



Handbook for Investigators using Recombinant DNA in Research

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I. Preface

A knowledge and understanding of the information presented in this handbook is essential for those investigators using or contemplating the use of recombinant DNA in their research.

II. Institutional Biosafety Committee Policies and Procedures

A. Policy

Towson University (TU) is actively committed to preserving the health and safety of its students, staff, and faculty, and to protecting the environment and the community. It is recognized that use of potentially pathogenic microorganisms and organisms containing recombinant DNA is necessary in many university research and teaching laboratories. To ensure the safe handling of these organisms, the university requires compliance with the ***NIH Guidelines for Research Involving Recombinant DNA Molecules*** and with the recommendations in the ***Biosafety in Microbiological and Biomedical Laboratories***, current edition. Compliance with other applicable federal, state, and local regulations is also required.

III. Authority, Responsibilities and Membership

A. Authority

The policies of the Institutional Biosafety Committee (IBC) as stated herein are consistent with the current ***NIH Guidelines for Research Involving Recombinant DNA Molecules*** (NIH Guidelines).

B. Responsibilities

The primary mission of the IBC is to ensure that research with recombinant DNA is conducted in full compliance with the ***NIH Guidelines***. The IBC is obligated to require information from the Principal Investigator (PI) for a thorough review of the proposed research. The quality of research is enhanced through careful planning and forethought. The cooperative efforts of the IBC and the investigators will play a significant role in the success of our research program.

Specifically, the IBC shall:

1. Review all research protocols involving recombinant DNA, which are conducted or sponsored by TU for compliance with the ***NIH Guidelines***, and approving those research projects that are found to conform to the ***NIH Guidelines***.
2. Notify the PI of the results of the IBC's review and approval.
3. Lower the containment levels for certain experiments as specified in Section III-D-2-a of the ***NIH Guidelines***.
4. Set containment levels as specified in Sections III-D-4-b and III-D-5 of the ***NIH Guidelines***.
5. Periodically review recombinant DNA research conducted at TU to ensure compliance with the ***NIH Guidelines***.

6. Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.
7. Report 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 (Office of Biotechnology Activities) within 30 days, unless the PI has already filed a report.
8. The IBC may not authorize initiation of experiments, which are not explicitly covered by the **NIH Guidelines** until NIH (with the advice of the Recombinant DNA Advisory Committee [RAC] when required) establishes the containment requirement.
9. Perform other functions as may be delegated to the IBC.
10. Maintain records of all committee meetings, inspections, protocols and personnel training.
11. Inspect TU facilities annually. Protocols performed at external facilities will be evaluated and inspected as necessary.
12. On behalf of TU, file an annual report with NIH/OBA, which includes: a) a roster of all IBC members indicating Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), or **ad hoc** consultant (if applicable); and, b) biographical sketches of all IBC members (including community members).

C. Membership

The IBC must be composed of no fewer than five (5) people who collectively have experience and expertise in recombinant DNA technology and are capable of assessing the safety of recombinant DNA research and identify any potential risk to public health or the environment. At least two members shall not be associated with TU. The committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, **Physical and Biological Containment for Recombinant DNA Research Involving Plants**, require prior approval by the IBC. The committee shall also include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, **Physical and Biological Containment for Recombinant DNA Research Involving Animals**, require IBC prior approval. A Biological Safety Officer shall be included if research at BL3, BL4, or Large Scale (greater than 10 liters) is conducted.

The IBC Chairperson will be elected annually by the IBC members. All IBC members, with the exception of the Biological Safety Officer/Environmental Health & Safety (EHS) representative, are eligible to hold this position. Members of the IBC are appointed by the IBC Chairperson for an indefinite term.

IV. Exempt Experiments

A “TU Registration Document for Recombinant DNA Experiments” form must be submitted for **all** research involving recombinant DNA. The IBC Chairperson and Biological Safety Officer/EHS representative will determine the exempt status by reviewing the registration document and confirming that the work is classified correctly according to the **NIH Guidelines**. If it is determined that an experiment is exempt, an exemption registration number will be assigned and notification will be provided to the PI.

Exempt experiments are those that:

1. Use recombinant DNA molecules that are not in organisms or viruses.
2. 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.
3. 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.
4. Consist entirely of DNA from a 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).
5. 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 Recombinant DNA Advisory Committee after appropriate notice and opportunity for public comment.
6. Do not present a significant risk to health or the environment as determined by the NIH Director, with the advice of the Recombinant DNA Advisory Committee, and following appropriate notice and opportunity for public comment.
7. Contain no more than one-half of the genome of any eukaryotic virus (all viruses from a single Family being considered identical) that are propagated and maintained in cells in tissue culture using BL1 containment (with the exceptions listed in Appendix C-1-A of the **NIH Guidelines**).
8. Use *E. coli* K12 host-vector systems (with the restrictions outlined in Appendix C-II and exceptions listed in Appendix C-II-A of the **NIH Guidelines**).
9. Use *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems (with the exceptions listed in Appendix C-III-A of the **NIH Guidelines**).
10. Use any asporogenic *Bacillus subtilis* or asporogenic *Bacillus licheniformis* strain which does not revert to a spore-former with a frequency greater than 10^{-7} may be used for cloning DNA (with the exception of those experiments listed in Appendix C-IV-A of the **NIH Guidelines**).
11. Involve the purchase or transfer of transgenic rodents for experiments that require BL1 containment.

V. Applying for Approval to Use Recombinant DNA

A. **Requirements for a Principal Investigator (PI)**

The PI of a research protocol must be a member of the TU faculty. Under special circumstances, a scientist from another institution may be eligible to use recombinant DNA at TU, but the PI of the protocol must still be a faculty member. The PI has authority over all other personnel listed on the protocol and is responsible for all aspects of the care and use of recombinant DNA.

Anyone representing TU for experiments performed outside of this institution is required to submit the appropriate paperwork to the IBC for approval prior to the start of the research. This requirement also applies to exempt experiments.

B. Registration Documents

The PI must submit a "TU Registration Document for Recombinant DNA Experiments" form (Registration Document) and an abstract describing in layman's terms, the research and its objectives for each experiment involving recombinant DNA. If research involves working with human pathogens or human blood, body fluids or tissue, a "Registration of Materials (Potentially) Infectious for Humans" form also must be completed and submitted. To avoid possible delays in the approval of an experiment, a typewritten or computer-generated form is requested. The IBC will have the forms available in Word format. Assistance is available from the IBC Chairperson, Biological Safety Officer/EHS representative or any member of the IBC. It is strongly recommended that investigators seek consultation during the planning stage of a project involving recombinant DNA.

Use of radioactive materials must be reviewed and approved by TU's Radiation Safety Officer (RSO) at the Department of Environmental Health & Safety (EHS). Submission of the protocol to the Maryland Department of the Environment (MDE) is required. Approval must be received from MDE *prior* to performing experiments using radioactive materials. Use of other hazards, including chemicals and infectious agents, must be reviewed and approved by EHS and/or the Faculty Development and Research Committee. The Institutional Animal Care and Use Committee (IACUC) must approve research involving animals. There are no expectations of involvement of human subjects at TU; therefore, all such research is prohibited at this time.

C. Submission of Registration Documents

The completed registration documents must be submitted to the IBC Chairperson for review/approval. Although IBC meetings will be held at least once per year, protocol approval may be granted at anytime throughout the year.

D. Committee Review

Upon submission, the protocol will be assigned a registration number and a pending status. New PIs will be provided with a copy of the "Handbook for Investigators using Recombinant DNA in Research" and the *TU Biosafety Manual*. The IBC will vote whether to exempt, approve, recommend that the PI provide additional information, conditionally approve with modifications or disapprove the protocol. A simple majority of voting members present at the meeting rules. Committee members listed on the protocol may be present at the meeting for the discussion but must leave the room for the vote. It is not unusual for a protocol to be approved pending specific modifications.

A notification letter and a copy of the IBC's approval of the protocol will be provided to external facilities requesting a copy.

E. Making Modifications

If a protocol is approved pending modifications, the IBC Chairperson is authorized to provide full approval once it has been determined that the revised protocol incorporates the recommended changes.

F. Final Approval Documentation

Once a protocol is approved, the PI will receive a formal approval letter from the IBC Chairperson.

VI. Other Approved Policies

A. Addenda

A PI may submit an addendum, using the Registration Document listing the registration number, to an approved protocol to make minor changes such as:

1. Addition or deletion of personnel to the protocol
2. Extension of time
3. Addition or deletion of strains of the same host or vector
4. Addition or deletion of a gene that does not significantly alter the original protocol in intent or the biosafety level

Addenda cannot be used if:

1. The changes increase the biosafety level
2. There is a change in species of the host
3. There is a change in the overall objective of the research

The IBC makes the final decision as to whether an addendum is sufficient for applying for permission for a specific procedure or change in protocol. It may be necessary to submit a new registration document.

B. Administrative Approval

The IBC Chairperson has the authority to grant interim approval for an addendum to an existing protocol. However, final approval from the IBC is required. If final approval is not granted, the PI must stop the procedure immediately upon notification of the IBC's ruling.

VII. Training

All persons involved in the use of recombinant DNA must have adequate training. The PI must be familiar with the handling of recombinant DNA samples and the guidelines outlined in this handbook, and be responsible for the training of personnel working under their supervision for work requiring Biosafety Level 2 or greater. All personnel working under the PI must have completed and signed a ***Laboratory Personnel Safety Checklist*** form prior to their beginning any work. Members of the IBC are readily available for answering questions about safe and practical handling of recombinant DNA samples.

VIII. Verification of an Approved Protocol for Grant Application

The IBC Chairperson will provide University Research Services with the registration numbers of approved protocols.

IX. Administrative Actions

Upon learning of any possibility that protocols involving recombinant DNA are performed in an unapproved or unsafe manner, the IBC Chairperson, Biological Safety Officer/EHS representative or any superior administrative officer has the authority (depending on the severity of the problem) to:

1. Warn the PI
2. Suspend approval of the protocol
3. Suspend approval of all use of recombinant DNA by the PI

Any such action will be reported to the IBC and the Department Chairperson. The IBC will act by making a recommendation to the PI. Failure to abide by the recommendation of the IBC represents possible misconduct. If this occurs, the IBC Chairperson will advise the Department Chairperson and work with them to resolve the issue.

If a protocol or all work with recombinant DNA by the PI has been suspended, a full committee meeting will be called within two weeks at which time the committee will make its recommendation. The IBC has the option to continue the suspension of approval for the use of recombinant DNA by the PI until the problem is rectified.

X. Annual Meetings

The IBC will meet at least annually. The IBC Chairperson may call for a special meeting if so required. The meeting will be conducted by the IBC Chairperson or, in their absence, the Biological Safety Officer/EHS representative. A quorum is defined as greater than 50% of the voting membership. Business can be conducted in the absence of a quorum but no action will be official until the absent members are polled for their votes of the specific business. If a member is unable to attend the meeting, they may provide comments to the IBC Chairperson for discussion at the meeting.

Minutes will be recorded by a committee member, distributed to the membership at least 1-2 weeks before the next meeting and a vote for the approval of the minutes will be held as the first order of business of each meeting.

The IBC Chairperson and the Biological Safety Officer/EHS representative will give reports on their activities since the last meeting. If any administrative actions are reported, the committee will then vote on whether or not to confirm the actions.

This will be followed by old and new business matters.

The last order of business will be the review of the protocols and addenda. This review may include comments from outside consultants but the consultants have no authority to withhold, approve or vote on protocols unless they are members of the committee.

XI. Annual Inspection of TU Facilities

At least once every twelve (12) months and prior to the annual meeting, all laboratories where recombinant DNA work is performed will be inspected by at least two (2) voting members of the committee. The inspection will include the review of records and procedures as well as a general laboratory inspection. The PI will be informed of the inspection of his or her laboratory at least one (1) day in advance. The IBC Chairperson, or a designated representative, will write the report for presentation to the full committee at the next meeting. All members of the committee must have an opportunity to sign the report. Dissenting members may add a minority viewpoint and sign only that portion.

XII. Continuing Review of Protocols

Once a year, each investigator will receive a form for each of their active protocols. They are to complete the form, note any changes (i.e., personnel, etc.) and return it promptly. Failure to do so could lead to suspension of approval to use recombinant DNA. After three (3) years, the full protocol must be submitted for review by the committee.

XIII. Annual IBC Report

The IBC Chairperson will provide an annual report to the President and the Provost stating the membership of the committee and stating that the committee has inspected the facilities. This report, indicating that all documentation is available for review, will be provided within two (2) weeks of the annual meeting.

XIV. Changing Policy

Changes to IBC policy may be made by a simple majority of voting members present at the meeting.

XV. Laboratory Policies and Procedures

The following policies and procedures have been approved by the IBC. They reflect a sincere effort to help the PI in conducting research of the highest quality and to comply with all local, state and federal regulations and guidelines pertaining to the use of recombinant DNA in research.

A. General Policies and Laboratory Procedures

1. No food or drinks are allowed in the laboratory areas where research involving recombinant DNA is performed.
2. Only authorized personnel are permitted in the laboratories where recombinant DNA work is performed. Examples include PI's, trained personnel, IBC members, EHS representatives, regulatory inspectors, building maintenance staff, approved contractors, and emergency response personnel.
3. Emergency situations that occur after normal business hours (weekdays between 7 a.m. and 4:30 p.m. excluding holidays), on weekends or during holidays should be reported to the TU Police Department (x42133). The TUPD will contact the necessary personnel for response to the situation according to established policies. The IBC Chairperson and EHS representative will maintain home and work telephone numbers of PI's responsible for each laboratory in the event contact is needed.
4. It is prohibited to perform non-exempt experiments involving recombinant DNA outside of a designated area. Common areas (e.g., cold rooms, incubators, autoclave areas, etc.) will only be temporarily used for recombinant DNA research. In the event that a designated area is needed within a large undesignated area (e.g., the greenhouse), adequate notification will be placed within this area to identify where hazards exist.
5. Transport or transfer of recombinant DNA outside of TU must have the approval of the IBC Chairperson and, if necessary, must be packaged according to Department of Transportation (DOT) requirements.
6. Requests for exceptions to these policies should be communicated to the IBC Chairperson in writing. This will reduce confusion and misunderstanding and provide documentation for future reference.

B. Emergency Procedures

Personnel Contamination Procedures and Biological Spill Procedures can be found in the ***TU Biosafety Manual***.

C. Termination of Research

The PI must notify the IBC Chairperson and Biological Safety Officer/EHS representative prior to terminating work to ensure the laboratory has been decontaminated and that biological material has been secured or properly disposed of.

XVI. Forms used by the IBC

Use only up-to-date "Registration Document for Recombinant DNA Experiments" and "Registration of Materials (Potentially) Infectious for Humans" forms. These forms are available from the IBC Chairperson or EHS representative.

XVII. Documentation

Copies of the ***NIH Guidelines for Research Involving Recombinant DNA Molecules*** (NIH Guidelines), the ***Laboratory Safety Monograph***, the ***Biosafety in Microbiological and Biomedical Laboratories*** and IBC documents are available for review. Contact the IBC Chairperson to make the necessary arrangements.

Appendix A Sections of the *NIH Guidelines* Relevant to Towson University and TU's Institutional Biosafety Committee

Section IV. Roles and Responsibilities

Section IV-A. Policy

The safe conduct of experiments involving recombinant DNA depends on the individual conducting such activities. The *NIH Guidelines* cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and environment. The *NIH Guidelines* are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and the Principal Investigator in determining safeguards that should be implemented. The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to their specifics. Each institution (and the Institutional Biosafety Committee acting on its behalf) is responsible for ensuring that all recombinant DNA research conducted at or sponsored by that institution is conducted in compliance with the *NIH Guidelines*. General recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

Section IV-B. Responsibilities of the Institution

Section IV-B-1. General Information

Each institution conducting or sponsoring recombinant DNA research which 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*. In order to fulfill this responsibility, the institution shall:

Section IV-B-1-a. Establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the *NIH Guidelines*. As part of its general responsibilities for implementing the *NIH Guidelines*, the institution may establish additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the *NIH Guidelines*. Such procedures may include: (i) statements formulated by the institution for the general implementation of the *NIH Guidelines*, and (ii) any additional precautionary steps the institution deems appropriate.

Section IV-B-1-b. Establish an Institutional Biosafety Committee that meets the requirements set forth in Section IV-B-2-a and carries out the functions detailed in Section IV-B-2-b.

Section IV-B-1-c. Appoint a Biological Safety Officer (who is also a member of the Institutional Biosafety Committee) if the institution: (i) conducts recombinant DNA research at Biosafety Level BL3 or BL4, or (ii) engages in large scale (greater than 10 liters) research. The Biological Safety Officer carries out the duties specified in Section IV-B-3.

Section IV-B-1-d. Appoint at least one individual with expertise in plant, plant pathogen, or plant pest containment principles (who is a member of the Institutional Biosafety Committee) if the institution conducts recombinant DNA research that requires Institutional Biosafety Committee approval in accordance with Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*.

Section IV-B-1-e. Appoint at least one individual with expertise in animal containment principles (who is a member of the Institutional Biosafety Committee) if the institution conducts recombinant DNA research that requires Institutional Biosafety Committee approval in accordance with Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*.

Section IV-B-1-f. Ensure that when the institution participates in or sponsors recombinant DNA research involving human subjects: (i) the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary), (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; and (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*). Institutional Biosafety Committee approval must be obtained from each institution at which recombinant DNA material will be administered to human subjects (as opposed to each institution involved in the production of vectors for human application and each institution at which there is *ex vivo* transduction of recombinant DNA material into target cells for human application).

Section IV-B-1-g. Assist and ensure compliance with the *NIH Guidelines* by Principal Investigators conducting research at the institution as specified in Section IV-B-4.

Section IV-B-1-h. Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. The Institutional Biosafety Committee Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee.

Section IV-B-1-i. 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 such projects. The institution shall establish and maintain a health surveillance program for personnel engaged in large scale research or production activities involving viable organisms containing recombinant DNA molecules which require BL3 containment at the laboratory scale. The institution shall establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant DNA-containing microorganisms that require BL3 or greater containment in the laboratory. The *Laboratory Safety Monograph* discusses various components of such a program (e.g., records of agents handled, active investigation of relevant illnesses, and the maintenance of serial serum samples for monitoring serologic changes that may result from the employees' work experience). Certain medical conditions may place a laboratory worker at increased risk in any endeavor where infectious agents are handled. Examples cited in the *Laboratory Safety Monograph* include gastrointestinal disorders and treatment with steroids, immunosuppressive drugs, or antibiotics. Workers with such disorders or treatment should be evaluated to determine whether they should be engaged in research with potentially hazardous organisms during their treatment or illness. Copies of the *Laboratory Safety Monograph* are available from 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).

Section IV-B-1-j. Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/OBA within thirty days; unless the institution determines that a report has already been filed by the Principal Investigator or Institutional Biosafety Committee. Reports 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)).

Section IV-B-2. Institutional Biosafety Committee (IBC)

The institution shall establish an Institutional Biosafety Committee whose responsibilities need not be restricted to recombinant DNA. The Institutional Biosafety Committee shall meet the following requirements:

Section IV-B-2-a. Membership and Procedures

Section IV-B-2-a-(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, require Institutional Biosafety Committee prior approval. When the institution conducts recombinant DNA research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B-3, *Biological Safety Officer*). When the institution participates in or sponsors recombinant DNA research involving human research participants, the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary); (ii) all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and (iv) final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*). Institutional Biosafety Committee approval must be obtained from the institution at which recombinant DNA material will be administered to human research participants (rather than the site involved in manufacturing gene transfer products).

Note: Individuals, corporations, and institutions not otherwise covered by the *NIH Guidelines*, are encouraged to adhere to the standards and procedures set forth in Sections I through IV (see Section IV-E, *Voluntary Compliance*). The policy and procedures for establishing an Institutional Biosafety Committee under *Voluntary Compliance* are specified in Section IV-D-2, *Institutional Biosafety Committee Approval*.

Section IV-B-2-a-(2). In order to ensure the competence necessary to review and approve recombinant DNA activities, it is recommended that the Institutional Biosafety Committee: (i) include persons with expertise in recombinant DNA technology, biological safety, and physical containment; (ii) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (iii) include at least one member representing the laboratory technical staff.

Section IV-B-2-a-(3). The institution shall file an annual report with NIH/OBA which includes: (i) a roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person, Biological Safety Office (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or *ad hoc* consultant (if applicable); and (ii) biographical sketches of all Institutional Biosafety Committee members (including community members).

Section IV-B-2-a-(4). No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Section IV-B-2-a-(5). The institution, that is ultimately responsible for the effectiveness of the Institutional Biosafety Committee, may establish procedures that the Institutional Biosafety Committee shall follow in its initial and continuing review and approval of applications, proposals, and activities.

Section IV-B-2-a-(6). When possible and consistent with protection of privacy and proprietary interest, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public.

Section IV-B-2-a-(7). 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 latter are required to make available to the public. If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response 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).

Section IV-B-2-b. Functions

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

Section IV-B-2-b-(1). 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 to the *NIH Guidelines*. This review shall include: (i) independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research; (iii) ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iv) ensuring that no research participant is enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); (v) for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations; (vi) ensuring that final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and (vii) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.

Section IV-B-2-b-(2). Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.

Section IV-B-2-b-(3). 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 is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*.

Section IV-B-2-b-(4). Setting containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.

Section IV-B-2-b-(5). Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.

Section IV-B-2-b-(6). 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 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.

Section IV-B-2-b-(7). 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).

Section IV-B-2-b-(8). 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.

Section IV-B-2-b-(9). Performing such other functions as may be delegated to the Institutional Biosafety Committee under Section IV-B-2, *Institutional Biosafety Committee*.