Institutional Biosafety Committee

Policies and Procedures Governing the Possession and Use of Recombinant or Synthetic Nucleic Acid Molecules

February 2026

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Revisions and Updates

February 2026:
Updated links, office contacts, acronyms, formatting, form/system references
Clarification of review process for amendments
Harmonization with the current version of the NIH Guidelines (removal of duplicated language)
Clarification of the process for reviewing allegations of noncompliance
Change of requirement for BOHP enrollment to optional/voluntary

September 2025:
Clarification of PI eligibility
Removal of OSP requirement for IBC deferral
Addition of the requirement to make meeting minutes publicly available

June 2021:
Updated the Institutional Official to the VPRDO

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 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.

1 Introduction

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

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*) are applicable to all research involving Recombinant or Synthetic Nucleic Acid Molecules (hereafter referred to as rDNA) conducted within the United States at institutions that receive federal funding for research. The Georgia Institute of Technology (Georgia Tech) must ensure that rDNA 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 Georgia Tech.

Failure to comply with the NIH Guidelines may result in suspension, limitation, or termination of NIH funds for any and all rDNA at Georgia Tech, or a requirement for prior NIH approval of any or all rDNA projects at Georgia Tech.

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 Possession and Use of Recombinant or Synthetic Nucleic Acid Molecules*, as are collaborators and visitors from other organizations working with Georgia Tech faculty members, staff employees, or students (on Georgia Tech campus).

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

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

1.3 Definitions

For the purposes of these policies and procedures, the IBC applies the following definitions to recombinant DNA and biological agents containing rDNA.

1.3.1 Institutional Official

The Associate Vice President for Research Integrity Assurance (AVP-RIA) is the Institutional Official for the IBC. The AVP-RIA appoints committee members, receives

reports from the IBC, and ensures appropriate resources are available to support the program.

1.3.2 Recombinant nucleic acids

(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 nucleic acid 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.

1.3.3 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.

1.3.4 Categories of potentially infectious biological materials

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 Biological Materials Safeguards Committee (BMSC). If vertebrate laboratory animals are being utilized in activities with biological agents containing rDNA, the Institutional Animal Care and Use Committee (IACUC) must also review the proposed work.

2 Institutional Biosafety Committee

2.1 Authority Granted to the Institutional Biosafety Committee

Each institution conducting or sponsoring rDNA research that is covered by the *NIH Guidelines* is responsible for ensuring that the research is conducted in full conformity with the provisions of the *NIH Guidelines*. Therefore, Georgia Tech established the IBC 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 Tech IBC has established and implemented these policies and procedures to provide for the safe and ethical conduct of research and other activities involving rDNA 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 Center for Disease Control's (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL), or other legal or institute requirements.

Furthermore, the Chair of the IBC 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 Institutional Official. In accordance with the *NIH Guidelines*, the IBC is comprised of at least five members including one or more individuals with expertise in rDNA 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 IBC 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 (ORIA) as soon as possible, preferably at least 24 hours before the meeting.

2.2.1 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.

ORIA works closely with the Office of General Council (OGC) and with the Office of Sponsored Programs (Georgia Tech OSP) to ensure that such potential conflicts are identified and managed appropriately.

2.3 Specialized Expertise Requirements

2.3.1 Required Expertise When Reviewing rDNA 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 rDNA involving plants.

2.3.2 Required Expertise When Reviewing rDNA 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 rDNA involving animals.

2.3.3 Consultants

Should on occasion arise when the Georgia Tech IBC 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. 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 ORIA regarding new and continuing registrations they approve.

2.5 Biosafety Officer

The Georgia Tech Biosafety Officer (BSO) is a voting member of the IBC and must approve any facilities prior to the commencement therein of any rDNA work reviewed by the Institutional Biosafety Committee. In addition, the BSO 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 Biological Risk Assessment for the proposed activities.

2.6 Education of IBC Members

New members of the IBC receive introductory training from ORIA and Environmental Health & Safety (EHS) to ensure they are 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 monthly, or as needed, to review applications proposing use of rDNA. 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 Georgia Tech. Through use of telecommunications (e.g., telephone- or video-conferencing), the IBC may conduct official business without all members physically present. A mail ballot or individual telephone polling cannot substitute for participation in a convened meeting. Opinions of absent members that are transmitted by telephone or e-mail may be considered by the convened IBC members but shall not be counted as votes. Meetings are never conducted via email. In all cases, the usual and customary procedures shall apply, i.e.: a quorum shall be established (as defined below); votes shall be taken; and minutes shall be recorded.

IBC meetings are open to the public. Any member of the general public who wishes to attend an IBC meeting will be welcome to do so for the open portion of the meeting that involves discussion of research with rDNA subject to the *NIH Guidelines*. Section IV-B-2-a-(6) of the *NIH Guidelines* acknowledges that the protection of private or proprietary information is a legitimate basis for closing meetings to the public. The Institution reserves the right to restrict access to the closed portion of the meeting, which may include discussions on research activities that do not fall under the *NIH Guidelines*, or are closed to protect private or proprietary information. Proprietary information includes trade secrets, confidential commercial information, and specific information whose disclosure would directly compromise institutional or national security.

If public comments are made on Institutional Biosafety Committee's actions, the Institute shall forward both the public comments and the IBC's response to the Office of Biotechnology Activities, in accordance with Section IV-B-2-a-(7) of the *NIH Guidelines*.

2.8 Quorum

A simple majority of voting members of the IBC constitutes a quorum. A quorum must be present to conduct business of the IBC requiring a vote.

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 NIH OSP. An annual report is filed with NIH OSP and includes an updated list of IBC members, the role of each member, and biosketch for each member. The NIH OSP is also notified of any changes in IBC membership when they occur.

3 Responsibilities of the Committee

3.1 Overall responsibilities

On behalf of the institution, the IBC is responsible for reviewing rDNA 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*. Note: additional functions may be delegated to the IBC under Section IV-B-2 of the *NIH Guidelines*.

3.2 Protocol Review

IBC is responsible for review and assessment of

- 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 rDNA research;
- ensuring that all aspects of Appendix M of the *NIH Guidelines* have been appropriately addressed by the Principal Investigator (PI); and
- ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.

3.3 Notifying the PI of the results of the IBC's review

The IBC shall notify the PI of the results of the IBC review.

3.4 Set and modify containment levels

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*.

Setting containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.

3.5 Periodic review

Periodically reviewing rDNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.

3.6 Implement contingency plans

Adopting emergency plans covering accidental spills and personnel contamination resulting from rDNA 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.

3.7 Reporting to NIH OSP

Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days, unless the IBC determines that a report has already been filed by the PI. Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail.

Through ORIA, The IBC shall report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Animal Facility Director (where applicable), IBC, NIH OSP, and other appropriate authorities (if applicable) within 30 days. Reports to NIH OSP shall be submitted through ORIA using the NIH OSP template.

Through ORIA, report any new information bearing on the *NIH Guidelines* to the IBC and to NIH OSP per NIH OSP Guidelines.

3.8 Training / Education

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 ORIA that these IBC Policies and Procedures are posted to the IBC website. Hard copies will be made available upon request. The *NIH Guidelines* are also linked from the NIH 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.

3.9 Containment requirement limitations

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

4 Administrative Support for the IBC

4.1 Office of Research Integrity Assurance

The IBC is supported and administered by ORIA, which has offices in the Dalney Building (Dalney). The Committee customarily meets virtually or in the Dalney Board Room.

4.2 Responsibilities of the Office of Research Integrity Assurance

ORIA is responsible for maintaining Georgia Tech's registration with NIH OSP; reporting to NIH OSP at least annually; updating the committee roster and biosketches; and facilitating the Institute's responsibilities for administrative, oversight, review and reporting functions. ORIA accepts, screens, and tracks rDNA registrations and, in collaboration with the IBC Chair, coordinates the committee's activities.

ORIA has further responsibility for maintaining the official records of the IBC, including correspondence with NIH OSP, meeting minutes, rDNA registration records, and committee rosters and biosketches. The website for the IBC is maintained by this office.

4.3 Meeting Minutes

Minutes of IBC meetings, taken by a member of ORIA 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

The Institution makes available to the public all IBC meeting minutes on the ORIA website.

Per NIH Guidance, Minutes must be posted publicly for a minimum of 5 years. Additionally, the records may need to be kept longer in accordance with record retention requirements. Section 8.4.2 of the NIH Grants Policy Statement requires recipients of its awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states in part "The recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report." When IBC minutes contain records related to awards, they would have to be maintained for at least as long as stated in this requirement and must be made available to the public during this time if requested. IBC minutes may contain records related to multiple protocols which may be in different stages of the grant cycle.

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 Tech 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 are represented by a code, which would not be redacted from a list of attendees at committee meetings.

The *NIH Guidelines*, Section IV-B-a-2-6, acknowledges that the protection of privacy and proprietary interests is sufficient to redact portions of minutes. In addition to trade secret and commercial information, the *NIH Guidelines* also allows for redaction of personal information of IBC members and "specific information whose disclosure would directly compromise institutional or national security."

To ensure redaction is performed consistently, the following redaction procedure has been adopted in accordance with provisions allowed by the *NIH Guidelines* and applicable laws. Information not released to the Public under this procedure include:

- Portions of the IBC meeting conducted as a closed meeting
- Private information of IBC members and Guest
- Information whose disclosure is likely to compromise institutional or national security
- Proprietary, confidential or trade secret information

4.5 Records Retention

The records of the IBC shall be retained by ORIA in accordance with the University System of Georgia's Board of Regents Records Retention Guidelines.

Records relating to research shall be retained in accordance with USG Guidelines. 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 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 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 protocol and reviewed by the BSO or EHS designee during the IACUC protocol review process. If, during the review of the IACUC protocol, the BSO (or designee) identifies any additional questions or experiments that fall outside of these two exemptions, the PI will be notified by the BSO or ORIA that they are required to submit an IBC registration for review and approval.

5.3 Review of Exempt Registrations by Chair or Designee

PIs applying for Exempt registrations must complete the protocol application in the Topaz system, attach a Biological Risk Assessment, 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 IBC 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

PIs applying for Non-Exempt registrations must complete protocol application in the Topaz system, attach a Biological Risk Assessment, and submit it to the IBC for approval. Any new 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:

- Approve the registration without modification;
- Approve the registration subject to modification (modification(s) must be satisfactorily made before a letter of approval will be issued);

- Table the decision pending additional information; or
- Disapprove the registration.

In the event that the full board determines to disapprove the work, the applicant will be offered an opportunity to meet with the IBC to resolve issues of concern. A subset of board members may meet separately with the applicant to assist in preparing modifications to secure approval.

5.5 Notice of IBC Action

ORIA or the IBC Chair 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

All IBC registrations, Exempt and non-exempt, are granted approval for three years.

5.7 Revisions to Approved Registrations

PIs wanting to revise a currently approved registration must complete the Amendment application in the Topaz system 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.

*An amendment to add materials to an approved registration can be done administratively as long as the following conditions are met: 1) the materials being added are of the same or lower classification category (i.e., III-A, B, C, etc.), 2) the biosafety level is the same or lower than the initial approved registration, and 3) the amendment does not introduce any new agents with rDNA (as defined above).

5.8 Notice of Termination

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, the PI must request ORIA to inactivate the Biosafety Protocol in the Topaz system.

6 Principal Investigator's Responsibility

Only Georgia Tech academic faculty or research faculty members are eligible to hold the title of PI 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 or Protocol Associates. *See Appendix A of these policies regarding eligibility for status as PI.*

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*, PIs planning to utilize biological agents containing rDNA shall secure prior approval from the Institutional Biological Materials Safeguards Committee. Additionally, those PIs shall consult the CDC's *BMBL*, which specifies additional safety requirements. Further guidance may be provided by EHS.

On behalf of the institution, the PI 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 PI shall:

- Not initiate or modify rDNA research which requires IBC approval until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the *NIH Guidelines*;
- 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;
- Be appropriately trained in good microbiological techniques, where appropriate, or other techniques related to handling rDNA or biological agents containing rDNA;
- Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination; and
- Comply with EHS shipping requirements for rDNA molecules.

6.2 Submissions by the Principal Investigator to the Institutional Biosafety Committee

Any faculty member who desires to possess or use rDNA subject to the *NIH Guidelines* must submit the "Biosafety Protocol" and "Biological Risk Assessment" to ORIA (through the Topaz system) with sufficient lead time for review.

The PI shall:

- Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;
- Select appropriate microbiological practices and laboratory techniques to be used for the research;

- 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, III-E, or III-F of the *NIH Guidelines* to the IBC for review and approval or disapproval;
- PI shall remain in communication with the IBC throughout the conduct of the project.

6.3 PI Responsibilities Prior to Initiating Research

The PI shall:

- Make available to all laboratory staff the registrations that describe the potential biohazards and the precautions to be taken;
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
- Inform the laboratory staff and students of the option or requirement to enroll in the Biological Occupational Health Program (as noted in this policy) and
- Secure approval from the IBC before initiating any activities involving rDNA.

6.4 PI Responsibilities during the Conduct of the Research

The PI shall:

- Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
- Report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the IBC, ORIA and, where applicable to the Biological Safety Officer, Animal Facility Director. When appropriate, ORIA will report activities to NIH OSP and other appropriate authorities.
- 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 EHS on-call personnel (404.216.5237).
- Correct work errors and conditions that may result in the release of rDNA materials; and
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

6.5 Additional Responsibilities of the Principal Investigator

- 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.
- Establish policies and procedures to limit access exclusively to those individuals who have been advised of the potential hazards and meet specific entry requirements.
- Select and provide appropriate personal protective equipment required for work with hazardous materials. Contact EHS for assistance.

- 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.
- 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.
- Reporting Serious Adverse Events in Human in vivo Gene Transfer Trials. Note: Currently, there are no human gene transfer trials underway or contemplated at Georgia Tech.

6.6 Requirement for Completion of rDNA Training through EHS

In accordance with the *NIH Guidelines,* Section IV-B-1-h, the IBC requires that all personnel named in rDNA registrations complete certain training. New rDNA registrations, revision requests, and continuing review applications will be screened by ORIA or EHS to ensure that all personnel have completed the training requirements before letters of approval will be issued.

Registration for the required training, presented by EHS, may be accomplished online at. There is no charge for the courses.

6.7 Availability of the Biological Occupational Health Program through EHS

EHS administers the Georgia Tech Biological Occupational Health Program (BOHP) for employees and certain students who may be exposed to health risks as part of their jobs or research activities. All individuals working with vertebrate animals or human materials (with or without rDNA) are required to enroll in the BOHP. Others may voluntarily enroll in the program.

6.8 Attend Institutional Biosafety Committee Meetings

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

7 Categories of Activities Involving rDNA

7.1 rDNA Experiments Subject to the NIH Guidelines

It is the policy of Georgia Tech's IBC that all activities involving rDNA must be reviewed and approved prior to initiation.

The following paragraphs summarize rDNA experiments covered by the *NIH Guidelines*, including those that require review by the NIH Director or NIH OSP. Refer directly to the *NIH Guidelines* for a more detailed description of experiments and specific requirements.

7.2 Section III-A Experiments Requiring IBC and NIH Director Approval

Experiments Requiring IBC approval and NIH Director Approval under *NIH Guidelines* Section III-A—Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that do not acquire the trait naturally. These experiments are considered "Major Action" and require review by the NIH Director and specific approval by NIH prior to initiation. In addition, approval by the IBC is required prior to initiation of the experiment.

7.3 Section III-B Experiments Requiring IBC and NIH Director Approval

Experiments Requiring IBC and NIH OSP Approval under *NIH Guidelines* 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 NIH. IBC approval is required *prior to initiation* of the experiments.

7.4 Section III-C Experiments Requiring IBC Approval

Experiments requiring IBC Approval under *NIH Guidelines* Section III-C—These experiments involve the deliberate transfer into human research participants of either:

- Recombinant DNA, or DNA or RNA derived from recombinant DNA, or
- Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
- Contain more than 100 nucleotides; or
  - Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
  - Have the potential to replicate in a cell; or
  - Can be translated or transcribed.

The PI is responsible for submitting documentation regarding a proposed human gene transfer protocol to the Georgia Tech IBC.

7.5 Section III-D Experiments Requiring IBC Approval

Experiments Requiring IBC Approval under NIH Guidelines 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.

7.6 Section III-E Experiments Requiring IBC Approval

Experiments Using Recombinant DNA from Risk Group 1 Agents (NIH Guidelines 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. At Georgia Tech, IBC approval is required prior to initiation of the experiments.

7.7 Section III-F Experiments Requiring IBC Approval

NIH Exempt Experiments—Georgia Tech requires registration with the IBC for exempt projects (NIH Guidelines Section III-F). Refer to Section III-F of the *NIH Guidelines* for a full list of recombinant DNA molecules that are exempt from the NIH Guidelines. At Georgia Tech, IBC approval is required prior to initiation of the experiments.

In accordance with the NIH Guidelines, the Georgia Tech IBC has established two categories of registration: Exempt and Non-Exempt. Both require review by the IBC, and both have a 3-year approval period.

7.8 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. Coordination with EH&S is required for all studies. Coordination with Research Security is required for BSL-3 or BSL-4 activities.

Category	Examples Covered
Exempt	• 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 *E. coli* K12*, S. cerevisiae, and B. subtilis* host-vector systems (with the exception of DNA from Risk Group 3, 4, or restricted agents) • Other experiments/materials specified in Section III-F of the NIH Guidelines Review Note: IBC Chair as Primary Reviewer; Secondary Reviewer at Chair's discretion; or review may be accomplished by Chair's designee
Non-Exempt	• Deliberate transfer of a drug trait to *a* microorganism not known to acquire it naturally • Formation of recombinant DNA encoding molecules lethal to vertebrates at an LD 50 of <l00 ug/kg body weight • Human gene transfer experiments • Experiments using Risk Group (RG) 2, RG3, RG4, or Restricted Agents as host-vector systems • Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems • 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 • Larger scale DNA project (>10 liters of culture combined) • Experiments with recombinant/synthetic influenza viruses • Experiments involving gene drive modified organisms • Other experiments/materials covered in Sections III-A to III-E of NIH Guidelines Review note: Reviewed by the Full Board of IBC, at convened meeting

8 Risk Assessment and Selection of Appropriate Safeguards

The following guidance is provided to assist PIs 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 Tech certified to conduct Biosafety Level 3 BSL-3) or Biosafety Level 4 (BSL-4) research.

8.1 PI Risk Assessment

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:

8.1.1 Risk Group 1 (RG-1)

RG-1 agents are not associated with disease in healthy adult humans.

8.1.2 Risk Group 2 (RG-2)

RG-2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

8.1.3 Risk Group 3 (RG-3)

RG-3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

8.1.4 Risk Group 4 (RG-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:

8.2.1 Pathogenicity of the biohazardous material(s)

Consideration should include disease incidence and severity.

8.2.2 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.

8.2.3 Agent stability

Should include a consideration of factors such as desiccation, exposure to sunlight or ultraviolet light, or exposure to chemical disinfectants,

8.2.4 Infectious dose of the agent and communicability

Consideration should include the range from the healthiest immunized worker to the worker with lesser resistance.

8.2.5 Concentration

Include consideration of the milieu containing the organism (e.g., solid tissue, viscous blood or sputum, liquid medium) and the activity planned.

8.2.6 Origin of the biohazardous material(s)

Consideration should include factors such as geographic location, host, and nature of the source.

8.2.7 Availability of data from animal studies

This information may be useful in the risk assessment process in the absence of human data.

8.2.8 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).

8.2.9 Gene product effects

Geen product effects including 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 IBC, which makes the final determination of the appropriate biosafety level.

The following is a general description of biosafety levels:

8.3.1 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.

8.3.2 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.

8.3.3 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. There is no laboratory at Georgia Tech that has been certified as BSL-3. Therefore, projects involving biohazardous agents requiring BSL-3 cannot be conducted at Georgia Tech at this time and will not be approved by the IBC.

8.3.4 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 CDC's BMBL, 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 Review Requirements for Activities at Another Institution

9.1 Georgia Tech Personnel Working at Off-Campus Site with NIH OSP Registration

In cases where the Georgia Tech faculty member, staff employee, or student is involved in work located at an off-campus site with an NIH OSP-registered Biosafety Committee, the Georgia Tech IBC may accept an approval statement from another IBC, in lieu of performing a duplicate review. The Georgia Tech IBC must 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 complete the "*Off-campus IBC Registration*" in the Topaz system and include 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.

9.2 Georgia Tech Personnel Working at Off-Campus Site with Non-NIH OSP-Registered Biosafety Committee

In cases where the IBC work is performed off-campus at a facility with a non-NIH OSP-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 NIH OSP-registered Biosafety Committee, the current Georgia Tech IBC registration review process described elsewhere in this policy.

9.3 Non-Georgia Tech Personnel Working at Off-Campus Site with NIH SOP-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 NIH OSP-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.

Georgia Tech investigators in this situation must complete the "*Off-campus IBC Registration*" in the Topaz system and include 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.

10 Coordination with Other Compliance Committees

Coordination with other compliance committees may be necessary, as proposed research may require.

It is the responsibility of the PI to seek the appropriate reviews. ORIA will also refer registrations to these committees, as warranted. These committee reviews occur in parallel under the coordination of ORIA.

10.1 Institutional Review Board (IRB)

The IRB is administered by the Office of Research Integrity Assurance. IRB policies and requirements are available on the IRB website.

IRB letters of approval will not be issued by ORIA until outstanding IBC issues are resolved.

10.2 Institutional Animal Care & Use Committee (IACUC)

The IACUC is administered by the Office of Research Integrity Assurance. IACUC policies and requirements are available on the IACUC website.

IACUC letters of approval will not be issued by ORIA until outstanding IBC issues are resolved.

10.3 Dual Use Research of Concern (DURC)

The DURC Institutional Review Entity is administered by the Office of Research Integrity Assurance. DURC policies and requirements are available on the DURC website.

10.4 Biological Materials Safeguards Committee (BMSC)

The Biological Materials Safeguards Committee is administered through Environmental Health & Safety. BMSC policies and requirements are available on the EHS BMSC website.

11 Appendix A: Principal Investigator Eligibility

11.1 Eligibility for Title of Principal Investigator

The term "Principal Investigator" refers to the single individual who shall have full and final responsibility for the conduct of a research study involving rDNA. Therefore, for IBC purposes, the title of Principal Investigator (PI) or co-Principal Investigator (Co-PI) will be allowed in the following cases:

- The individual is an employee of the Institute and holds a title of Academic Faculty or Research Faculty as defined in the faculty handbook;
- If retired, the individual is working on an hourly-as-needed basis, and there is at least one School, Laboratory, or Department willing to provide the necessary administrative commitment to permit the protocol to be carried out.
- OR, the individual has received an exception letter from the Executive Vice President for Research (EVPR) or Institutional Official/VPRDO, as described in item B., below.

Adjunct faculty affiliates may not serve as PI or Co-PI on an IBC protocol *unless they are also eligible to be a PI as described above*; they may hold the title of protocol associate if they sign a Visiting Scholar Agreement. (Some personnel are faculty in the Georgia Tech Research Institute (GTRI) and also adjunct in an academic unit; some personnel may be faculty in one academic unit and adjuncts in another).

Other affiliates may not be named as PI or Co-PI.

Non-employees are not eligible to serve as a PI or co-PI on IBC protocols.

11.2 Exceptions Requiring Approval by Executive Vice President for Research or Institutional Official

Exceptions to the general eligibility requirements for designation as PI or Co-PI will be considered upon submission of a written request to the Executive Vice President for Research (EVPR) or the Institutional Official. The request should justify why the individual should be designated as the PI and must be signed by the appropriate departmental representative (Chair/Director/Department Head). A copy of the approved exception, signed by the EVPR or Institutional Official and the requesting department's head, must be uploaded to each IBC protocol prior to approval.

11.3 Circumstances that Require Appointment of a New Principal Investigator

The PI has full and final responsibility for the conduct of a research study involving rDNA. As such, the following conditions require the appointment of a new PI or prior IBC approval:

- Leave of Absence: A new PI must be appointed anytime a faculty member is absent for more than half of the semester including all intermittent absences (see Faculty Affairs time away for details).*
- Absence from Campus: Any absence longer than 2 weeks but shorter than 8.5 weeks, or half of the semester, requires IBC and EHS notification. The PI must notify the IBC and EHS to arrange for an alternate contact during the absence. The IBC and EHS will determine if a new PI must be appointed on a case-by-case basis (depending on duration, research protocol and oversight requirements).*
- Administrative Leave: A new PI must be appointed for the duration of an Administrative leave.
- Termination of employment: A new PI must be appointed prior to a current PI permanently leaving the institution.
- No longer meets the above criteria: A new PI must be appointed if a current PI fails to continue to meet the criteria set forth in paragraphs A-C above.

*Other Leave of Absence and Absence from Campus requirements are detailed on the Faculty Affairs page.

11.4 Non-Georgia Institute of Technology Personnel Participating in Protocols at Georgia Institute of Technology (Visiting Scholars and Volunteer Researchers)

Georgia Tech seeks to foster collaborative relationships with researchers, scientists, and students who visit the Institute and who may participate in research projects involving vertebrate animals at Georgia Tech. In order to ensure appropriate protections for those visitors/volunteers and for Georgia Tech faculty and staff, this policy has been developed.

Prior to participating in rDNA research, non-Georgia Tech personnel must complete formal in-processing, as follows:

- The host department and visitor/volunteer must complete and sign the Volunteer Services Description Form and the Volunteer Services Application and return both to Risk Management.
- Office of Legal Affairs: The host department must prepare a Volunteer Program Agreement Form or Visiting Scholar Agreement obtain the signature of the visitor/volunteer, and forward the form to the Office of Legal Affairs.
- Research Integrity Assurance: The visitor/volunteer must either be named in the original protocol application or be added in an amendment to an existing protocol prior to participating in the protocol. The volunteer/visitor's current CV or completed credentials form must be submitted to ORIA along with documentation of satisfactory completion of the required IBC CITI training module(s). Upon approval by the IBC, visitors/volunteers may serve as co-investigators working with Georgia Tech PI who are responsible for conducting the research and ensuring compliance with the approved protocol.

When visitors/volunteers are actively participating in research procedures on an approved protocol, the Georgia Tech PI or Co-PI must be present, in charge, and responsible. In cases where neither the PI nor co-PI is available, another Georgia Tech employee named in the protocol may be designated by the PI or co-PI to supervise the visitor/volunteer.

12 Appendix B: Allegations of Noncompliance

The Georgia Tech IBC requires that all recombinant and synthetic nucleic acid usage be conducted in an ethical and appropriate manner, in accordance with guidance from the NIH OSP and Institute policies. It is the PI's responsibility to report any accidents, illness, significant problems, or violations to the IBC within 30 days. Any failure to comply with these policies and regulations jeopardizes all use of recombinant and synthetic nucleic acids in research at Georgia Tech.

When appropriate, the IBC Chair, IBC Professional, and/or the Director of ORIA will meet with the individual(s) involved. The purpose of this discussion is to allow the researcher an opportunity to respond to the details of a reported incident and to clarify any potential misunderstanding. If the report is found to have merit, the above individual(s) may further investigate. ORIA participates in fact-finding, to facilitate documentation and to ensure that the rights and reputation of the accused individuals are protected.

ORIA shall review all allegations of noncompliance with the IBC Chair and present them to the IBC for appropriate corrective action, which may include suspension of the registration and/or possible referral to the appropriate Institute body if scholarly misconduct is alleged or apparent.

The IBC shall discuss at a convened meeting with a quorum of voting members and determine whether a report to NIH OSP is necessary. Reports to NIH OSP are made through ORIA in accordance with the NIH Guidelines. The Institution 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 OSP within 30 days.

The IBC 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 BMBL, requirements of EHS, or other legal or Institute requirements.

The IBC may notify the PI's Department Chair of noncompliance. The purpose of this action is to provide leadership in laboratory safety at the management level of the department. Per NIH Section IV-B-7-a General Responsibilities, as part of this general responsibility, the Principal Investigator shall:

> *"Section IV-B-7-a-(3). 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 OSP, and other appropriate authorities (if applicable) within 30 days. Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov)."*