

Georgia Institute of Technology Institutional Biosafety Committee

POLICIES AND PROCEDURES GOVERNING THE POSSESSION AND USE OF Recombinant DNA or Synthetic Nucleic Acid Molecules



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Revisions and Updates

April 2016:

- Updated review requirements for Section III-C per the April 27, 2016 version of the NIH Guidelines.

March 2016:

- Changed the approval length to three years for all protocols (exempt and non-exempt).

December 2015:

- Updated the statement from June 2015 (below) adding the following:
In the event that the Chair's own research is exempt, another qualified voting member of the committee will conduct the review and authorize approval.

June 2015:

- Clarified amendments to non-exempt registrations where materials being added with classification category remaining the same or lower (i.e., III-A, B, C, etc.) and biosafety level remaining the same or lower than initial approved registration, these amendments can be approved by IBC committee chair.

February 2015:

- Clarified section 5.2 Experiments that Require IBC Review as it relates to requirements for IBC approval involving transgenic rodents.

June 2014:

- Clarified chair review for exempt registration (BSL1 and BSL2)

April 2013:

- Clarified conflict of interest management for committee members. 2.2.A.
- Clarified that committee meetings are never conducted via email. 2.7.
- Noted that review and approval of Chair's exempt registration will be conducted by another qualified voting member. 5.3.
- Clarified that investigators may attend IBC meetings. 6.7.

August 2012:

- Updated the name of the Office of Research Compliance to the Office of Research Integrity Assurance

March 2012:

- Addition of Occupational Health Program. 6.7

September 2010:

- Clarification in Principal Investigator Eligibility Requirements. Appendix B.

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1.0 Introduction

1.1 National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules and Synthetic Nucleic Acid Molecules

The [*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*](#) are applicable to all research involving Recombinant DNA (rDNA) or Synthetic Nucleic Acid Molecules conducted within the United States at institutions that receive federal funding for research. The Georgia Institute of Technology must ensure that recombinant DNA or Synthetic Nucleic Acid research conducted at or sponsored by the Institute, irrespective of the funding source, if any, complies with the *NIH Guidelines* as a condition for NIH funding of such research at the Georgia Institute of Technology.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of NIH funds for any and all recombinant DNA research and Synthetic Nucleic Acid at the Georgia Institute of Technology, or a requirement for prior NIH approval of any or all recombinant DNA projects at the Georgia Institute of Technology. The NIH Guidelines are available at www4.od.nih.gov/oba/rdna.htm.

1.2 Scope of Coverage of These Policies and Procedures

All faculty members, staff employees, and students are included within the scope of these *Policies and Procedures Governing the Use of Recombinant DNA and Synthetic Nucleic Acid*, as are collaborators and visitors from other organizations working with Georgia Tech faculty members, staff employees, or students.

The Institutional Biosafety Committee has oversight of all activities involving rDNA, including those:

- Sponsored by the Georgia Institute of Technology or any other source, whether funded or not;
- Conducted by Georgia Institute of Technology faculty members, staff employees, and students, regardless of location of work, i.e., on campus or off-campus;
- Conducted using Georgia Institute of Technology's property, facilities, or non-public information; or
- And those activities conducted by non-Georgia Tech personnel.

See section 9.A.4. for additional guidance regarding Visiting Scholars.

1.3 Institutional Official

The Executive Vice President for Research is the Institutional Official for the Institutional Biosafety Committee. The EVPR appoints committee members, receives reports from the committee,

Definitions

For the purposes of these policies and procedures, the Georgia Institute of Technology Institutional Biosafety Committee applies the following definitions to *recombinant DNA* and *biological agents containing rDNA*.

Recombinant DNA

Recombinant DNA is defined as either:

- (a) 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
- (b) molecules that result from the replication of those described in (a) above.

In addition, synthetic DNA segments that 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.

Biological Agents Containing rDNA

Biological agents (containing rDNA) include those biological agents and biologically derived materials that present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment.

Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses);
- All human blood, blood products, tissues, and certain body fluids (excluding routine use of human blood and body fluid for clinical purposes);
- Cultured human or animal cells and potentially infectious agents these cells may contain;
- Clinical specimens; and
- Infected animals, their tissues and bodily fluids.

Use or possession of biological agents containing rDNA must be approved by the IBC. These activities may also require prior review and approval by the Institutional Biological Materials Safeguards Committee. If vertebrate laboratory animals are

being utilized in activities with biological agents containing rDNA, the Institutional Animal Care and Use Committee must also review the proposed work.

2.0 Institutional Biosafety Committee

2.1 Authority Granted to Institutional Biosafety Committee

Each institution conducting or sponsoring recombinant DNA research that is covered by the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* is responsible for ensuring that the research is conducted in full conformity with the provisions of the *NIH Guidelines*. Therefore, Georgia Institute of Technology established the Institutional Biosafety Committee that meets those requirements and that carries out the functions, as set forth in Section IV-B-2-a and Section IV-B-2-b of the *NIH Guidelines*.

In accordance with that authority, the Georgia Institute of Technology Institutional Biosafety Committee (IBC) has established and implemented these policies and procedures to provide for the safe and ethical conduct of research and other activities involving recombinant DNA and to facilitate compliance with the *NIH Guidelines* and other requirements.

Further, the IBC has authority to terminate approval of registration due to a researcher's failure or refusal to comply with these Policies and Procedures, the *NIH Guidelines*, the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), or other legal or institute requirements.

Furthermore, the Chair of the Institutional Biosafety Committee has a seat on the Institutional Council for Environmental Health & Safety and regularly collaborates with the Council on related matters affecting faculty members, staff employees, students, visitors and/or the surrounding community.

2.2 Committee Composition

Members of the committee are appointed by the Executive Vice President for Research who is also the Institutional Official for these matters. In accordance with the *NIH Guidelines*, the IBC is comprised of at least five members including one or more individuals with expertise in recombinant DNA technology and/or biological safety and/or physical containment. Some members are drawn from Georgia Tech faculty and staff, and at least two members are not affiliated with the Institute.

The committee collectively has experience and expertise in the possession and use of rDNA, including those biological agents containing rDNA. The committee has the capability to assess the safety of biological agents and to identify potential risks to public health or the environment. Consultants with specialized expertise may be invited from time to time to assist in a review, but such consultants shall not vote.

Members are expected to attend a majority of IBC meetings. Anticipated absences from an IBC meeting should be communicated to the IBC Chair and the Office of Research Integrity Assurance as soon as possible, preferably at least 24 hours before the meeting.

The IBC roster is posted on the Office of Research Integrity Assurance website at <http://www.researchintegrity.gatech.edu/IBC/boardmbrs.shtml>.

2.2.A Committee Member Conflict of Interest

IBC members with a conflict of interest (i.e., are acting as a research investigator, have financial interest in the project, are related to a member of the research team, etc.) in a particular project being reviewed shall be recused during the IBC's deliberations. They may be asked to provide clarifying information to the IBC, but they shall not vote, nor shall they be present when the vote is taken.

The Office of Research Integrity Assurance works closely with the Office of Conflict of Interest Management and with Sponsored Programs to ensure that such potential conflicts are identified and managed appropriately.

2.3 Specialized Expertise Requirements

2.3.A Required Expertise When Reviewing Recombinant DNA Research Involving Plants

The IBC shall include as a voting member at least one individual with expertise in plant, plant pathogen, or plant pest containment principles before reviewing and approving experiments with recombinant DNA involving plants.

2.3.B Required Expertise When Reviewing Recombinant DNA Research Involving Animals

The IBC shall include as a voting member at least one individual with expertise in animal containment principles before reviewing and approving experiments with recombinant DNA involving animals.

2.3.C Consultants

Should on occasion arise when the Georgia Tech Institutional Biosafety Committee lacks the specialized expertise necessary to review proposed work, suitable consultants will be retained to advise the committee and to assist in the review. The consultant may attend meetings but will not vote, nor will his/her attendance count toward quorum.

2.4 Chair of Institutional Biosafety Committee

A voting member of the committee, the Chair presides over the IBC meetings and, when necessary, designates a member of the committee to serve in his or her absence. In addition to providing committee leadership, the Chair performs an initial review of registration materials to ensure appropriate assignment of biosafety level as specified in *"Biosafety in Microbiological and Biomedical Laboratories"* and submission of a satisfactory Blood Borne Pathogen Plan and/or Chemical Hygiene Plan for the proposed activities. Research considered exempt will be reviewed and approved by the Chair, as may continuation registrations that contain no modifications and for which there have been no adverse events. The Chair informs the Office of Research Integrity Assurance regarding new and continuing registrations he or she approves.

2.5 Biosafety Officer

The Georgia Institute of Technology's Biosafety Officer is a voting member of the IBC and must approve any facilities prior to the commencement therein of any recombinant DNA work reviewed by the Institutional Biosafety Committee.

2.6 Education of IBC Members

New members of the IBC receive introductory training from the Office of Research Integrity Assurance and Environmental Health & Safety to ensure their familiar with the NIH Guidelines. IBC members shall receive updates at IBC meetings on changes affecting the possession and/or use of biohazardous materials involving rDNA. Other educational opportunities may include professional conferences and symposia.

2.7 Committee Meeting Schedule and Access

The Institutional Biosafety Committee meets as needed to review applications proposing use of recombinant DNA. A calendar of scheduled meetings is posted to

the IBC website at <http://www.researchintegrity.gatech.edu/>. The IBC Chair may call an emergency meeting of the IBC as necessary to address noncompliance or serious and/or unexpected events involving rDNA at the Georgia Institute of Technology. It is the general practice of the IBC to convene meetings attended by a quorum of members. However, in accordance with guidance from the Office of Biotechnology Activities, the use of teleconferencing allows for participation by board members who are unable to physically attend a meeting. On rare occasions, a meeting may be convened entirely by teleconference, should sufficiently time-sensitive or urgent matters arise. In these cases, the usual and customary procedures shall apply, i.e.: a quorum shall be established; votes shall be taken; and minutes shall be recorded. Meetings are never conducted via email.

Institutional Biosafety Committee meetings are open to the public except for the rare occasion when proprietary information will be discussed. Proprietary information includes, for example, trade secrets, confidential commercial information, and similar material. If public comments are made on Institutional Biosafety Committee's actions, the Institute shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Biotechnology Activities, National Institutes of Health.

2.8 Quorum

A simple majority of members constitutes a quorum. A quorum must be present to conduct business of the IBC requiring a vote. No proxy votes will be accepted for business conducted at a convened meeting.

The final approval or disapproval of registration of non-exempt rDNA requires a majority vote of IBC members present and voting.

If a quorum is lost at any time during the meeting, no further official action will be taken until a quorum is attained.

2.9 Registration Materials Distributed to Committee Members for Review

Prior to the meeting, each member shall have access to all registrations and related documentation to be reviewed at the meeting. Minutes of the previous meetings will also be distributed in advance.

2.10 Institutional Biosafety Committee Registration

The IBC is registered with the National Institutes of Health's Office of Biotechnology Activities (OBA). An annual report is filed with OBA and includes an updated list of

IBC members, the role of each member, and biosketches for each member. The OBA is notified of any changes in IBC membership when they occur.

3.0 Responsibilities of the Committee

3.1 On behalf of the institution, the Institutional Biosafety Committee is responsible for:

- A. Reviewing recombinant DNA research conducted at or sponsored by the institution 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*. This review shall include:
- independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research;
 - assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research;
 - ensuring that all aspects of [Appendix M](#) of the *NIH Guidelines* have been appropriately addressed by the Principal Investigator; and
 - ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.
- B. Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review.
- C. Lowering containment levels for certain experiments as specified in [Section III-D-2-a, Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems](#).
- D. Setting containment levels as specified in [Sections III-D-4-b, Experiments Involving Whole Animals](#), and [III-D-5, Experiments Involving Whole Plants](#).
- E. Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.
- F. Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

Note: The *Laboratory Safety Monograph* describes basic elements for developing specific procedures dealing with major spills of potentially hazardous materials in the laboratory, including information and references about decontamination and emergency plans. The NIH and the Centers for

Disease Control and Prevention are available to provide consultation and direct assistance, if necessary, as posted in the *Laboratory Safety Monograph*. The institution shall cooperate with the state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.

G. 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/OBA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

H. The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the RAC when required) establishes the containment requirement.

I. Performing such other functions as may be delegated to the Institutional Biosafety Committee under [Section IV-B-2](#) of the *NIH Guidelines*.

J. The IBC shall provide initial and on-going education to faculty on the use of rDNA and biological agents containing rDNA. Each faculty member using or possessing, or planning to use or possess, these biological agents shall be informed by the Office of Research Integrity Assurance that these IBC Policies and Procedures are posted to the Institutional Biosafety Committee website. Hard copies will be made available upon request. The *NIH Guidelines for Research Involving Recombinant DNA Molecules* are also linked from that site. From time to time, symposia will be held on the campus for faculty to receive introductory and advanced guidance on working safely with rDNA.

4.0 Administrative Support for the Institutional Biosafety Committee

4.1 Office of Research Integrity Assurance

The IBC is supported and administered by the Office of Research Integrity Assurance (ORIA), which has offices in the Research Administration Building (RAB). The Committee customarily meets in the RAB Board Room.

4.2 Responsibilities of the Office of Research Integrity Assurance

The Office of Research Integrity Assurance is responsible for maintaining Georgia Institute of Technology's registration with the NIH Office of Biotechnology Activities (OBA); reporting to OBA at least annually; updating the committee roster and biosketches; and facilitating the Institute's responsibilities for administrative, oversight, review and reporting functions. The Office of Research Integrity Assurance accepts, screens, and tracks rDNA registrations and, in collaboration with the IBC Chair, coordinates the committee's activities.

The Office of Research Integrity Assurance has further responsibility for maintaining the official records of the Institutional Biosafety Committee, including correspondence with the Office of Biotechnology Activities, meeting minutes, rDNA registration records, and committee rosters and biosketches. The website for the Institutional Biosafety Committee, located at <http://www.researchintegrity.gatech.edu/IBC>, is maintained by this office.

4.3 Meeting Minutes

Minutes of IBC meetings shall be taken by a Research Associate from the Office of Research Integrity Assurance and shall, at a minimum, document the date and place of the meeting; attendees; whether minutes of the prior meeting were approved; whether and why the meeting was open or closed; all major motions and major points of order; and whether motions were approved. Minutes shall be recorded in sufficient detail to serve as a record for major points of discussion and the committee's rationale for particular decisions, thus documenting that the IBC fulfilled its review and responsibilities as outlined in Section IV-B-2-b of the *NIH Guidelines*.

Particular care shall be taken to record deliberation relative to the assessment of the containment level required, the facilities, and the procedures, practices, and training of personnel involved in rDNA research. When appropriate, the minutes will include agent characteristics (virulence, pathogenicity, environmental stability); types of manipulations planned; sources of the inserted DNA sequences (species); nature of the inserted DNA sequences (structural gene, oncogene); host(s) and vector(s) to be used; whether an attempt will be made to obtain expression of a foreign gene and, if so, the protein that will be produced; containment conditions to be implemented; and applicable section(s) of the *NIH Guidelines*.

Minutes shall also document IBC actions taken on each registration reviewed; votes on actions; required modifications for IBC approval; and notation of members not present during deliberations. Members who are recused will be recorded, and the basis for disapproving any proposed registration, continuation, or amendment shall be recorded.

4.4 Access to Minutes and Other Official Records of the IBC

Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the Institute is required to make available to the public. Occasionally, it will be necessary to redact certain private, proprietary information from documents requested by the public. In those rare cases, it is the intention of Georgia Institute of Technology to redact only that information which truly is private or proprietary in nature and not to obfuscate the records. For example, IBC members' home addresses and telephone numbers would be redacted, should they appear in the roster or other records; their names would not be redacted from a list of attendees at committee meetings.

4.5 Records Retention

In accordance with the University System of Georgia's Board of Regents Records Retention Guidelines, records of the Institutional Biosafety Committee shall be retained by the Office of Research Integrity Assurance.

Meeting minutes shall be retained for at least five years. Records relating to research shall be retained at least three years after completion of research. All other records will be retained for at least three years; these include records of continuing review, registrations and attachments thereto, IBC rosters and biographical sketches.

5.0 IBC Registration Review Process

5.1 Lead Time for Review

Review of registrations, whether exempt or non-exempt, may take three months or more. Review periods for non-exempt registrations requiring federal submission can take longer than a year.

5.2 Experiments that Require IBC Review

IBC approval must be obtained prior to obtaining or working with rDNA.

For research involving transgenic rodents, experiments that fall under either of the following may not require an IBC registration.

- Section III-F-8 of the NIH Guidelines, specifically Appendix C-VII (the purchase or transfer of transgenic rodents)
- Section III-F-8 of the NIH Guidelines, specifically Appendix C-VIII (the generation of BL1 transgenic rodents via breeding)

Work with these materials is described by the PI in their IACUC registration and reviewed by the Biosafety Officer during the IACUC registration review process. If, during the review of the IACUC registration, the Biosafety Officer identifies any additional questions or experiments that fall outside of these two exemptions, the PI will be notified by the Biosafety Officer that they are required to submit an IBC registration for review and approval.

5.3 Review of Exempt Registrations by Chair or Designee

Faculty members applying for Exempt registrations must complete the “*Notice of Intent to Possess or Work with Recombinant DNA Molecules or Synthetic Nucleic Acid Molecules*” and “*Biological Hygiene Plan Template for Registrations Involving rDNA*” and submit it to the IBC for approval. The IBC Chair is authorized to review and approve registrations involving rDNA in a risk category of RG-1 and RG-2 and/or that require containment at a level of BSL-1 and BSL-2. The Chair may, at his/her discretion, forward these registrations to another IBC member for secondary review, or assign another qualified member of the Institutional Biosafety Committee to conduct the review and issue approval.

In the event that the Chair’s own research is exempt, another qualified voting member of the committee will conduct the review and authorize approval.

5.4 Review of Non-Exempt Registrations

Faculty members applying for Non-Exempt registrations must complete the “*Notice of Intent to Possess or Work with Recombinant DNA Molecules or Synthetic Nucleic Acid Molecules*” and “*Biological Hygiene Plan Template for Registrations Involving rDNA*” and submit it to the IBC for approval. Any *non-exempt activity involving rDNA must be discussed at a meeting of the Board wherein a full quorum is present and a vote shall be taken whether to:

- A. Approve the registration without modification;
- B. Approve the registration subject to modification;
 - 1. In these cases, the modification(s) must be satisfactorily made before a letter of approval will be issued.
 - 2. Approvals will never be contingent upon a required modification.
- C. Table the decision pending additional information; or
- D. Disapprove the registration.
 - 1. In the event that the full board determines to disapprove the work, the applicant will be offered an opportunity to meet with the full board to resolve issues of concern.
 - 2. A subset of board members may meet separately with the applicant to assist in preparing modifications to secure approval.

* When submitting an amendment to non-exempt registration where materials being added are of the same or lower classification category (i.e., III-A, B, C, etc.) and the biosafety level is same or lower than initial approved registration, this amendment can be approved by IBC chair. In the event that the Chair’s own research is non-exempt or there is conflict of interest, another qualified voting member of the committee will conduct the review and authorize approval.

5.5 Notice of IBC Action

The Office of Research Integrity Assurance or the Chair of the IBC shall provide written notification of the Chair’s/IBC’s decision to the faculty member. This notification may be by official email or letter.

5.6 Duration of Approval

As of February 24, 2016, all IBC registrations are granted approval for three years. Prior to this date, exempt registrations were approved for five years; non-exempt registrations were approved for one to three years, depending on several factors.

Protocols approved prior to February 24, 2016 will fall to the new, three year approval cycle when they expire.

5.7 Revisions to Approved Registrations

Faculty members wanting to revise a currently approved registration must complete the “*Notice of Intent to Possess or Work with Recombinant DNA Molecules or Synthetic Nucleic Acid Molecules*” and submit it to the IBC for approval. Changes involving modification of biological agents containing rDNA, significant procedure changes (including change of the responsible faculty member), change in study location, or changes that increase the risk of the project and/or the biosafety level must be approved by the IBC prior to implementing the changes. If changes are sufficiently substantive, a new registration may be required. Minor amendments such as addition of funding may be added and approved by ORIA.

5.8 Notice of Termination

Faculty members must complete “rDNA Notice of Termination,” and file it with the Office of Research Integrity Assurance when a project is completed or no longer active, or when the rDNA or biohazardous material containing rDNA is properly disposed of or no longer in the possession of the faculty member.

6.0 Principal Investigator's Responsibility

Only Georgia Institute of Technology academic track or research track faculty members are eligible to hold the title of Principal Investigator for the purposes of possessing or using rDNA or biological agents containing rDNA. For research purposes, all non-faculty personnel and students are classified as co-investigators. *See Appendix B of these policies regarding eligibility for status as Principal Investigator.*

6.1 General Responsibilities of the Principal Investigator Possessing or Using rDNA or Biological Agents Containing rDNA

In addition to complying with the *NIH Guidelines*, Principal Investigators planning to utilize biological agents containing rDNA shall secure prior approval from the Institutional Biological Materials Safeguards Committee. Additionally, those Principal Investigators shall consult the Centers for Disease Control's *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, which specifies additional safety requirements. Further guidance may be provided by Environmental Health & Safety.

On behalf of the institution, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of rDNA research or any other use. As part of this general responsibility, the Principal Investigator shall:

- a. Initiate or modify no rDNA research which requires Institutional Biosafety Committee approval until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the *NIH Guidelines*;
- b. Determine whether experiments are covered by [Section III-E](#), *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that the appropriate procedures are followed;
- c. Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax);

- d. Report any new information bearing on the *NIH Guidelines* to the Institutional Biosafety Committee and to NIH/OBA (reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax));
- e. Be adequately trained in good microbiological techniques, where appropriate, or other techniques related to handling rDNA or biological agents containing rDNA;
- f. Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination; and
- g. Comply with shipping requirements for recombinant DNA molecules.

6.2 Submissions by the Principal Investigator to the Institutional Biosafety Committee

Any faculty member who desires to possess or use recombinant DNA subject to the *NIH Guidelines* must submit the “IBC rDNA Registration Form” and “Biological Hygiene Plan Template for Registrations Involving rDNA” to the Office of Research Integrity Assurance with sufficient lead time for review.

The Principal Investigator shall:

- a. Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;
- b. Select appropriate microbiological practices and laboratory techniques to be used for the research;
- c. Submit the initial research registration and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections [III-A](#), [III-B](#), [III-C](#), [III-D](#), or [III-E](#) (*Experiments Covered by the NIH Guidelines*), to the Institutional Biosafety Committee for review and approval or disapproval;
 - 1. The Principal Investigator shall complete the [IBC registration form](#), sign it, and save it as a PDF file. Email the registration form to biosafety@gatech.edu (Office of Research Integrity Assurance).
 - 2. To the email, attach a Biological Hygiene Plan or and the related

grant or contract pages. Model plans are posted to the web and may be accessed at <http://www.researchintegrity.gatech.edu/IBC/forms.shtml>.

3. The Principal Investigator's department head or Chair should also sign the registration form; in lieu of that signature, the department head or Chair may send an email to biosafety@gatech.edu stating something like, "*I have reviewed the referenced rDNA registration and concur with its submission to the Institutional Biosafety Committee for review.*"

- d. The Principal Investigator shall remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

6.3 Responsibilities of the Principal Investigator Prior to Initiating Research

The Principal Investigator shall:

- a. Make available to all laboratory staff the registrations that describe the potential biohazards and the precautions to be taken;
- b. Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
- c. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection); and
- d. Secure approval from the Institutional Biosafety Committee before initiating any activities involving rDNA.

6.4 Responsibilities of the Principal Investigator during the Conduct of the Research

The Principal Investigator shall:

- a. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
- b. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Institutional Biosafety Committee, Office of Research Integrity Assurance and, where applicable to the Biological Safety Officer, Animal Facility Director,

NIH/OBA and other appropriate authorities.

Reports to NIH/OBA shall be sent to:
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750
MSC 7985
Bethesda, MD 20892-7985 (20817 for non-USPS mail)
301-496-9838, 301-496-9839 (fax)

- c. Events requiring emergency response (ambulance, police, biohazard clean up) shall be reported immediately to the appropriate authority. *As soon as possible, but within 14 days*, all adverse events, illness, or significant accidents leading to, or potentially leading to illness, or that are environmentally dangerous to humans and/or animals shall be reported to the Office of Research Integrity Assurance and the Institutional Biosafety Committee. The Adverse Biosafety Event Report Form is posted at <http://www.researchintegrity.gatech.edu/IBC/forms.shtml> and may be used to facilitate reporting to the Institutional Biosafety Committee and the Office of Research Integrity Assurance.

Notify the Office of Research Integrity Assurance by telephone:

404 / 894-6949 404 / 894-6944 404 / 894-6942

404 / 385-2083 404 / 385-7316 FAX: 404 / 385-2081

- d. Correct work errors and conditions that may result in the release of recombinant DNA materials; and
- e. Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).
- f. Comply with reporting requirements for human gene transfer experiments conducted in compliance with the *NIH Guidelines* (see *NIH Guidelines Appendix M-I-C, Reporting Requirements*).

6.5 Additional Responsibilities of the Principal Investigator

- a. Limit or restrict access to the laboratory when work with biological agents containing rDNA is in progress; this includes making a determination of who may be at increased risk.

- b. Establish policies and procedures to limit access exclusively to those individuals who have been advised of the potential hazards and meet specific entry requirements.
- c. Ensure that laboratory personnel are offered, at no cost, appropriate immunizations or tests for the infectious agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine, tuberculosis skin testing). Contact the Office of Environmental Health & Safety for assistance.
- d. Select and provide appropriate personal protective equipment required for work with hazardous materials. Contact the Office of Environmental Health & Safety for assistance.
- e. Ensure that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures, and that personnel receive annual updates or additional training as necessary for procedural or policy changes.
- f. Develop standard operating procedures incorporating biosafety procedures or a biosafety manual prepared specifically for the laboratory; advise personnel of special hazards; and require them to read and follow instructions on practices and procedures.
- g. Reporting Serious Adverse Events in Human *in vivo* Gene Transfer Trials: There are no human gene transfer trials underway or contemplated at Georgia Tech. The NIH Office of Biotechnology Activities (OBA) has posted related guidance on its website at www4.od.nih.gov/oba.

6.6 Requirement for Completion of rDNA Training through EHS

In accordance with the *NIH Guidelines, Section IV-B-1-h1*, the Institutional Biosafety Committee requires that all personnel named in rDNA registrations complete certain training. New rDNA registrations, revision requests, and continuing review applications will be screened by the Office of Research Integrity Assurance to ensure that all personnel have completed the training requirement before letters of approval will be issued.

Registration for the 1½ hour course, presented by Environmental Health& Safety (EHS), may be accomplished online at <http://www.orgdev.gatech.edu/>. There is no charge for the course. Contact EHS at 404 / 894-6120 for more information regarding registration and scheduling.

6.7 Requirement for Enrollment in Occupational Health Program through EHS

The Office of Environmental Health & Safety administers the GT Occupational Health Program for employees and certain students who may be exposed to health risks as part of their jobs or research activities at GT. All individuals working with

Non-Exempt rDNA must enroll in the program prior to working with rDNA. For more information, please visit the EH&S website at:

<http://www.ehs.gatech.edu/occupational/>. New Non-Exempt rDNA registrations and amendment requests will be screened by the Office of Research Integrity Assurance to ensure that all personnel have enrolled in the Occupational Health Program before letters of approval will be issued.

6.8 Attend Institutional Biosafety Committee Meeting

Investigators are welcome to attend committee meetings, particularly when their studies will be reviewed. While investigators must leave the room during voting, they may present their studies and take questions from the committee.

7.0 Categories of Activities Involving Recombinant DNA

7.1 rDNA Experiments Subject to the NIH Guidelines

It is the policy of the Georgia Institute of Technology's Institutional Biosafety Committee that all activities involving recombinant DNA must be reviewed and approved prior to initiation.

The following paragraphs summarize recombinant DNA experiments covered by the *NIH Guidelines*, including those that require review by the NIH's Recombinant DNA Advisory Committee. Refer directly to the *NIH Guidelines* for a more detailed description of experiments and specific requirements:

- a. Experiments Requiring IBC approval, RAC review, and NIH Approval (NIH Section III-A)—Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that do not acquire the trait naturally, where such acquisition could compromise the use of the drug to control disease in humans, veterinary medicine, or agriculture, are included in this category. These experiments are considered “Major Action” and require review by the Recombinant DNA Advisory Committee (RAC) at NIH and specific approval by NIH prior to initiation. In addition, approval by the IBC is required *prior to initiation* of the experiment.
- b. Experiments Requiring IBC and NIH Approval (NIH Section III-B)—Experiments in this category include the cloning of genes encoding toxic molecules with an LD50 for vertebrates less than or equal to 100 ng/kg. This includes microbial toxins such as botulinum toxins, tetanus toxins, and diphtheria toxin. These experiments cannot be initiated without submission of relevant information on the proposed experiment to the Office of Biotechnology (OBA) at NIH. IBC approval is required *prior to initiation* of the experiments.
- c. Experiments requiring IBC Approval, Institutional Review Board (IRB) Approval and RAC Review (in some cases), with NIH Registration Prior to Initiation (NIH Section III-C)—These experiments involve the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into humans (human gene transfer).

During institutional review, if the IBC or IRB determines that a protocol would significantly benefit from RAC review, and the protocol has been determined to meet one or more of the following criteria, it will be submitted to the NIH for RAC review:

- The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; or
- The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or
- The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies involved to evaluate the protocol rigorously.

The PI is responsible for submitting documentation regarding a proposed human gene transfer protocol to the GT IBC/IRB and to the NIH as outlined in the NIH Guidelines. Documentation submitted to the NIH shall also include written assessments originating from the GT oversight bodies involved in the review as to whether RAC review is warranted.

d. Experiments Requiring IBC Approval (NIH Section III-D)—This category includes whole animal or plant experiments, as well as experiments involving DNA from agents in a risk category of RG-2 to RG-4. These experiments must be approved by the IBC *prior to initiation*.

e. Experiments Using Recombinant DNA from Risk Group 1 Agents (NIH Section III-E)—Experiments in this category are low risk and can be conducted using BSL-1 containment. Examples include experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes. IBC approval is required *prior to initiation* of the experiments.

f. NIH Exempt Experiments—The Georgia Institute of Technology requires registration with the IBC for exempt projects, as listed in Section III-F of the *NIH Guidelines*. Refer to Appendix A for a list of recombinant DNA molecules that are exempt from the *NIH Guidelines*.

In accordance with the *NIH Guidelines*, the Institutional Biosafety Committee has established two categories of registration: Exempt (3 year approval period) and Non-Exempt (3 year approval period).

7.2 Categories of Registration

The following table is a graphical representation of the exempt and non-exempt review categories and the review process at Georgia Tech.

Category	Covers	Coordination with EH&S or Research Security Required?	Length of Approval Period	Georgia Tech review handled by:
Exempt	<ul style="list-style-type: none"> rDNA containing less than 1/2 of a eukaryotic viral genome propagated in cell culture (with the exception of DNA from Risk Group 3, 4 or restricted agents) rDNA work involving <10 liters of <i>E. coli</i> K12, <i>S. cerevisiae</i>, and <i>B. subtilis</i> host-vector systems (with the exception of DNA from Risk Group 3, 4, or restricted agents) All experiments not specified on this sheet 	EH&S	3 Years. New registration required after 3 rd year.	Chair as Primary Reviewer; send to Secondary Reviewer at Chair's discretion; or review may be accomplished by Chair's designee
Non-Exempt	<ul style="list-style-type: none"> Deliberate transfer of a drug trait to a microorganism not known to acquire it naturally (if it could compromise the use of the drug to control disease agents in humans, animal or agriculture) Formation of recombinant DNA encoding molecules lethal to vertebrates at an LD 50 of <100 ug/kg body weight Human gene transfer experiments <i>Experiments using as vectors ≤2/3 of the genome of a eukaryotic virus, free of helper virus*</i> <i>BL1 transgenic or knockout rodent experiments. (Note: the purchase of transgenic rodents for BL1 experiments is exempt from registration)*</i> Experiments using Risk Group (RG) 2, RG3, RG4, or Restricted Agents as host-vector systems Experiments in which DNA from Risk Group (RG) 2, RG3, RG4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems 	EH&S Research Security for BSL-3, -4	3 Years. New registration required after 3 rd year.	Full Board of IBC, at convened meeting

	<ul style="list-style-type: none">• Experiments using more than 2/3 of the genome of infectious animal or plant viruses or defective viruses grown in the presence of helper virus• Recombinant DNA experiments involving whole animals or plants• Large scale DNA project (>10 liters of culture combined)			
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8.0 Guidance Relative to Risk Assessment and Selection of Appropriate Safeguards

The following guidance is provided to assist Principal Investigators in classifying proposed rDNA activities on the basis of perceived risk to humans. The risk classification determines the required biological and physical containment level. The IBC will make the final decision as to the level of risk and appropriate biological and physical containment levels for biological agents containing rDNA and subject to its review and approval.

There are currently no laboratories at the Georgia Institute of Technology certified to conduct Biosafety Level 4 (BSL-4) research.

8.1 Risk Groups

The faculty member registering to possess and/or use biological agents containing rDNA must make an initial risk assessment based on the Risk Group (RG) of the agent that will be used to convey rDNA in order to establish the biosafety level. *Risk* implies the probability that harm, injury, or disease will occur. The primary focus of risk assessment is to prevent or reduce the risk of laboratory-associated infections. Once a risk group determination has been made from among Risk Groups 1 to 4, this information is used to set the appropriate biosafety level (BSL-1 to BSL-4) for the biohazardous agents containing rDNA. Agents are classified into four Risk Groups according to their relative pathogenicity for healthy adult humans as follows:

- a. Risk Group 1 (RG-1) agents are not associated with disease in healthy adult humans.
- b. Risk Group 2 (RG-2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
- c. Risk Group 3 (RG-3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.
- d. Risk Group 4 (RG-4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

8.2 Factors to Consider When Conducting Risk Assessment

Risk assessment is one component in assigning the appropriate biosafety level to reduce the risk of exposure to an agent by employees and the population in general. The following factors should be considered when conducting a risk assessment and determining the level of containment:

- a. Pathogenicity of the biohazardous material(s)—Consideration should include disease incidence and severity.
- b. Route of transmission (e.g., parenteral, airborne, by ingestion)—When planning to work with a relatively uncharacterized agent with an uncertain mode of transmission, the potential for aerosol transmission should be strongly considered.
- c. Agent stability—Should include a consideration of factors such as desiccation, exposure to sunlight or ultraviolet light, or exposure to chemical disinfectants,
- d. Infectious dose of the agent and communicability—Consideration should include the range from the healthiest immunized worker to the worker with lesser resistance.
- e. Concentration—Include consideration of the milieu containing the organism (e.g., solid tissue, viscous blood or sputum, liquid medium) and the activity planned.
- f. Origin of the biohazardous material(s)—Consideration should include factors such as geographic location, host, and nature of the source.
- g. Availability of data from animal studies—This information may be useful in the risk assessment process in the absence of human data.
- h. Established availability of immunization/vaccine or treatment—The unavailability of immunization/vaccine or treatment may impact the risk involved in the use of biohazardous material(s).
- i. Gene product effects, such as toxicity, physiological activity, and allergenicity.

8.3 Biosafety Level (Biological and Physical Containment Level)

The biosafety level describes the degree of physical containment required to confine biohazardous materials containing rDNA and to reduce the potential for exposure of laboratory workers, persons outside the laboratory, and the environment. The biosafety level may be equivalent to the Risk Group classification of the agent or it may be raised or lowered based on the evaluation of risk factors. If you have any questions regarding the risk assessment or appropriate containment level, you may consult with the Institutional Biosafety Committee, which makes the final determination of the appropriate biosafety level.

The following is a general description of biosafety levels:

- a. Biosafety Level 1 (BSL-1)—The BSL-1 containment level is suitable for work involving biohazardous materials of a minimal potential hazard to laboratory personnel and the environment.
- b. Biosafety Level 2 (BSL-2)—The BSL-2 containment level is suitable for work involving biohazardous materials of a moderate potential hazard to personnel and the environment. The biohazardous materials are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often reliable.
- c. Biosafety Level 3 (BSL-3)—The BSL-3 containment level is suitable for work involving biohazardous materials that are associated with human disease which may have serious or lethal consequences or that has a potential for aerosol transmission.
- d. Biosafety Level 4 (BSL-4)—There is no laboratory at Georgia Tech that has been certified as BSL-4. Therefore, projects involving biohazardous agents requiring BSL-4 cannot be conducted at Georgia Tech at this time and will not be approved by the IBC.

8.4 Additional Resources for Determining Biosafety Levels

Various resources are available when assessing containment levels, including [Appendices B, G, I, K, P, and Q of the NIH Guidelines, the Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) published by the CDC and NIH, [the American Biological Safety Association's Risk Group Classification for Infectious Agents, Georgia Tech's Office of Environmental Health and Safety](#), institutional policies and procedures, and expert personnel. There are also biosafety levels for work with infectious agents in vertebrate animals. For assistance with animal biosafety levels, consult the [BMBL](#).

9.0 Review Requirements for rDNA Activities Taking Place at Another Institution or Being Conducted at Ga Tech by Visitor

A. Off-Campus Activities Requiring IBC Approval

1. Georgia Tech Personnel Working at Off-Campus Site with OBA-Registration

In cases where the Georgia Institute of Technology faculty member, staff employee, or student is involved in work located at an off-campus site with an Office of Biotechnology Activities (OBA)-registered Biosafety Committee, the Georgia Tech IBC may accept an approval statement from that other Biosafety Committee, in lieu of performing a duplicate review. The Georgia Institute of Technology IBC must be allowed to assess whether or not a separate registration should be submitted to the Georgia Tech IBC under these circumstances. The committee reserves the right to request additional information and to require modifications. Non-substantive issues will not be raised.

Georgia Tech investigators in this situation must provide a copy of the registration submitted to the other reviewing institution, a copy of that institution's approval letter, and, if externally funded, a copy of the funding proposal statement of work. The Georgia Tech member's department head must send an email or memo to the Office of Research Integrity Assurance (biosafety@gatech.edu) in which he/she states something like, "*I have reviewed this research registration and concur with its submission to the X institution for review.*" The investigator must also submit the signed and dated signature page from the Georgia Tech IBC registration form.

2. Georgia Tech Personnel Working at Off-Campus Site with Non-OBA-Registered Biosafety Committee

In cases where the IBC work is performed off-campus at a facility with a non-OBA-registered Biosafety Committee, the Georgia Tech faculty member, staff employee, or student shall provide for the Georgia Tech IBC's consideration a copy of the biosafety registration submitted to that institution. If the Georgia Tech member has direct involvement with the off-campus work at a location

with no OBA-registered Biosafety Committee, the current GT IBC registration process must be followed.

The Georgia Tech member's department head must send an email or memo to the Office of Research Integrity Assurance (biosafety@gatech.edu) in which he/she states something like, *"I have reviewed this research registration and concur with its submission to the Institutional Biosafety Committee for review."* The Georgia Tech member must also submit the signed/dated signature page from the Georgia Tech IBC registration form.

3. Non-Georgia Tech Personnel Working at Off-Campus Site with OBA-Registration When There Is a Relationship Due to Funding or Other Involvement

In cases where all IBC-relevant work is performed off-campus by non-Georgia Tech personnel and under an OBA-registered Biosafety Committee registration approval, and where there is a relationship to Georgia Tech due to funding or other involvement, the Georgia Tech faculty member, staff employee, or student shall provide for the Georgia Tech IBC's consideration a copy of that institution's biosafety registration and letter of approval. The committee reserves the right to request additional information and to require modifications, however unlikely.

In the event there is a subcontract between Georgia Tech and the other institution, these requirements shall be incorporated into the subcontract.

4. Non-Georgia Tech Personnel Participating in rDNA Registrations at Georgia Tech

Georgia Tech seeks to foster collaborative relationships with researchers and scientists who visit the Institute to participate in research projects at Georgia Tech. In order to ensure the appropriate proper protections for those visitors and for Georgia Tech faculty and staff, this policy has been developed: *Prior to actively participating in activities involving rDNA at Georgia Tech, all non-Georgia Tech personnel must be appointed as Visiting Scholars by the Office of Human Resources. They must also either be named in the original registration application or added by registration amendment prior to participating in the rDNA activities. Visiting Scholars may use the title of co-investigator.*

The visitor's current CV must be submitted to the Office of Research Integrity Assurance at the time that the original registration or amendment is submitted.

10.0 Coordination with Other Compliance Committees and Offices

Coordination with other compliance committees may be necessary, as proposed research may require review by the Institutional Review Board (IRB)¹, the Institutional Animal Care & Use Committee (IACUC)², or the Biological Materials Safeguards Committee³. It is the responsibility of the Principal Investigator to seek the appropriate reviews. The Office of Research Integrity Assurance will also refer registrations to these committees, as warranted. These committee reviews occur in parallel under the coordination of the Office of Research Integrity Assurance.

IRB and IACUC letters of approval will not be issued by the Office of Research Integrity Assurance until outstanding IBC issues are resolved.

¹ The Institutional Review Board is administered by the Office of Research Integrity Assurance.

² The Institutional Animal Care & Use Committee is administered by the Office of Research Integrity Assurance.

³ The Biological Materials Safeguards Committee is administered through Environmental Health & Safety.

11.0 Office of Sponsored Programs Requirement for IBC Review Prior to Submission of Funding Proposal

It is the policy of the Georgia Institute of Technology's Office of Sponsored Programs (OSP) that funding proposals requiring related review by the Institutional Biosafety Committee must be supported by a letter of approval from IBC.

11.1 Temporary Deferral of IBC Approval

If IBC review and approval have not been accomplished prior to submission of the funding proposal to the potential sponsor, the Contracting Officer in the Office of Sponsored Programs may request a deferral on behalf of the Principal Investigator. The deferral allows submission of the IBC registration for review *after* submission of the funding proposal and *before* an award is made.

A deferral may be granted only by the Associate VP for Research or by the OSP Director or Associate Director. Should a deferral be granted, the Principal Investigator is to be advised by the Contracting Officer to ensure that the IBC registration is submitted in time for review to be accomplished prior to funding. Should no IBC registration be received by the Office of Research Integrity Assurance by the time funding arrives, the Office of Sponsored Programs may decline the award.

Appendices

Appendix A	Experiments Exempt from Recombinant DNA Guidelines
Appendix B	Principal Investigator Eligibility Requirements
Appendix C	Allegations of Noncompliance

Appendix A Experiments Exempt from Recombinant DNA Guidelines

The following recombinant DNA molecules are exempt from the *NIH Guidelines*, and registration with the Institutional Biosafety Committee is required, but such activities will usually be approved as “Exempt”:

Section III-F-1. Those that are not in organisms or viruses.

Section III-F-2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

Section III-F-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.

Section III-F-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).

Section III-F-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 [Section IV-C-1-b-\(1\)-\(c\)](#), *Major Actions*). See [Appendices A-I](#) through A-VI, *Exemptions Under Section III-F-5--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

Section III-F-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 [Appendix C](#), *Exemptions under Section III-F-6* for other classes of experiments which are exempt from the *NIH Guidelines*.

Appendix B Principal Investigator Eligibility Requirements

The term *Principal Investigator* refers to the single individual who shall have full and final responsibility for the conduct of a research study involving biosafety registrations. The designation of Principal Investigator is for assignment of responsibility in the context of IBC approval only, and not for any other purposes (e.g. Authorship, Intellectual property). Therefore, for IBC purposes, the title of Principal Investigator will be authorized in the following cases:

- The individual is a member of the General Faculty;
- The individual is a Post-doctoral fellow who is employed by the Institute; or
- The individual holds the title of “Adjunct” and has received an exception letter from the Executive Vice President for Research.

Definitions

- **Principal Investigator:** This title identifies the individual responsible for the conduct of the study. This responsibility includes the conduct of the study, all administrative aspects, and the study’s adherence to relevant policies and regulations (institutional, state and federal).
- **Co-Principal Investigator:** This designation refers to individuals who share the responsibility for the study with the Principal Investigator and therefore requires the same qualifications as the PI.
- **Co-Investigator:** This title designates key personnel for a project, but without the oversight responsibility of a Principal Investigator. Individuals do not need to meet the qualifications of PI under this policy to be named a Co-Investigator, but should be considered as key personnel on the project. For example, a Master's or PhD student submitting his or her dissertation for IBC approval may be listed as the Co-investigator. The thesis or dissertation chair/advisor should be listed as the PI on the IBC registration. An undergraduate student working on a senior thesis or other class research project should list him- or herself as the Co-investigator. The faculty member who is advising the student on the research should be listed as the PI for IBC purposes.
- **Authorship:** The title of Principal Investigator is a designation of institutional responsibility for the conduct of an IBC reviewed study. Therefore, the title does not necessarily represent principal authorship on subsequent papers. Authorship is a separate consideration that should be agreed upon by all members of the research team. It is important that authorship be appropriately attributed.

Role of Graduate and Undergraduate Students in Activities involving rDNA

Only those persons meeting the definition of Principal Investigator, defined herein, may serve as a Principal Investigator (PI) or co-PI on an IBC registration. Graduate and undergraduate students may be named as Co-Investigator, as this title

designates key personnel but does not have the oversight responsibilities of a Principal Investigator or co-PI.

Exceptions

Exceptions to the general eligibility requirements will be considered upon submission of a written request to the Executive Vice President for Research. The request should justify why the individual should qualify for the role of Principal Investigator and must be signed by the appropriate administrator (Chair/Dean/Director/Department Head). Upon approval, a copy of the exception, signed by the Executive Vice President for Research, should be forwarded to the Office of Research Integrity Assurance, along with the IBC registration.

Appendix C Allegations of Noncompliance

In accordance with the *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules*, the IBC shall report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the Institutional Official and NIH/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator. In that case, the Principal Investigator shall provide a copy of such written notice to the Office of Research Integrity Assurance at the time the report is made to OBA.

Reports to NIH/OBA shall be sent to the following address:

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985 (20817 for non-USPS mail)
Phone: 301-496-9838
Fax: 301-496-9839

The Institutional Biosafety Committee has the authority to suspend or terminate approval of any registration due to failure or refusal by the faculty member, staff employee, student, or visitor/collaborator to comply with these procedures or the *NIH Guidelines*, the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), requirements of the Office of Environmental Health and Safety, or other legal or institute requirements.

The Chair shall review all allegations of noncompliance with the Office of Research Integrity Assurance and present them to the IBC for appropriate corrective action, which may include suspension of the registration for possession and/or use of biohazardous materials and possible referral to the appropriate institute body if scholarly misconduct is alleged or apparent.