**1. Purpose**

The purpose of this document is to provide details of the responsibilities, scope of authority and structure of the Institutional Biosafety Committee (IBC).

**2. Mission**

The mission of the Institutional Biosafety Committee is to:

2.1. ensure that all recombinant DNA research activities at the Rochester Institute of Technology comply with Department of Health and Human Services, National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (hereinafter termed “NIH Guidelines”).

2.2. ensure that protocols of all research undertaken at RIT which use or produce biohazardous organisms requiring Biological Safety Level 1 (BSL1) or higher precautions, including but not limited to recombinant DNA, are reviewed and found to protect personnel, the environment and public safety by complying with the applicable NIH Guidelines.

**3. Institutional Responsibility**

It is the responsibility of RIT to ensure that the IBS remains active to carry out its mission.

**4. Institutional Official**

The Institutional Official charged with the responsibility of ensuring that research conducted at or sponsored by RIT fully conforms to the provision of the NIH Guidelines. The Institutional Official for the IBC is the Vice President for Research and the IBC reports directly to him or her. If needed, the Institutional Official may serve as an advisor to the IBC Chair.

**5. IBC Responsibility**

 5.1 The IBC is responsible for reviewing research conducted at or sponsored by the Rochester Institute of Technology for compliance with:

5.1.2 NIH Guidelines for Research Involving Recombinant DNA Molecules

5.1.3 CDC/NIH Biosafety in Microbiological and Biomedical Laboratories

5.1.4 OSHA Blood borne Pathogens Standard (29 CFR 1019.1030)

5.1.5 RIT institutional policies and procedures

5.2 The IBC is responsible for approving those research projects, which are found to conform to the above regulations and guidelines.

5.3 The IBC is responsible for ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements required by the NIH Guidelines.

5.4 The IBC is responsible for investigating allegations of non-compliance with the NIH Guidelines and determining the appropriate follow up actions on a case-by-case basis. Actions taken following an investigation are subject to approval by institutional officers.

5.5 The IBC is responsible for maintaining standard operating procedures (SOPs), which apply to all IBC activities.

5.6 Specific responsibilities given to the IBC under the NIH Guidelines.

5.6.1 Notifying the Principal Investigator (PI) of the results of IBC review and approval of submitted projects.

5.6.2 Lowering containment levels for certain experiments in which DNA from Risk Groups 2, 3,4 or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.

5.6.3 Setting containment levels for experiments involving whole animals and experiments involving whole plants.

5.6.4 Periodically reviewing recombinant DNA research conducted at RIT to ensure compliance with the NIH Guidelines.

5.6.5 Adopting emergency plans covering accidental spills and personnel contaminations resulting from recombinant DNA research.

5.6.6 The IBC may not authorize initiation of recombinant DNA experiments, which are not explicitly covered by the NIH Guidelines until the NIH establishes the containment requirement.

5.6.7 Appointing individuals with appropriate expertise and experience to the IBC.

5.6.8 Reviewing and approving all studies at RIT in which the following will be administered to human subjects: recombinant DNA (plasmids) or gene transfer vectors (including, but not limited to, viruses); genetically engineered microorganisms; infectious agents (including live vaccines if they are experimental in nature and/or not FDA approved for use in specific study populations).

5.6.9 Assist and ensure compliance with NIH Guidelines by PIs conducting research at RIT.

5.6.10 Ensure appropriate qualifications for the IBC Chair and members, Biosafety Officer and other containment experts, when and if applicable, regarding laboratory safety and implementation of the NIH Guidelines.

5.6.11 Provide a copy of the NIH Guidelines to all PIs.

5.6.12 Determine the necessity for health surveillance of personnel involved in connection with individual recombinant DNA projects; and if appropriate, conduct a health surveillance program for those projects. This health surveillance program shall include personnel engaged in large scale research or production activities involving viable organisms containing recombinant DNA molecules which require BL3 containment at the laboratory scale and personnel engaged in animal research involving viable recombinant DNA-containing microorganisms which require BL3 or greater containment in the laboratory.

5.6.13 Report any significant problems, violations fo the NIH Guidelines or any significant research-related accidents and illnesses to the NIH Office of Biotechnology Activities (OBA) within 30 days.

**6. IBC Authority**

 6.1 The Rochester Institute of Technology, through its Institutioal Biosafety Committee (IBC), is assigned by NIH with the responsibility of assuring research with recombinant DNA molecules is performed as safely as possible and in ways that eliminate or reduce the potential exposure of personnel and the environment. The functions of the IBC were expanded to include overseeing the use of other biohazards not included in the NIH Guidelines.

 6.2 The IBC has authority over all research usage of recombinant DNA molecules, including viral vectors and genetically modified organisms at RIT and the use of biohazardous infectious agents including pathogens and those materials which may harbor infectious agents.

 6.3 The IBC also has authority over all human gene transfer studies at RIT.

 6.4 Specific authorities of the IBC

6.4.1 The IBC has the authority and responsibility to review all research involving recombinant DNA matierials or biohazardous (particulary infectious) agents conduced at RIT facilities or by RIT faculty when they are acting in their roles as RIT faculty.

6.4.2 The IBC has the authority and responsibility to approve, require modifications to, and disapprove research which it reviews. Decisions made by the IBC may not be overturned except by subsequent actions by the IBC itself. Research which has been disapproved by the IBC may not be permitted to proceed by other institutional offices or personnel. Research approved by the IBC may be subject to further review and approval or disapproval by institutional officials.

6.4.3 The IBC has the authority and responsibility to require progress reports from investigators, when appropriate, and to conduct continuing review of studies which it has approved.

6.4.4 The IBC has the authority and responsibility to place restrictions on, suspend or terminate approval of studies in order to protect the safety of laboratory workers or the general public.

**7. IBC Membership**

7.1 The IBC will be comprised of no fewer than five members selected so that they collectively have the experience and expertise in recombinant DNA technology, biological safety and physical containment along with the capability to assess the safety of recombinant DNA research and to identify potential risks to public health or the

environment.

7.2 The IBC shall include or have available as consultants persons who are knowledgeable in institutional policies, applicable law, standards of professional conduct and practice, community attitudes and the environment.

7.3 At least two members shall not be affilated wth RIT, apart from their membership on the IBC, and who represent the interest of the surrounding community with respect to health and protection of the environment. Examples of members not affiliated with RIT are officials of state or local public health or environmental protection agencies, members of other local governmental bodies and/or persons active in medical, occupational health or environmental concerns in the community.

7.4 The IBC shall include at least one individual with expertise in plant, plant pathogen or plant pest containment principles when experiments involving recombinant DNA in plants are reviewed.

7.5 The IBC shall include at least one scientist with expertise in animal containment principles when experiments involving recombinant DNA materials or biohazardous (particularly infectious) agents in animals are reviewed.

7.6 The IBC shall include the RIT Biological Safety Officer.

7.7 The IBC shall have adequate expertise for the review of recombinant DNA research involving human subjects. If necessary, consultants should be involved as deemed necessary.

7.8 The IBC shall include at least one member representing the laboratory technical staff.

7.9 *Ex officio* members include the Director of Environmental Health and Safety and the Director of the Office of Sponsored Research Services. These members are not expected to participate in the protocol review process on a routine basis but they will be available to provide guidance and assist in enforcing RIT standards and policies. *Ex officio* members are voting members of the IBC.

7.10 Consultants will be provided upon request of the IBC. Consultants with competence in special areas may be invited to assist in the review of complex issues which require expertise beyone or in addition to that available among IBC members. Consultants, whether internal or external to RIT, cannot vote. Rather, they can only

provide their expert opinion. The IBC remains responsible for its decisions which may be based on information provided by consultants. The IBC may also consult other RIT committees (e.g. the IRB or IACUC) as appropriate.

7.11 Appointments to the IBC are at the discretion of and will be makde by the Insititutional Officials upon the recommendation of the IBC Chair and Biological Safety Officer. The initial term of appointment for the Chair and members will be for one year, appointments may be renewed for subsequent three year terms.

7.12 Criteria for removal of the IBC Chair or members include failure to act in compliance with applicable federal and institutional regulations and failure to attend at least 50% of the IBC meetings. The Chair and the Biological Safety Officer will remove members from the IBC with the concurrence of the IBC’s institutional officials. Members may resign at any time but they are encouraged to provide at least a two month advance notice in order to maintain the integrity of the committee.

7.13 In order to avoid conflicts of interest, no member of the IBC may be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct pecuniary interest. When a potential conflict of interest is identified, the IBC member involved will recuse himself or herself for the duration of the discussion in order to permit the IBC to discuss the proposal without bias. The only acceptable exception is when the IBC member has been asked to provide information to the IBC.

7.14 Training will be provided to each IBC member as part of the initial appointment process and on an ongoing basis. Training will cover issues such as applicable laws, federal regulations and institutional policies and procedures.

7.15 Indemnification of members will be provided by RIT for actions taken as members of the IBC. Indemnification is expressly extended to non RIT affiliated members while perfoming the duties of an IBC member.

**8. IBC Reporting Requirements**

 8.1 Membership

8.1.1 The IBC shall file an annual report with the NIH/OBA which includes a roster of all IBC members (clearly indicating the Chair), the contact person, the Biological Safety Officer, the plant expert (if applicable), the animal expert (if applicable), the human gene therapy expert, the consultants (if applicable), the *ex offico* members. Biographical sketches of all members, including community members, will be included with the annual report.

8.1.2 More frequent reports to OBA may be necessary if membership changes.

8.2 Minutes

8.2.1 Upon request, all IBC meeting minutes shall be made public along with any documents submitted to or received from funding agencies, which are required to be made available to the public.

8.2.2 Meeting minutes and other IBC official documentation may be redacted before release to the public in order to protect proprietary information only.

8.2.3 If public comments are made on IBC actions, both the public comments and the IBC response will be provided to the Office of Science Policy, NIH at NIHGuidelines@od.nih.gov.

 8.3 Violations, accidents and illnesses

8.3.1 The IBC shall report any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the IBC’s institutional official and the Director of Environmental Health and Safety immediately upon notification from the cognizant PI. Such reports will be investigated by the IBC with assistance from the office of Environmental Health and Safety.

8.3.2 NIH/OBA must be notified by the IBC within 30 days unless the IBC determines that the PI has already filed a report.

8.3.3 Reports to the NIH/OBA shall be sent to the Office of Biological Activities, National Institutes of Health, at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985 (301.496.9838).

**9. IBC Chair**

A Chair who has overall responsibility for the functioning of the committee shall lead the IBC. Further duties of the IBC chair include, but are not limited to:

9.1 Initiate IBC policy development or designate qualified individuals to do so.

9.2 Participate in biological assessment or other committee activities.

9.3 Liaison with RIT senior administration for biological safety issues.

9.4 Interact with the IBC of record concerning gene transfer issues.

9.5 Carry the responsibility for ensuring appropriate training for IBC members.

**10. Biological Safety Officer (BSO)**

RIT shall appoint a Biological Safety Officer (BSO) to the IBC. This is required under the NIH Guidelines if RIT conducts recombinant DNA research at Biological Safety Level (BSL) 3. The BSO’s responsibilities include, but are not limited to:

10.1 Performing periodic inspections to ensure laboratory standards are rigorously followed.

10.2 Reporting to the IBC and to RIT officials any significant problems, violations of NIH Guidelines and any significant research-related accidents or illness of which the BSO becomes aware unless the BSO determines that the PI has already filed a report.

10.3 Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research and/or other biological agents.

10.4 Providing advice on the control and containment of biohazards and on the security of biological agents.

10.5 Screening new protocols for completion prior to IBC review.

10.6 Following up on IBC concerns for any protocol.

10.7 Developing, implementing and providing training that addresses laboratory biosafety.

10.8 Providing technical advice to PIs, laboratory staff and the IBC on research safety procedures.

**11. IBC Program Coordinator**

The IBC Program Coordinator shall be primarily responsible for recording the activities of the IBC. Additional duties of the IBC Program Coordinator include, but are not limited to:

11.1 Documenting all IBC meeting activities including attendance.

11.2 Scheduling meeting times and locations and sending schedules to committee members and RIT institutional officials.

11.3 Preparing meeting agendas and protocol review packets and distributing them to IBC members.

11.4 Maintaining IBC records in accordance with RIT’s record retention policy.

11.5 Maintaining a computerized database for tracking the activity of protocols.

11.6 Maintaining IBC registration documents.

11.7 Maintaining IBC web pages.

11.8 Maintaining records of IBC training. Currently all Environmental Health & Safety training is tracked through the RIT Center for Professional Development.

11.9 Providing reminders to PIs of their IBC registration responsibilities.

11.10 Assisting PIs with the IBC registration process.

11.11 Initiating and tracking annual protocol renewal forms and protocol terminations.

11.12 Notifying PIs of approval continuations and expiration dates.

11.13 Corresponding with the NIH and other regulators as directed by the Chair.

11.14 Providing clerical support to the Chair and the BSO.

11.15 Retaining a non-voting position with the IBC.

**12. IBC Meetings**

The IBC shall meet at least once each year or as many times as necessary to fulfill its mission.

12.1 A quorum consists of a total of 6 voting members, including 1 non-RIT affiliated members and 5 RIT affiliated members who have the collective experience and expertise to review the protocols for a given meeting.

12.2 Motions for voting may be made by any voting IBC member.

12.3 Meetings are conducted in a face-to-face format. Members may contribute to IBC meetings via teleconference if they are off site and for convenience. Any teleconferencing members may complete a quorum and they may vote.

12.4 A majority vote rules but valid votes must represent the five members described in 7.1 above.

12.5 Executive sessions of the IBC are held as needed following regular IBC meetings or at other times determined by the Chair. These meetings are not open to visitors (i.e.

non-members) and may be used to discuss topics such as budgets, specific laboratory security concerns and the removal of members from the IBC.

12.6 Meetings are open to the public. Visitors are instructed through the IBC website to contact the IBC Program Coordinator for meeting dates, times and locations. IBC meeting announcements will be posted on the IBC website. Visitors are provided with an agenda but are not provided with other written or electronic information. They may receive a summary of meeting minutes, which are subject to redaction as described above in section 8.2.2.