The GW Institutional Biosafety Committee Charter

I. Purpose and Appointment

The George Washington University (GW) Institutional Biosafety Committee (IBC) is a formal committee of subject matter experts and community representatives whose purpose is to ensure safe work practices of biological research conducted at or sponsored by GW.

Institutions that conduct research involving recombinant DNA (rDNA) and receive funding from the National Institutes of Health (NIH) for at least part of this research are required to establish and register an IBC with the NIH Office of Science Policy (OSP) in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*).
The establishment of the GW IBC complies with this federal regulation. The NIH requires all institutions receiving research funds to have all of their recombinant or synthetic nucleic acid research reviewed by an IBC (regardless of whether that research is directly supported by the NIH), as stipulated by the *NIH Guidelines*. If such research is conducted without approval, the NIH has the authority to withdraw research support from that lab or institution. The GW IBC additionally reviews all research involving biohazardous materials as defined in Section II.

II. Definitions

A. Biological Agents

Biological agents are defined as any biologically derived material that originated from a living organism. Living organisms include plants, animals (including humans), bacteria, viruses, fungi, parasites, prions, and algae. Biological agents also include all materials derived from these organisms, such as tissues, fluids, cells, and biotoxins (including select agents), and environmental samples that may include biological materials, such as soil, and water.

B. Recombinant or Synthetic Nucleic Acid Molecules

In the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

i. Molecules that a) are constructed by joining nucleic acids 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

Section III of the *NIH Guidelines* covers the different types of rDNA research and the levels of review required for each, ranging from exempt to full review by the NIH depending on the safety risk posed. At GW, ALL rDNA research must be reviewed by the IBC even if it is “exempt” to ensure the correct status.

C. Biohazardous Materials

Biohazardous materials are defined as any biological agents that are known or suspected to be hazardous to humans, animals, plants, or other forms of life. These include, but are not limited to, known or suspected human, animal, or plant pathogens; human and nonhuman primate tissues, bodily fluids, blood products, and cell lines; wild-caught or laboratory animals and their tissues and bodily fluids; insects that may harbor zoonotic pathogens; recombinant or synthetic DNA; and biotoxins.

III. Scope of Review

Experiments involving the use of recombinant or synthetic nucleic acids and/or biohazardous agents can pose a potential risk to researchers, the community, and the environment.

The function of the IBC is to ensure that all biological aspects of research are conducted in a safe manner according to established biosafety standards, principles, practices, and authorizations. To serve this function, the IBC uses a review and approval process of all biological research involving biohazards and recombinant or synthetic technology to identify and reduce potential risks to lab personnel, the community, and the environment.
The Office of Research Safety (ORS) administers the IBC and helps with the development and maintenance of GW's Biosafety Program policies and general standard operating procedures (SOPs) on the proper use of biohazards and recombinant materials. These SOPs serve as guidance documents and do not replace laboratory-specific SOPs. The IBC assists and advises principal investigators and other researchers in meeting their responsibilities to ensure that the handling of biohazardous materials is conducted in a safe manner. Guidance from the IBC takes into consideration worker safety, public health, agricultural and environmental protection, research integrity and ethics, and compliance with applicable biosafety standards outlined by federal, state, and local regulations.

IV. Review of Charter

This charter shall be reviewed and reassessed by the IBC at least every three years and any proposed changes shall be submitted to the IBC for approval**.**

V. The Committee

The NIH priorities of transparency and community partnership are upheld by the GW IBC. GW and the IBC are committed to research that is safe for the community as well as those doing the research.

The committee is composed of ten to twelve members with expertise in rDNA and/or biosafety. The committee will be comprised of:

- Three to six scientists from GW who conduct research with potentially hazardous biological materials, including recombinant or synthetic nucleic acids
- The Institutional Biosafety Officer (BSO)
- Two non-affiliated members who work or live in the Washington DC area and who represent the interest of the surrounding community with respect to health and protection of the environment.
- An expert in animal containment

- An expert in human research protocols
- An institutional official from GW

The IBC may use consulting experts or establish subcommittees of members or nonmembers to execute its responsibilities or acquire needed expertise for select tasks.
Consultants or working group members may include, for example, persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, the environment, or any scientific area where the IBC members do not have expertise. Consultants or working group members are not IBC voting members unless nominated and appointed as described below.

The Associate Vice Provost for Research Integrity, with advice from the BSO, will appoint members and select the chair of the committee. The expected term of service is three (3) years. Members may be appointed for subsequent three-year terms if they are willing to continue to serve. If a member does not attend four meetings throughout the calendar year, the IBC Chair may motion that a replacement is nominated.

IBC members are required to maintain confidential and/or proprietary information that they may have access to in connection with their role on the IBC strictly confidential, and to use it only for the purposes of carrying out their duties as IBC members. IBC members who are GW employees are bound by GW policies related to the Confidentiality of Business Information. IBC members who are not GW affiliated will be asked to sign an acknowledgment of their confidentiality obligations in connection with their service on the IBC.

No member of the IBC may be involved (except to provide the information requested by the IBC) in the review or approval of a project in which he/she has been (or expects to be) engaged or in which he/she has a direct financial interest. IBC members are also asked to withdraw from decisions where owing to their personal relationships, there might be either real or perceived conflicts of interest. Each member is expected to notify the IBC Chair in these circumstances and recuse him/herself when such proposals are being discussed and are up for a vote. In addition, if the IBC Chair is the principal investigator on a project, the BSO or another IBC committee member present at the meeting will sign the approval letter or any resulting correspondence.

A quorum is met when a majority of IBC members are present, and the IBC chair, the BSO, and relevant subject matter experts are present for reviewing protocols and voting for approval. The meeting must be conducted by the Chair or the BSO. If the type of work being reviewed requires the advice of a particular expert, then this person must be present or in rare instances, if they are unable to come in person, they may participate by videoconference.

All members will have appropriate training to be able to effectively review projects. This training will be conducted by the BSO.

The IBC will convene monthly. Additional meetings may be called as needed to review and approve research in a timely manner.

A proposed agenda will be developed by the BSO, in collaboration with the IBC Chair. The agenda, together with all relevant materials, shall be sent to the committee members at least five (5) days before \the meeting by the BSO or his/her designee. Meeting minutes will be taken by the BSO or his/her designee to accurately reflect the topics of discussion. Meeting minutes

will be reviewed, approved by the members, and maintained on file at ORS for at least five (5) years.

Principal Investigators are always welcome to present their work to the IBC and are encouraged to attend.

When possible and consistent with the protection of privacy and proprietary interests, IBC meetings will be made publicly accessible upon request. Anyone interested in attending an IBC meeting should contact the ORS at 202-994-8258 or labsafety@gwu.edu. Please visit the ORS website for details on the next meeting. ORS will accommodate requests, when possible, in accordance with privacy and proprietary concerns. If public comments are made on IBC actions, GW will forward both the public comments and the Institutional Biosafety Committee's response to the NIH/OSP.

Meeting minutes, or other documents that must be made available to the public may be obtained by placing a request with ORS and allowing at least two weeks for processing and, if necessary, redaction of documents. Requests of 15 pages or less are free. Requests of more than 15 pages will require a fee of $10 plus 10 cents per page to cover processing and materials. The requestor will also be responsible for shipping costs. Information that may be redacted includes but is not limited to proprietary information such as trade secrets or other intellectual property, personal information such as home phone numbers or addresses, or information that could compromise institutional or national security.

VI. Roles and Responsibilities

A. Institution (in accordance with the *NIH Guidelines* Section IV-B-1)

GW is ultimately responsible for the effectiveness of the IBC and may establish procedures that the IBC shall follow in its initial and continuing review and approval of applications. Institutional responsibilities will fall under the auspices of the Vice Provost for Research. Responsibilities include:

i. maintaining the IBC meets the requirements and carries out the functions detailed in the *NIH Guidelines*;

ii. appointing the required expertise to the IBC, including a BSO, an individual with expertise in plant pathogen containment principles (if applicable), an individual with expertise in animal containment principles, an expert in human gene transfer studies, experts in handling potentially hazardous biological materials, experts in the handling of recombinant or synthetic nucleic acids, and community members;

iii. ensuring appropriate training for the IBC Chair and members, BSO and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines.*

B. Institutional Biosafety Committee (IBC) (in accordance with *NIH Guidelines*, Section iV-b-2)

IBC duties include:

i. review of all biological research conducted at GW on a five-year basis, including a review of recombinant or synthetic nucleic acid molecule research for

compliance with the NIH Guidelines as specified in Section III: Experiments Covered by the NIH Guidelines, and approving those research projects that are found to conform with the *NIH Guidelines*;

ii. establish, implement, and review policies every three years that provide for the safe conduct of hazardous biological and rDNA research;

iii. assessment of the facilities, procedures, practices, training, and expertise of personnel involved in biological research to determine appropriate biocontainment
levels required by the NIH Guidelines for the proposed research;

iv. lowering biocontainment levels for certain experiments as specified in NIH Guidelines Section III-D;

v. notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval;

vi. developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory incidents involving rDNA and infectious agent research;

vii. ensuring that the research community is in compliance with the policies of the IBC and Biosafety Program. In the event of non-compliance and upon the recommendation of the BSO, the IBC Chair will notify the Principal Investigator (PI) of non-compliance in writing indicating steps required to rectify the situation. If the PI still does not comply with the regulations, the IBC Chair will notify the Department Chair. If compliance is still not met, the IBC has the authority to suspend all activities involving biohazardous agent usage in the offending laboratory. Upon request, the PI will be granted a hearing before the IBC. The decision of the IBC is final.

viii. Investigating and reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OSP within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator. Reports of incidents can be emailed to NIH/OSP at NIHGuidelines@od.nih.gov.

C. Biosafety Officer (BSO) (in accordance with *NIH Guidelines* Section Iv-B-3)

The BSO's duties include, but are not limited to:

i. submit an annual report to NIH/OBA that includes a roster of IBC members, indicating the Chair, contact person, BSO, plant expert, animal expert, human gene therapy expert or ad hoc consultant (if applicable), other member roles, and biographical sketches of each member;

ii. report to the IBC any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the BSO becomes aware;

iii. conduct or oversee biological safety laboratory audits as part of the IBC review process of new or five-year renewals;

iv. develop emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research;

v. develop rDNA and biosafety training materials for students, faculty, and IBC members;

vi. provide administrative support for IBC activities, including preparation of meeting agendas, minutes, and materials;

vii. provide technical advice to Principal Investigators and the IBC on research safety procedures;

viii. follow-up on contingent approvals to ensure all contingencies are met and report to the IBC when contingencies have been met and final approval is given.

D. Principal Investigator (in accordance with *NIH Guidelines* Section IV-B-7)

The Principal Investigator (PI) designation is given to a GW faculty member who has primary responsibility and accountability to direct the proper conduct of a scientific research project or program. If the research is conducted by a team of researchers at a research site, the Principal Investigator is the leader responsible for that team whose name appears as Principal Investigator on the Grant Application or Award. With regard to the IBC, the PI has overall responsibility for laboratory personnel working under the requirements of the *NIH Guidelines*.

To comply with the *NIH Guidelines* and adhere to the institutional requirements of the GW IBC, the PI shall:

i. not initiate or modify any research involving recombinant or synthetic nucleic acids, infectious agents, biological toxins (including select agents), human or non-human primate blood, tissues, or cells prior to review and approval by the GW IBC;

ii. submit the initial research protocol and any subsequent changes to the IBC for review and approval or disapproval and make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;

iii. remain in communication with the IBC throughout the conduct of the project;

iv. immediately report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the BSO, Greenhouse/Animal Facility Director, IBC, NIH/OSP, and other applicable authorities;

v. adhere to the GW IBC emergency plans for handling accidental spills and personnel contamination;

vi. comply with national and international shipping requirements for infectious agents and recombinant or synthetic nucleic acid molecules;

vii. instruct and train laboratory staff in (a) the practices and techniques required to ensure safety, (b) the procedures for dealing with accidents, and (c) the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection);

viii. supervise and correct the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

ix. ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

VII. IBC Submission and Approval Processes

A. IBC Submission

The online submission to the IBC is achieved using the iRIS online registration system. All information pertaining to biological agent usage (rDNA technology, including viral vectors, animal research, human source material, infectious agents, biotoxins, etc.) and the personnel involved with the research will be queried in this system. This information is maintained in iRIS and can be updated or revised any time there is a change in the research program. Proposals must be received at least 2 weeks prior to a meeting to be on the agenda for that meeting. Meeting dates are available on the ORS website.

Note: the IBC application may require other documents to be submitted, depending on other hazards that may be involved in the proposed work or as deemed necessary

B. IBC Approval Process of New Research Projects, 5-Year Renewals, Annual Review and Amendments

i. **ORS Pre-Review:** The BSO will review the submitted research information and conduct a risk assessment based on the information provided. A biosafety audit of the lab will be conducted as part of the risk assessment for all new laboratories, as part of the 5-year renewal cycle, or more frequently as needed. Any questions/problems/concerns will be directed back to the principal investigator (PI) for clarification. Once all aspects of the risk assessment have been satisfied by ORS, the research will be presented for review by the IBC.

ii. **IBC Review**: The IBC will review the research information submitted through iRIS at a regularly scheduled meeting. One member will be asked to summarize the proposal at the meeting and discuss the safety and regulatory aspects of the research project. Discussion topics include the nature of experimentation, biohazards and use of other hazardous materials, containment, location, recombinant or synthetic nucleic acid aspects, training requirements fulfilled by research staff, past laboratory inspection records, etc. The PI for the lab or representatives sent by the PI may be invited to the meeting to answer questions

by the committee but may not be present during the discussion. There may be times when attendance by the PI or their representatives is mandatory.

If anyone on the committee, due to a conflict of interest may not be able to provide an unbiased opinion, they must be excused from the discussion of that particular proposal. If someone must be excused from the discussion on a protocol, the minimum attendance, and expertise must still be maintained.

Approval requires a two-thirds vote but every effort should be made to gain unanimous approval. If more information is needed or if there are serious problems with the proposal, the committee will notify the applicant as to what is needed and take it up again at the next scheduled meeting. If there are only some small changes needed, the committee may approve the proposal contingent on these items being corrected. When the items are corrected, only review from the BSO and the Committee Chair is required for full approval.

iii. **Decision Letter Sent to PI**: Once the IBC has made a decision regarding the research project reviewed, a decision letter will be sent to the PI signed by the IBC Chair.

iv. **Research Starts**: Once an approval letter has been received from the IBC, only then may the proposed research begin.

v. **5-Year Renewals:** Approvals are effective for 5 years. Protocols may be re-approved only by full committee review when they expire or at the discretion of the committee. The IBC may revoke an approval if it is determined that the research is not in compliance with NIH Guidelines or the GW biosafety manual. To renew a protocol after 5 years, a complete IBC application must be submitted along with supporting documents; similar to a new submission.

vi. **Annual Review:** Each approved project will be reviewed annually. The PI must submit via iRIS the Annual Review form and indicate if there are any changes or not to the approved research project. If there are changes, the PI must amend the IBC application form to reflect any changes.

vii. **Amendments:** If significant changes are made during the course of ongoing approved research, then the proposal must be amended. The PI must make the amendment when the change occurs and not wait until the annual review. A substantial change would include a change in research personnel; a change in the biosafety level; a new pathogen; a major modification of a unique, non-commercial expression vector; any change in an expression vector resulting in increased levels of transgene expression; large changes in the nature of an inserted gene, etc. The PI must submit an Amendment form via the iRIS system.

C. Administrative Approval of Modifications to Currently Approved Research

Any modifications to currently IBC-approved research (e.g., changes or updates to the iRIS registration that occur during the 5-year approval timeframe) will be initially reviewed by the BSO. The BSO, in consultation with the IBC Chair or committee expert, if needed,

will determine whether the full committee must review the research or if it may be reviewed by the BSO and/or IBC Chair without going to the full committee.

Factors that may determine whether a full committee review is warranted include:

i. a new project is added that has not been previously reviewed by the IBC;

ii. a new agent or procedure is added to a current project that would require different practices or containment from what is currently approved for that laboratory;

iii. research involving non-exempt work covered by the *NIH Guidelines* (Section III-A through III-E).

The BSO, in consultation with the IBC Chair or committee expert, has the authority to administratively review and approve modifications if a risk assessment determines a full committee review is not warranted, and a decision letter will be sent to the PI. All administratively approved research will be reported to the IBC at a regularly scheduled meeting.

D. Administrative Approval of Biological Research

At the discretion of the BSO and in consultation with the IBC Chair, administrative review and approval of an IBC submission is permitted for work that does not involve recombinant or synthetic nucleic acids, is exempt from the *NIH Guidelines* as per *Section III-F,* and may be conducted at Biosafety Level (BSL) 1 or 2. The BSO, in consultation with the IBC Chair or committee expert, has the authority to review and approve such research after conducting a risk assessment, and a decision letter will be sent to the PI. All administratively approved will be reported to the IBC at regularly scheduled meetings.

VIII. Inspections

Laboratory facilities and other areas where research is conducted will be inspected annually by ORS to ensure that work is being done at the proper containment and in compliance with the GW biosafety manual. Inspections may be unannounced and may be more frequent depending on risk or if violations have been found previously.

IX. Resources

- *Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines),* Federal Register (2016).
- *Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research,* Office of Research Safety, National Cancer Institute, Special Committee of Safety and Health Experts, July 1978.
- *Biosafety in Microbiological and Biomedical Laboratories,* 6th Edition, CDC and NIH.
- *Bloodborne Pathogens Standard*, Occupational Safety and Health Administration (OSHA), 29 CFR 1910,1030.
- *Select Agents and Toxins*, Health and Human Services (HHS), 42 CFR 121.
- *Plant Pathogens and Pests*, USDA, 9 CFR Parts 92,94,95,96, 122 and 130.
- *Importation of Human Pathogens*, U.S. Public Health Service (USPHS), 42 CFR 71