June 2013

POLICIES AND PROCEDURES FOR

THE HOWARD UNIVERSITY

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

CONTENTS

SECTION 1: PURPOSE AND SCOPE OF POLICIES AND PROCEDURES

1.1 Purpose: The purpose of these Policies and Procedures is to set forth the charge of the University's Institutional Biosafety Committee (IBC). The IBC is charged with

1.1.1 Reviewing and approving any proposed IBC Research prior to its initiation in compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* and CDC/NIH Guidelines for *Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH Guidelines)*. The scope of IBC research is defined in Section 1.2.

1.1.2 Establishing policies and procedures that the IBC will follow in its initial and continuing review of IBC Research.

1.2 Scope: These policies and procedures apply to all investigators, who intent to and who are involved in research sponsored by the University and/or conducted at the University facilities (regardless of its funding source) that involves:

a) biological toxins,
b) infectious agents,
c) select biologic agents,
d) recombinant or synthetic nucleic acid molecules, cells, organisms or viruses containing such molecules (*NIH Guideline* Research), and
e) blood, unfixed tissues, primary and established cell culture derived from human or non-human primates.

(These terms will be defined in Section 6.1, including exempt experiments.)

SECTION 2: RESPONSIBILITIES OF THE UNIVERSITY

2.1 General Information: In order to ensure that all IBC Research is carried out in accordance with the *NIH Guidelines* and *CDC/NIH Guidelines*. Howard, acting through these Policies and Procedures, and through the committees and positions established by these Policies and Procedures, has performed the responsibilities set forth below and continues to carry out any such ongoing responsibilities:

2.1.1 Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecules research and that ensure compliance with the *NIH Guidelines*.

2.1.2 Establish an Institutional Biosafety Committee (IBC) that meets the requirements and carries out the functions detailed in Sections 4 and 5.

2.1.3 Appoint a University Biosafety Officer (UBSO). The University Biosafety Officer carries out the duties specified in Section 3.

2.1.4 Appoint at least one individual with expertise in plant, plant pathogen, or plant containment principles (who is a member of the IBC) if the University conducts recombinant or synthetic nucleic acid molecules research that requires IBC approval in accordance with *Appendix P, Physical and Biological Containment for Recombinant or synthetic nucleic acid molecules Research Involving Plants* in *NIH Guidelines.*

2.1.5 Appoint at least one individual with expertise in animal containment principles (who is a member of the IBC) if the University conducts recombinant or synthetic nucleic acid molecules research that requires IBC approval in accordance with *Appendix Q, Physical and Biological Containment for Recombinant or synthetic nucleic acid molecules Research Involving Animals* in *NIH Guidelines.*

2.1.6 Ensure that when the University participates in or sponsors recombinant or synthetic nucleic acid molecules research involving human subjects: a) the IBC has adequate expertise and training (using *ad hoc* committee *or* consultants as deemed necessary), b) all aspects of *Appendix M* in *NIH Guidelines* have been appropriately addressed by the principal investigator (PI); and c) no research participant shall be enrolled in a human gene transfer experiment until the Recombinant or synthetic nucleic acid molecules Advisory Committee (RAC) review process has been completed (see *Appendix M-I-B* in *NIH Guidelines, RAC Review Requirements*), IBC approval has been obtained, Institutional Review Board (IRB) approval has been obtained, and all applicable regulatory authorizations have been obtained. IBC approval must be obtained when recombinant or synthetic nucleic acid molecules material will be administered to human subjects.

2.1.7 Assist and ensure compliance with the *NIH Guidelines* by PIs conducting research at the University as specified in Section 7.

2.1.8 Ensure appropriate training for the IBC Chair and members, University Biosafety Officer and other containment experts (when applicable), PIs, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. The IBC Chair is responsible for ensuring that IBC members are appropriately trained (define training?). The PI is responsible for ensuring that laboratory staffs are appropriately trained. The University is responsible for ensuring that the PI has sufficient training; however, this responsibility may be delegated to the IBC.

2.1.9 Determine the necessity for health surveillance of personnel involved in connection with individual recombinant or synthetic nucleic acid molecules projects; and if appropriate, conduct a health surveillance program for such projects. The University shall establish and maintain a health surveillance program for personnel engaged in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules molecules that require BL3 containment at the laboratory.

SECTION 3: UNIVERSITY BIOSAFETY OFFICER

3.1 Qualifications: The University Biosafety Officer shall have the experience, education and background that make him/her knowledgeable about laboratory research, biohazards, containment and recombinant or synthetic nucleic acid molecules technology and give him/her the capability to assess the safety of recombinant or synthetic nucleic acid molecules research and identify potential risks to public health and/or the environment. The University Biosafety Officer shall be trained in and receive on-going training in laboratory safety and topics necessary for the implementation of the *NIH Guidelines* and *CDC/NIH Guidelines*. The University Biosafety Officer shall be a member of the Safety Officer's Committee under Howard's Environmental Health and Safety Office (EHSO) and shall be a voting member of the IBC.

3.2 Duties: The University Biosafety Officer's duties shall include, but shall not be limited to, the following:

3.2.1 Making periodic inspections of laboratories at which research, subject to the jurisdiction of the IBC, is being conducted in to ensure that laboratory standards at the biosafety level for proposed research are rigorously followed and reporting the results of such inspections to the IBC, as well as to any other appropriate compliance units or committees at Howard (e.g., Office of Regulatory Research Compliance (ORRC), IRB).

3.2.2 Reporting to the IBC, as well as to any other appropriate compliance units or committees at Howard any significant problems involving or violations of the *NIH Guidelines*, as well any significant accidents or illnesses related to research under the IBC's jurisdiction of which the University Biosafety Officer becomes aware (see section 7.2). The Biosafety Officer also shall be responsible for generating and submitting any reports to NIH OBA or other governmental agencies or sponsors that are required by the *NIH Guidelines*, or other applicable laws or regulations (Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Dr., Suite 750, MSC 7985, Bethesda, MD 20892-7985; Phone – (301) 496-9838; FAX – (301) 496-9839.), and that copies of any such reports have been provided to the Biosafety Officer, Chair of the IBC and the Vice President of Research Compliance Office.

3.2.3 Developing an emergency plan for handling accidental spills and personnel contamination and investigating laboratory accidents that concern recombinant or synthetic nucleic acid molecules IBC Research, which plans shall be reviewed and approved by the IBC. In addition, the IBC may require PIs to develop specific plans for handling such incidents.

3.2.4 Providing advice on laboratory security.

3.2.5 Providing technical advice to PIs and the IBC on research safety procedures.

3.2.6 Carrying out such other duties as may be assigned from time to time by the IBC, EHSO or other appropriate Howard administrative units.

SECTION 4: DUTIES OF INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

4.1 General Duties of the IBC: The IBC's general duties shall include the following:

4.1.1 Reviewing and evaluating protocols for IBC research set forth in Section 1.2 that are sponsored or conducted at Howard.

4.1.2 Making policy recommendations regarding biosafety, laboratory safety, and related occupational health and safety matters to the University President or his/her designee, for approval and implementation by appropriate units, including, but not limited to, the Environmental Health and Safety Office (EHSO).

4.1.3 Recommending procedures for approval of activities involving microbial agents, biological toxins, and hazardous materials of human origin that require special containment facilities or practices,

which, in the judgment of the IBC, may constitute a hazard to faculty, staff, students or the university and community environment.

4.1.4 Reviewing the University Biosafety Officer's reports of accidents or other incidents resulting in the exposure of faculty, staff, students, or the community environment to infectious microorganisms or biohazardous materials, as well as report of non-compliance with established Howard University policies and regulatory requirements regarding the safe conduct or research or use of these materials which are set based on *NIH Guidelines*.

4.1.5 Upon the request of the EHSO or the University Biosafety Officer, the IBC also may participate in any inquiry or investigation into suspected incidents of laboratory acquired or zoonotic infections. In particular, the expertise of selected IBC members may be utilized to investigate specific epidemiologic features of the suspected agent and to prepare appropriate prevention strategies.

4.1.6 Establishing working subcommittees within the IBC and appointing to the IBC, as necessary, *ad hoc* members or consultants with particular expertise that is deemed necessary by the IBC to effectively carry out the duties of the IBC.

4.1.7 Maintaining an effective liaison with pertinent Howard University administrative units, departments and committees, including, but not limited to, the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) and Office of Regulatory Research Compliance (ORRC).

4.1.8 On an annual basis the IBC will conduct a self-assessment of the operational procedures of the biosafety program; including, but not limited to: protocol review, approvals, laboratory inspections, and committee function.

4.1.9 Carrying out such other duties as may be assigned from time to time by the University President or his/her designee.

4.2 Duties of the IBC under the NIH Guidelines: The IBC's specific duties under the *NIH Guidelines* shall include the following:

4.2.1 Reviewing recombinant or synthetic nucleic acid molecules research conducted at or sponsored by Howard University to determine if it constitutes IBC Research per *NIH Guidelines, Section III, Experiments Covered by the NIH Guidelines*, and if so reviewing the research for compliance with the *NIH Guidelines*. The IBC may grant approval only to those research protocols that are in conformance with the *NIH Guidelines, CDC/NIH Guidelines*, and any other applicable legal or University requirements.

4.2.2 Notifying the PI of the results of the IBC's review and approval or disapproval.

4.2.3 Reviewing and evaluating any request for the lowering of containment levels for certain experiments as specified in *NIH Guidelines, Section III-D-2-a, Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.*

4.2.4 Setting containment levels for protocols as set forth in *NIH Guidelines, Sections III-D-4, Experiments Involving Whole Animals and III-D-5, Experiments Involving Whole Plants.*

4.2.5 Establishing and implementing a method whereby the IBC periodically reviews recombinant or synthetic nucleic acid molecules research conducted at Howard to ensure compliance with *NIH Guidelines* (e.g., through conduct of compliance review, inspections, audits, etc.).

4.2.6 Reviewing and adopting emergency plans covering accidental spills and personnel contamination resulting from DNA research. Such plans shall follow recommendations found in the NIH Laboratory Safety Monograph *(link here)* and shall include provisions for cooperating with state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.

4.2.7 Reporting any significant violations of the *NIH Guidelines* or any significant research related accidents or illness to the appropriate institutional officials, institutional committees and NIH OBA at the address specified in Section 3.2.2 immediately; i.e. within 3 business days dependent upon the severity of the incident. Reports shall be sent to NIH OBA and copies of any such reports shall be maintained by the University Biosafety Officer and the ORRC at Howard University.

4.2.8 Performing such other duties and functions as may be delegated to the IBC in accordance with *NIH Guidelines, Section IV-B-2, Institutional Biosafety Committee.*

SECTION 5: MEMBERSHIP AND ORGANIZATION OF THE IBC

5.1 Number of Members: The IBC may have up to twelve (12) members, each of whom shall be appointed by the University President or his/her designee. President, or his/her designee, may increase or decrease the number of members on the IBC, but in no event shall the number of members be less than five (5).

5.2 Qualifications of Members: The IBC membership shall be composed of persons who collectively have experience and expertise in recombinant or synthetic nucleic acid molecules technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecules research and to identify any potential risk to public health or the environment. In addition to including members with expertise in recombinant or synthetic nucleic acid molecules technology, the IBC also shall include members with expertise in biological safety and physical containment, as well as including, or having available as ex officio members or consultants, persons who are knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community standards and the environment. The IBC members shall have:

5.2.1 At least one (1) but no more two (2) members will be selected from the community (hereinafter the "Community Members") and shall have no present affiliation with Howard apart from their membership on the IBC. These members shall represent the interests of the surrounding community with respect to health and protection of the environment, and they may be individuals such as state or local public health or environmental agency officials, members of

local governmental bodies or persons active in medical, occupational health or environmental concerns in the community.

5.2.2 University Biosafety Officer.

5.2.3 Other members of the IBC shall be scientists from Howard University communities, (schools, departments, units or centers) that are involved in biomedical research or on-going activities involving infectious diseases, and recombinant or synthetic nucleic acid molecules in microorganisms, plants, or vertebrates**.**

5.3 Ex Officio Members: The following persons shall be members of the IBC by virtue of the positions that they hold at Howard:

5.3.1 Vice President of the Office of Research Compliance: The Vice President of the ORRC shall serve as a non-voting member of the IBC.

5.3.2 Director of the EHSO: The Director of the EHSO shall be a non-voting member of the IBC.

5.4 IBC Chair and Co-Chair

5.4.1 Chair: The University President, or his/her designee, shall appoint a Chair of the IBC among the members appointed to the IBC.

5.4.2 Co-Chair: The IBC members shall elect a Co-Chair by majority vote. The Co-Chair shall exercise all rights and responsibilities of the Chair in the event of the absence or unavailability of the Chair.

5.5 IBC Administrative Support Staff

5.5.1 The administrative support staff shall be member(s) of the staff of Office of Regulatory Research Compliance.

5.5.2 Duties: The administrative support staff shall be responsible for performing the following duties:

5.5.2.1 Membership Roster: Keeping a current roster of all members (including the Community Members) of the IBC that specifies for each member (and any alternate members): (a) name; (b) title; (c) contact information; (d) biographical sketch, e) effective date of appointment and ending date of member's term; (f) specification of whether member is appointed or ex-officio; (g) specification of whether member is voting or non-voting; (h) specification of any office or post held within the IBC by the member (e.g., Chair, Co-Chair, etc.), including effective date and ending date of terms for which office or post is held; (i) specification of each member's expertise.

5.5.2.2 Contact Person: Serving as a "Contact Person" for the IBC to receive IBC application from PI, set up IBC meetings, and serve as liaison among IBC members and between IBC and ORRC, PI, and NIH/OBA.

5.5.2.3 Attendance: Keeping accurate attendance of all members at each meeting of the IBC.

5.5.2.4 Quorum: Keeping track to ensure that there is a quorum of members at the beginning and throughout the course of each IBC meeting, including noting within the meeting minutes when any IBC member leaves the meeting and when he/she returns. A quorum shall be constituted when a majority of the voting members (1/2 of the committee members) of the IBC are present and the presence of at least one Community Member is a part of that majority. No IBC business shall be conducted unless a quorum is present.

5.5.2.5 Minutes: Keeping accurate minutes of each IBC meeting, including, but not limited to the following: (a) the date, time and place of the meeting; (b) a list of all individuals in attendance and a record of the presence of a quorum in accordance with Section 5.5.2.3 above, including a record of any persons who leave or enter during the course of the meeting and any resulting failure in quorum; (c) a description of whether the meeting was open or closed to the public, and if closed, the reasons for closing it; (d) a description of any discussion regarding the prior meeting's minutes, including any recommendations for corrections thereto, and a description of the vote as to whether the prior meeting's minutes were approved or disapproved; (e) a description of all items of old and new business discussed; (f) a description of all protocols reviewed and of all items of discussion regarding each such protocol; (g) a record of all motions made and whether the motions were approved/disapproved; (h) a record of the votes taken with regard to each protocol or any other item of business requiring a vote by the IBC, including the number of members in favor, those opposed and those who abstained; and (i) the time of the meeting's adjournment. To assist with the preparation of minutes, the meeting can be tape-recorded.

5.5.2.6 Circulation and Approval of Minutes: Drafting minutes of each IBC meeting promptly after the conclusion of each such meeting, and circulating these minutes to all IBC members at least one week prior to the next scheduled IBC meeting for comment and a vote of approval at that meeting. Final copies of each IBC meeting minutes (including any comments or changes suggested at the meeting at which approval was voted) shall be signed by the ORRC Administrative Support Staff and the IBC Chairperson and maintained in a record of "Official Minutes" by the Administrative Support Staff.

5.5.2.7 Availability of Minutes: The IBC Official Minutes shall be made available to the public upon request in accordance with *NIH Guidelines*, Section IV-B-2-a-(7), along with any documents that the IBC has submitted to or received from funding agencies that the funding agencies are required to make public. In the event that the IBC receives any public comments regarding its actions, the ORRC Administrative Support Staff shall forward such comments and the IBC's response to the NIH OBA at the address specified in Section 3.2.2

5.5.2.8 Annual Report: On behalf of the IBC, and subject to IBC approval, compiling and submitting an annual report to the NIH/OBA, in accordance with NIH Guidelines, Section IV-B-2-a-(3), which includes: (i) a roster of all IBC members clearly indicating the Chair, contact person, University Biosafety Officer (if applicable), plant expert (if applicable), animal

expert (if applicable), human gene therapy expertise or *ad hoc* consultant(if applicable); and (ii) biographical sketches of all IBC members (including community members).

5.5.2.9 Records: Collecting and maintaining all records of any actions and activities of the University Biosafety Officer and the IBC, including the Official Minutes as set forth in Sections 5.5.2.5 above. All records shall be kept for the longest of any retention period required by the *NIH Guidelines*, or any other applicable federal, state, local or university requirement.

5.6 Membership Terms & Conditions

5.6.1 Member Terms: Each appointed member of the IBC (excluding ex-officio members) shall be appointed to serve for a term of three (3) years from the effective date of appointment.

5.6.2 Officer Terms: The Chair and Co-Chair shall be appointed/ elected to serve for a term of 3-years from the effective date of appointment/election.

5.6.3 Additional Terms: IBC members, Chair and Co-Chair may be appointed/ elected to serve an unlimited number of additional three (3) year terms, whether consecutive or non-consecutive.

5.6.4 Appointment/Resignation/Removal: (incorporate nomination from the compliance office and IBC chair) All members and officers of the IBC, aside from ex-officio members/officers, serve at the discretion of Howard's President (or his/her designee) and may be removed from membership and/or have their term as an officer terminated by the President (or his/her designee) at any time by written notice from the President (or his/her designee), to the ORRC Administrative Support Staff of the IBC. In the event that a member or officer is removed or resigns from membership/office prior to the expiration of his/her term, the President (or his/her designee) shall appoint (or in the case of the Co-Chair, the IBC shall elect) a replacement to serve for the remainder of that person's term. Members and officers may resign by submitting their written resignations (including the effective date of their resignation) to the Administrative Support Staff. If possible, resigning members/officers shall provide the Administrative Support Staff with the names of potential successors who are interested in being appointed to the IBC. The Administrative Support Staff, in turn, shall pass such names onto the President, or his/her designee, for consideration. The Administrative Support Staff shall announce any appointment/resignations, along with their effective dates, at the soonest possible IBC meeting or by written communication to IBC members. Members shall not be permitted to vote or take place in IBC activities until their appointment has become effective and been announced to the other IBC members.

5.6.5 Voting: Each member shall be entitled to one vote. In order to vote, a member must be present at a duly-constituted IBC meeting at which a quorum is present; there shall be no voting by proxy.

5.6.6 Conflicts-of-Interest: No IBC member may be involved in the review or approval of a protocol or project in which he/she has been or expects to be engaged or has a direct financial interest, except to provide information to the IBC regarding the protocol/project. Any such IBC member shall recuse himself/herself from the portion of the IBC meeting in which any such protocol is considered; shall

not vote on the protocol or be present for the vote; and shall not be counted towards a quorum necessary for the consideration of the protocol/project.

5.6.7 Attendance at Meeting via Computer or Telephonic Means: An IBC member may attend a meeting of the IBC via conference call, video teleconference or webcam, provided that the member has received in advance the materials to be reviewed at the meeting; the member can hear the meeting and be heard by the other members; the member advises the Administrative Support Staff if he/she needs to leave at any time during the meeting; and conference call; and the member votes by voice on matters submitted for a vote. Members who attend the IBC in this manner may be counted toward establishing quorum for the meeting.

SECTION 6: PROTOCOLS REQUIRING SUBMISSION TO THE IBC & REVIEW PROCESS

6.1 IBC Registration Document. In accordance to the *NIH Guidelines*, all PIs who conduct research sponsored by Howard University or conducted at Howard facilities that involve work with "Biological Toxins," "Infectious Agents," "Select Agents", or "Recombinant or synthetic nucleic acid molecules Molecules", as those terms are defined below, must submit IBC Registration Document (IBC application for Study Approval) along with research protocol to be reviewed by the IBC. All documents requiring full IBC review must be received at least 3 weeks in advance of an IBC meeting in order to be reviewed at the meeting.

6.1.1 Biological Toxins: "Poisonous material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology; produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance." [See 42 CFR § 73.1].

6.1.2 Infectious Agent: An organism, usually a microorganism, but including helminthes, that is capable of producing infection or infectious disease, and any organism (such as a virus, rickettsiae, bacteria, fungus or parasite) that is capable of invading and multiplying in tissues and having the capacity to cause disease or adverse health impacts on humans, plants or animals. (See *NIH Guidelines, Appendix B* and *CDC/NIH Guideline, Section VIII*)

6.1.3 Select Agents: All biological agents or toxins listed at 42CFR part 73, 7CFR331, and 9CFR121. *(link 1)(link 2)(link 3)*

6.1.4 Recombinant or synthetic nucleic acid molecules Molecules:

6.1.4.1 In the context of the *NIH Guidelines*, recombinant or synthetic nucleic acid molecules molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

6.1.4.2 Exempt experiments: The following recombinant or synthetic nucleic acid molecules are exempt from the *NIH Guidelines* and registration with the IBC is not required. (*NIH Guidelines, Section III-F and Appendix C*)

6.1.4.2.1 Those that are not in organisms or viruses.

6.1.4.2.2 Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

6.1.4.2.3 Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.

6.1.4.2.4 Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

6.1.4.2.5 Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see *NIH Guidelines, Section IV-C-1-b-(1), Major Actions).(* See *NIH Guidelines, Appendices A-I through A-VI, Exemptions Under Section III-F-6-Sublists of Natural Exchangers,* for a list of natural exchangers that are exempt from the *NIH Guidelines.)*

6.1.4.2.6 Those that do not present a significant risk to health or the environment (*see Section IV-C-1-b-(1)-(c), Major Actions),* as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. (See *NIH Guidelines*, Appendix C, *Exemptions under Section III-F* for other classes of experiments which are exempt from the *NIH Guidelines*.)

6.1.5 Blood, unfixed tissues, primary and established cell cultures derived from human or non-human primates.

6.2 Type of Review. All research that involves recombinant or synthetic nucleic acid molecules molecules, infectious agents, selected biological agents or human tissues described in Section 6.1 receives review by the full IBC.

6.3 Tracking of Research Protocols: Upon receipt of the completed IBC Registration Document and the accompanying research protocol, the Administrative Support Staff shall assign a number to the research protocol, which shall be used for tracking. Any amendments/modifications received for a protocol shall be numbered sequentially upon receipt. The PI should refer to the assigned protocol number in all correspondence with the Administrative Support Staff and the IBC regarding the research protocol.

6.4 Initial Review by IBC Chair and University Biosafety Officer. The IBC Chair shall review each submitted research protocol for completeness and make a determination as to the type of review that should be provided per Section 6.2 above. An obviously incomplete protocol shall be returned to the PI for completion prior to being presented to the IBC for review. Copies of all protocols to be reviewed by the IBC shall be provided to each member of the IBC. The University Biosafety Officer shall review each submitted research protocol and schedule a laboratory biosafety inspection.

6.5 Assignment for Presentation: For all protocols for which full IBC review is required, the IBC Chair shall assign a primary and secondary reviewer for each protocol or protocol amendment to be reviewed; provided, however, that the following protocol amendments may be reviewed solely by the Chair of the IBC:

6.5.1 A change in the title of a protocol, that does not involve any other changes to the protocol or personnel involved in the protocol; and

6.5.2 A change to a protocol for research that is not *NIH Guidelines* Research, when the change pertains only to a change in research personnel, other than the PI, assigned to the protocol.

6.6 Presentation at the IBC Meeting. All protocols that require review by the full IBC shall be scheduled for presentation by the assigned reviewers at an upcoming IBC meeting. Either the primary or secondary reviewer must be present at the meeting in order for the protocol to receive proper review. Otherwise, the protocol shall be deferred until the next meeting of the IBC at which the primary or secondary reviewer can be present.

6.7 Notification of the PI: The PI shall receive notice from the IBC indicating that his/her IBC Registration and research protocol or protocol amendment have been received, along with the type of review process that the protocol will undergo, and if full IBC review is required, the date of the IBC meeting at which the protocol or amendment is scheduled for review and the status designated for this application.

6.8 Amendments to Protocols: If a PI makes an addition or modification (referred to herein as an "amendment") to a Protocol that has been reviewed by the Biosafety Office or full IBC, then the PI must resubmit the Intent of Notice along with a copy of the modified protocol highlighted to show additions/modifications. The amendment will be processed as described in Section 6.2 – 6.7 above.

6.9 Protocol/Amendment Status: As a part of its review of a protocol or an amendment to a protocol, the IBC will assign one of the following statuses to the protocol or amendment:

6.9.1 Approved: This status is given if the IBC approves the protocol/amendment without the need for any changes to the protocol/amendment by the PI. An approval is good for three years, unless a shorter timeframe is specified by the IBC. The IBC approval is nontransferable to another PI.

6.9.2 Approved with Provision: This status is given if the IBC has just a few minor questions or issues about the protocol/amendment that the PI must resolve before the protocol can receive full approval. The IBC shall provide the PI with a list of these questions or issues, and the PI must respond to each of these questions/issues in full within 30 days after receiving the list. If the PI fails to respond

within this period, then the protocol/amendment will be withdrawn by the IBC. The PI's response to the questions/issues will be given to the primary and secondary reviewers assigned to the protocol. They will review these responses and report to the IBC Chair as to whether the response is adequate, and if so, the protocol/amendment will be granted the "Approved" status. No work under the protocol/amendment may take place until the protocol/amendment is granted "Approved" status.

6.9.3 Disapproved: This status is given if the IBC has major substantive concerns with the protocol/amendment. For example, the protocol/amendment may not be justified; it may pose severe or unnecessary risk; or the PI may have failed to adequately address issues or questions about the protocol/amendment. Further revisions to a Disapproved protocol/amendment will not be accepted by the IBC. The PI may re-write the protocol/amendment with substantial changes and submit it as a new protocol/amendment.

6.9.4 Withdrawn: This status is given to protocols/amendments that the IBC has removed from further consideration. This may occur at the PI's request or when the PI has failed to respond to questions from the IBC in the allotted time which is 90 days from receipt of correspondence. Extenuating circumstances will be discussed on a case-by-case basis.

6.9.5 Suspended: This status is given if the IBC determines that serious questions or issues have arisen with regard to a protocol, or the manner in which the protocol is being conducted that should cause its Approved status to be removed. For example, the IBC may receive allegations that the protocol is not being conducted in accordance with the *NIH Guidelines* or it may receive notice from another University committee with jurisdiction over the protocol that the protocol has been suspended by that group. The IBC may, in its discretion, suspend all or part of a protocol. The IBC, in connection with the Office of Regulatory Research Compliance, shall immediately notify the PI of any Suspension, and the PI shall immediately stop any work under the Suspended protocol (or Suspended portion of the protocol) until clearance to resume work is received from the IBC. The IBC may conduct or cooperate in such inquiries/ investigations as it deems necessary to determine if a protocol should be suspended, or to determine if a Suspended protocol may have its Approved status reinstated.

6.9.6 Terminated: This status is given to protocols that are no longer active. Research cannot be conducted under protocols that are terminated. The PI may terminate a protocol by writing to the IBC Chair. If a PI does not take proper steps to renew a protocol when its Approved status is set to expire, then the protocol will be terminated (within 60 days of expiration). The IBC may also take steps to terminate a protocol that has been suspended, based on the results of appropriate inquiries/investigations conducted by the IBC or other appropriate Howard University committees or units with jurisdiction over the protocol. The IBC shall send out a written notice of Termination to the PI on any protocol that is terminated. This notice may be copied to other University committees or units, as appropriate. No work should continue under a protocol after it is terminated. If the PI wishes to conduct future work under a terminated protocol, he/she must submit the protocol for approval as a new protocol. Termination of the IBC protocol will garner a response by other applicable regulatory committees; i.e., IACUC and IRB.

6.10 Protocol Terminations: A PI should request that the IBC terminate a protocol when the protocol has ended and Biological Toxins, Infectious Agents or Recombinant or synthetic nucleic acid molecules

Molecules are no longer being used. The PI should notify the IBC in writing of the request for termination. If a faculty member leaves the University, he/she should notify the IBC in writing that his/her protocol should be terminated. In addition, the IBC may terminate a protocol as set forth above in Section 6.9.6.

SECTION 7: RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

7.1 General Responsibilities

7.1.1 Principal Investigator is responsible for compliance with *NIH Guidelines* and University Policies: Each PI at Howard is responsible for ensuring that his/her research is in full compliance with those *NIH Guidelines* as well as with any other applicable laws and regulations or University policies and procedures. Any failure on the part of the PI to comply with such applicable laws, regulations, policies and procedures may result in Suspension or Termination of the research and/or other appropriate actions, including disciplinary actions, being taken against the PI by appropriate University committees or officials.

7.1.2 Research Subject to IBC Review: The PI shall be responsible for ensuring that all research under a protocol requiring IBC review is properly submitted to the IBC for review and that IBC approval is granted before any research under the protocol is initiated. The PI shall also be responsible for ensuring that any required approval from other University committees is obtained before initiating the research (e.g., IRB approval, IACUC approval, etc.). The PI shall also make any proper notification to IBC of the initiation of any Experiments that Require IBC Notice Simultaneous with Initiation in accordance with *NIH Guidelines*, Section III-E.

7.1.3 Reporting Responsibilities: The PI shall fulfill all required reporting responsibilities per Section 7.5 below.

7.1.4 Training: The PI shall be adequately trained in good laboratory practices, as defined by CDC Guidelines, and shall adhere to such techniques in his/her research. The PI also shall ensure that his/her employees and assistants are adequately trained (the training is documented with dates and subject matter covered), follow appropriate lab techniques and complete the Environmental Health and Safety training.

7.1.5 Adherence to IBC and Other University Safety Plans: The PI shall adhere to all IBC-approved and other University-approved plans for handling, managing, using, storing and shipping Biological Toxins, Infectious Agents, and Recombinant or synthetic nucleic acid molecules Molecules including plans regarding the handling of accidental spills and contamination.

7.2 Specific Responsibilities of the PI with Regard to the IBC

7.2.1 The PI shall:

7.2.1.1 Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*,

7.2.1.2 Select appropriate laboratory techniques to be used for the research,

7.2.1.3 Submit his/her initial research protocol and any subsequent amendment to that protocol to the IBC for review, and

7.2.1.4 Continue communication with the IBC throughout his/her conduct of any protocol subject to the IBC's jurisdiction for renewal or amendment of the protocol and immediately advising the IBC of any adverse events, significant problems, violations of *NIH Guidelines* or significant research-related accidents or illnesses related to the protocol.

7.2.2 Human Gene Transfer Experiments: The PI shall ensure that no human research participant shall be enrolled in a human gene transfer experiment until the NIH RAC review process has been completed; both IBC and IRB approvals have been obtained; and all other applicable regulatory authorizations have been obtained.

7.3 Responsibilities of Principal Investigator Prior to and During Conduct of Research

7.3.1 Prior to Initiating Research the PI shall:

7.3.1.1 Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;

7.3.1.2 Instruct and train laboratory staff in the practices and techniques required to ensure safety, as well as in the procedures for dealing with accidents; (all such training is documented with dates and subject matter covered); and

7.3.1.3 Inform the laboratory staff of the reasons and provision for any precautionary medical practices in which they are advised or requested to participate, e.g., vaccination, serum collection, etc. The investigator is then required to complete a risk assessment questionnaire and verify that they have undergone an occupational health assessment through Howard University Employee Health Department.

7.3.2 During the Conduct of the Research the PI shall:

7.3.2.1 Supervise the performance of the laboratory staff to ensure that the required safety practices and techniques are followed as specified in the BSL-1 or BSL-2 checklist.

7.3.2.2 Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecules materials;

7.3.2.3 Ensure the integrity of the physical containment and the biological containment used in the protocol.

7.3.2.4 Comply with reporting requirements for human gene transfer experiments conducted in compliance with the *NIH Guidelines.*

7.3.2.5 Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the University Biosafety Officer and the IBC. The Greenhouse/Animal Facility Director, NIH/OBA, and other appropriate authorities may be contacted when applicable. (Reports to NIH/OBA shall be sent to the address specified in Section 3.2.2)

7.4 Specific Responsibilities of Principal Investigator with Regard to Submission of Information/Petitions to NIH OBA

7.4.1 The PI shall be responsible for submitting the following information/petitions to NIH OBA with regard to the PI's protocols, and unless otherwise specified, copies of all such information/petitions shall also be provided to the IBC:

7.4.1.1 Certification of new host-vector systems;

7.4.1.2 Petitions for proposed exemption from the *NIH Guidelines*, along with a copy of notice of the request for the exemption sent to the IBC;

7.4.1.3 Petition, with a copy of the IBC's concurrence, for approval to conduct experiments specified in *NIH Guidelines, Section III-A-1, Major Actions Under the NIH Guidelines and III-B, Experiments that Require NIH OBA and IBC Approval before Initiation;* (Add Hyperlink)

7.4.1.4 Petition for determination of containment for experiments requiring case-by-case review; and

7.4.1.5 Petitions for determination of containment for experiments not covered by the *NIH Guidelines*.

7.4.1.6 Certification that all aspects of *Appendix M* of the *NIH Guidelines* have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA, including provision of a letter signed by the PI on institutional letterhead acknowledging that the document being submitted to NIH OBA complies with requirements set forth in Appendix M of the *NIH Guidelines*.

7.5 Principal Investigator Reporting of Adverse Events and other Events to University Biosafety Officer:

7.5.1 The PI shall immediately report the occurrence of the following events in writing to the University Biosafety Officer who in turn shall report such events to the IBC Chair and determine further reporting requirements. (Subsequent amendments to the original report should also be communicated to the UBSO.) A form for reporting incidents should be generated to allow for uniform reporting to the UBSO:

7.5.1.1 Significant problems pertaining to any protocol subject to the IBC's jurisdiction, including problems pertaining to the operation and implementation of containment practices and procedures.

7.5.1.2 Violations of *NIH Guidelines* and Howard University IBC Policies and Procedures.

7.5.1.3 Any significant research-related accidents, injuries, exposures and illnesses. Any protocols involving human subjects shall be reported to the Howard University IRB; any protocols involving animal subjects shall be reported to the Howard University IACUC.

7.5.1.4 Any activities that do not comply with reporting requirements for human gene transfer experiments as set forth in the *NIH Guidelines*, Appendix M-I-C, Reporting Requirements, including but not limited to reporting requirements for Serious Adverse Events associated with the use of a gene transfer product. (Add Hyperlink)

7.5.2 Reporting: The PI shall then, in conjunction with the University Biosafety Officer, further report any of the events set forth in the section above as follows. (Subsequent amendments to the original report should also be communicated to these entities.):

7.5.2.1 To the IBC by letter to the Chair of the IBC -- immediately

7.5.2.2 To any Greenhouse/Animal Facility Director; -- immediately

7.5.2.3 To NIH/OBA-- within 30 days.

7.5.2.4 To any other appropriate authorities within legally prescribed times or 30 days, whichever is less.

SECTION 8: CONDITIONS OF APPROVAL

8.1 Lab Inspections: As a condition of approval for all IBC protocols, the lab(s) at which the protocols are to be carried out must have passed a lab inspection carried out by the University Biosafety Officer in accordance with criteria established by the IBC in conjunction with the Environmental Health and Safety Officer (EHSO) (Add Hyperlink). The University Biosafety Officer shall establish the intervals at which labs must be re-inspected, which shall be no less than annually. (For Laboratory Biosafety Level Criteria, see *NIH Guidelines, Appendix* G and *CDC/NIH Guidelines Section IV and Appendix A*) (Add Hyperlink)

8.2 Safety Training Course: The laboratory employee should successfully complete all health safety training courses offered by the University EHSO and annual refresher course. The safety training course is offered online through https://www.ehetraining.com/howarduniv (Unit Passcode: COM1002b).

8.3 Occupational Health: As a condition of approval for IBC protocols, the IBC may establish occupational health requirements that must be fulfilled by the personnel working on the protocol, including, but not limited to enrollment with Employee Health; obtaining certain immunizations (or signing declination statements, as appropriate); and obtaining certain health screening or testing.

SECTION 9: RECORD KEEPING

9.1 Records to be kept by ORRC: In addition to keeping IBC Committee meeting minutes, the ORRC shall keep copies of all correspondence received from or sent to researchers, regulatory agencies or other persons concerning any of the IBC's duties set forth hereunder. Records shall be kept in the Office of Regulatory Research Compliance (ORRC). All records shall be kept for the longest of any retention period required by the *NIH Guidelines*, or any other applicable federal, state, local or university requirement.

SECTION 10: REVIEW AND UPDATE OF THESE POLICIES AND PROCEDURES

10.1 On an annual basis, the University Biosafety Officer, in conjunction with a subcommittee of members of the IBC, shall review these Policies and Procedures to ensure that they are in conformance with current laws, regulations and Howard University policies and procedures, and to suggest for the IBC consideration any proposed improvements thereto. The IBC will consider and vote on all suggested modifications and additions to these Policies and Procedures at a regularly convened meeting of the IBC at which a quorum is present.

10.2 Amendments to the Policies and Procedures shall become effective upon the specified effective date set forth in the amendment.

10.3 The ORRC shall be responsible for providing notice of these Policies and Procedures, and any changes thereto, to the affected members of the research community at Howard.