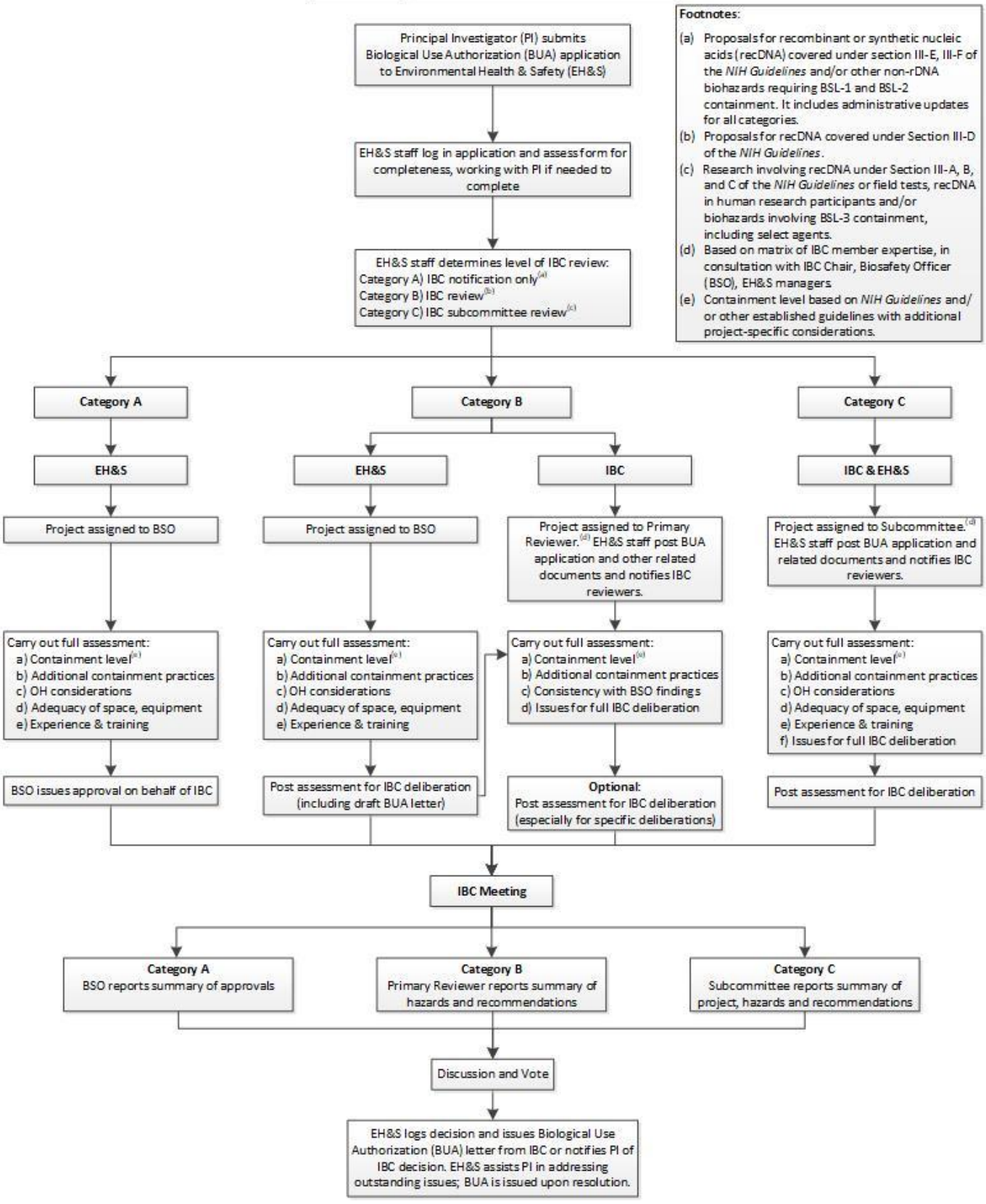
NIH Guidelines: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ; https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html).

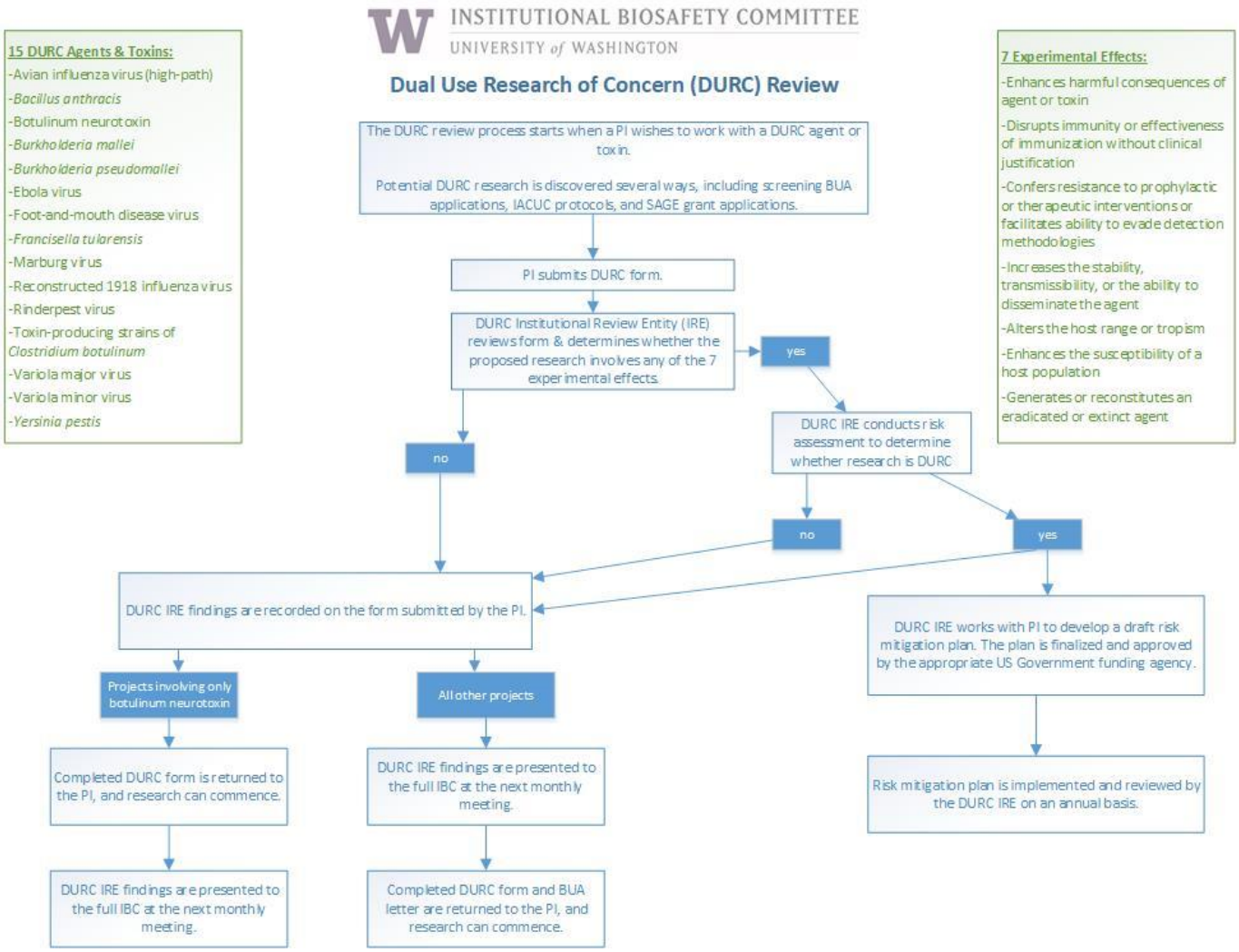
Principal Investigator (PI): The Principal Investigator is an individual who is designated and given the authority by a University department, school, or administrative unit to direct the research program or project. The PI has scientific and technical direction for the research. The PI has the responsibility 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 Biological Use Authorization 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."

UW: University of Washington

IBC Project Review Flowchart




INSTITUTIONAL BIOSAFETY COMMITTEE
UNIVERSITY of WASHINGTON
Dual Use Research of Concern (DURC) Review
15 DURC Agents & Toxins:
-Avian influenza virus (high-path)
-Bacillus anthracis
-Botulinum neurotoxin
-Burkholderia mallei
-Burkholderia pseudomallei
-Ebola virus
-Foot-and-mouth disease virus
-Francisella tularensis
-Marburg virus
-Reconstructed 1918 influenza virus
-Rinderpest virus
-Toxin-producing strains of Clostridium botulinum
-Variola major virus
-Variola minor virus
-Yersinia pestis
7 Experimental Effects:
-Enhances harmful consequences of agent or toxin
-Disrupts immunity or effectiveness of immunization without clinical justification
-Confers resistance to prophylactic or therapeutic interventions or facilitates ability to evade detection methodologies
-Increases the stability, transmissibility, or the ability to disseminate the agent
-Alters the host range or tropism
-Enhances the susceptibility of a host population
-Generates or reconstitutes an eradicated or extinct agent
The DURC review process starts when a PI wishes to work with a DURC agent or toxin.
Potential DURC research is discovered several ways, including screening BUA applications, IACUC protocols, and SAGE grant applications.
PI submits DURC form.
DURC Institutional Review Entity (IRE) reviews form & determines whether the proposed research involves any of the 7 experimental effects.
yes
no
DURC IRE conducts risk assessment to determine whether research is DURC
no
yes
DURC IRE findings are recorded on the form submitted by the PI.
DURC IRE works with PI to develop a draft risk mitigation plan. The plan is finalized and approved by the appropriate US Government funding agency.
Projects involving only botulinum neurotoxin
All other projects
Completed DURC form is returned to the PI, and research can commence.
DURC IRE findings are presented to the full IBC at the next monthly meeting.
Risk mitigation plan is implemented and reviewed by the DURC IRE on an annual basis.
DURC IRE findings are presented to the full IBC at the next monthly meeting.
Completed DURC form and BUA letter are returned to the PI, and research can commence.