STATEMENT OF POLICY (UNF Approved Policy, 1.14.09)
The IBC will oversee all University activities that use recombinant DNA and biohazardous materials. The IBC, in conjunction with the University’s Environmental Health and Safety Office, will establish and periodically review procedures and regulations, and will ensure adherence to these procedures and regulations to provide for the safe use of the recombinant DNA and biohazardous materials at the University and in activities sponsored by the University. The IBC will ensure compliance with Federal and State regulations and the most current practices and procedures for the safe use of recombinant DNA and biohazardous materials. The IBC will provide oversight for recombinant DNA activities as specified in the NIH Guidelines. All persons using recombinant DNA and/or biohazardous materials at the University, or in activities sponsored by the University, will be responsible for full compliance with the NIH Guidelines, all applicable governmental rules and regulations and the University’s policies, procedures and guidelines.

STATEMENT OF PROCEDURES (UNF Approved Policy, 1.14.09)
Governance, membership, member training, meeting conduct and functions of the IBC will comply with the NIH Guidelines, any other applicable governmental rules and regulations, and the IBC’s bylaws. Additionally, the Biosafety Officer (BSO), an employee of the University’s Environmental Health and Safety Office, will be a full member of the IBC. The Chair and Committee Members will be appointed by the Provost upon recommendation of the Assistant Vice President for Research. The IBC will operate administratively under the purview of the Assistant Vice President for Research.

All University users* of recombinant DNA and/or biohazardous materials must obtain the prior approval of the IBC for the use of these materials as outlined in the IBC bylaws and must successfully complete the University’s Biosafety program annually. Any protocol utilizing humans or animals will require the independent review, and if necessary, the approval of the IRB or the IACUC, respectively. IBC approval must be obtained prior to final IRB or IACUC approval. All required approvals must be obtained prior to initiation of any work. Continued work with recombinant DNA and/or biohazardous materials will require strict adherence to rules and regulations specified in the IBC bylaws and the University’s Biosafety Manual. The BSO in conjunction with the IBC has the authority to require modification and/or cessation of activities that are deemed unsafe. All University users* contemplating the use of any Select Agent or Toxin must notify, and obtain the approval of, both the BSO and the IBC prior to ordering or bringing such materials onto campus.

*University user shall be defined as any student, staff or faculty of the University and anyone conducting activities involving any of the aforementioned substances either on property owned or operated by the University or in activities sponsored by the University.

OVERVIEW
1. The Institutional Biosafety Committee of the University of North Florida will provide oversight for all university activities, involving recombinant DNA, culturing of microorganisms, agents infectious to plants, humans, and animals, human gene therapy, cultures of tissues, organs, and cells of human origin, and U.S. Federally-defined Select Agents.
2. All recombinant DNA activities at the University of North Florida must comply with NIH guidelines which includes approval by the IBC.
4. A UNF Biosafety registration is required for all activities (research and/or teaching) that involve the use, storage, possession and/or manipulation of biohazardous materials including but not limited to infectious
agents, biological toxins, Select Agents/Toxins and/or rDNA which are supervised or conducted by UNF faculty, staff and/or students, conducted on UNF property and/or supported by funds provided by or through UNF.

5. All activities involving biohazardous materials and/or rDNA will be performed under the supervision of a UNF employee who is designated as the principal user and who is responsible for proper acquisition, use, handling, storage, transportation and disposal of the biohazardous materials.

6. All individuals working with biohazardous materials must adhere to IBC policy, procedures and rules.

7. All work with biohazardous materials will be conducted in compliance with UNF IBC/EHS policies, the current edition of CDC’s BMBL, NIH Guidelines and 42CFR 73, 9CFR121 and 7CFR331 for Select Agents.

8. It is the policy of the IBC that BSL-3 and 4 agents may not be used or stored at UNF.

9. This policy does not cover activities at UNF that only generate human biohazardous waste and are not related to research (e.g. Student Health, athletic training etc.). These activities are regulated by the BSO and Environmental Health and Safety.

INSTITUTIONAL BIOSAFETY COMMITTEE BYLAWS CONTAINING POLICIES AND PROCEDURES

A. IBC Responsibilities
   a. UNF’s IBC is the appropriately constituted group designated to review and monitor all activities involving infectious agents (human, animal and/or plant), biological toxins, Select Agents/Toxins and/or rDNA in accordance with NIH guidelines and CDC BMBL requirements. To this end, the IBC is responsible for approving, requiring modification to secure approval, deferring or disapproving research involving biohazardous materials or rDNA.

   b. The IBC is empowered with the authority along with Environmental Health and Safety to suspend or terminate activities involving biohazardous materials and/or rDNA for [1] activities and/or practices that jeopardizes the health and safety of any UNF faculty, staff member, student, volunteers and/or visitors, [2] repeated safety violations and/or [3] continued noncompliance with IBC regulations and policy.

   c. The IBC operates administratively under the purview of the Assistant Vice President for Research. The IBC is responsible for advising the Assistant Vice President for Research on all matters pertaining to the safe use of biohazardous materials and/or rDNA.

   d. The IBC in consultation with the Assistant Vice President for Research is responsible for notifying the NIH/OBA and/or CDC of incidents or continuing noncompliance with IBC policy or applicable federal regulations.

   e. The IBC works with the BSO and Environmental Health and Safety to:
      i. Establish and enforce guidelines, policies, and procedures for the safe use of biohazardous materials at UNF;
      ii. Assure compliance with appropriate federal/state/local regulations;
      iii. Monitor and regulate safe use of biohazards; and,

B. IBC Membership
   a. Per NIH guidelines, UNF’s IBC will have ≥ five members appointed by the Provost upon recommendation of the Assistant Vice President for Research including two members external to the UNF community, a scientist with expertise in rDNA techniques, a scientist with expertise in biological safety and physical containment, a member representing UNF scientific staff, a member representing UNF laboratory technical staff and a member with expertise in the use of biohazardous materials in teaching.

   b. The Chairperson will be a tenured full-time UNF faculty member who is appointed by the Assistant Vice President for Research in consultation with the Environmental Health and Safety Office. The Assistant Vice President for Research may reappoint or remove the Chair.

   c. The Biosafety Officer (BSO), an employee of Environmental Health and Safety Office, is a full member of the IBC.
d. The IBC may appoint ad hoc temporary members to assist in the review of pending applications. Temporary members will not necessarily be appointed by Provost but as deemed necessary by the Committee. An ad hoc member has voting privileges only for specific proposals. Proposals on which ad hoc members may vote will be specifically identified by the IBC prior to the appointment.
e. In the following cases, the composition of the IBC will be increased by adding ad hoc temporary members to include the appropriate expertise. If rDNA research involving human subjects is proposed, the IBC must include a scientist with expertise in this area. If rDNA research involving plants is proposed, at least one scientist with expertise in plant pest containment must be a member. If rDNA research involving animals is proposed, at least one scientist with expertise in animal hazard containment must be a member.
f. No member of the IBC may be involved (except to provide information required by the 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.
g. Biosketches for each member will be maintained in the Office of Research and Sponsored Programs.
h. The IBC shall maintain diverse membership representing the community and a variety of University interests.
i. Members will serve three year terms but may be appointed for sequential terms.

C. Training of IBC Members
a. All IBC members must undergo no less than one training session per three year term. Training will be offered by UNF on an “as needed” basis.
b. Training will include but not necessarily be limited to IBC committee structure and function, NIH guidelines and basic principles of Biosafety.

D. Access to IBC Records and Activities
a. The IBC encourages university personnel and public citizens to participate in IBC activities.
b. The Office of Research and Sponsored Projects (ORSP) will make available all meeting minutes, proposals, and actions on proposals to any person making such requests. UNF reserves the right to ask the person requesting information cover the cost of providing these materials.

E. IBC Meetings
a. The IBC will hold regular meetings at least twice per year when UNF is not “closed for business”. Additional meetings will be called on an ad hoc basis based upon the workload. Non-exempt proposals for IBC review will trigger a meeting of the Committee in a reasonable time after being submitted.
b. Meetings will not take place by email. Members can join by conference call.
c. Meeting Minutes will include the following information: time, date, and place of meeting; approval of prior meeting minutes; individuals in attendance; whether the meeting was open or closed; all major motions and their outcome; major points of discussion with committee’s rationale for decisions; time of meeting adjournment and documentation that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the NIH Guideline.
d. IBC meeting times dates, and locations will be posted on the ORSP website and in the UNF Campus Update and Public Calendar no less than three days prior to the meeting.
e. A quorum is required in order to conduct IBC business. To establish a quorum the number of committee members present must equal one more than half of the total membership. A passing vote will be a simple majority of members present; minority views will be recorded in the minutes.

F. IBC Chairperson
The responsibilities of the IBC Chairperson include but are not limited to:
a. Conduct meetings in an orderly manner.
b. Conduct business so that each registration application is fairly and completely reviewed and that the committee reaches a decision of the deposition of each application.
c. Sign correspondence on behalf of the IBC.
d. Appoint a Vice Chairperson following consultation and agreement by a majority of IBC members to assume responsibilities of the Chairperson during any period of absence.
e. Preparation and filing of the annual IBC report to NIH/OBA in conjunction with ORSP.
G. Institutional Biosafety Officer (BSO)
The responsibilities of the BSO will include but are not limited to:
a. Periodic inspections of laboratories including all records to ensure that standards are rigorously followed with proper adherence to federal, state, and University regulations and IBC policies.
b. Reporting to the IBC any significant biohazard safety problems, violations of the NIH Guidelines and any significant Biosafety-related accidents or illnesses of which the BSO becomes aware unless the BSO determines that a report has already been filed by thePrincipal User.
c. Developing emergency plans for handling accidental spills and personal contamination and investigating laboratory accidents involving recombinant DNA research or biohazardous materials.
d. Providing advice on laboratory security.
e. Monitoring external regulatory trends and communicating these to the IBC.
f. Serving as a voting member of the IBC.
g. Providing technical advice to Principal Users and the IBC on research safety procedures.
h. Screening research applications in order to make recommendations to the IBC.

H. Office of Research and Sponsored Projects (ORSP)
The ORSP will serve as support staff for the IBC and will perform the following duties:
a. Maintain the roster of IBC members and collect members curriculum vitae.
b. Schedule IBC meetings and arrange for rooms for the meetings.
c. Post meeting times and location per regulations.
d. Distribute relevant materials prior to the meeting.
e. Compile and maintain the minutes of the IBC meetings in compliance with regulatory requirements.
f. Maintain all IBC documentations and records.
g. Facilitate communication between Principal Users and the IBC.
h. Track progress of applications submitted to IBC.
i. Serve as a resource and liaison for Principal Users.

I. The Principal User
The responsibilities of the Primary User will include but are not limited to:
a. Make initial determination of required levels of physical and biological containment in accordance with NIH guidelines and the BMBL.
b. Select appropriate microbiological practices and lab techniques;
c. Prior to initiation of activities (including possession) with biohazardous materials and/or rDNA must:
   i. Submit a completed application and proposed modifications to approved projects
   ii. Make available to all lab staff and involved facilities staff the protocol that describes potential biohazards and precautions to be taken;
   iii. instruct and train all personnel in protocol specific procedures including those to ensure safety, dealing with accidents and spills, and the reasons and provision for any precautional practices.
d. Ensure transportation will comply with all applicable and package and shipping requirements.
e. Supervise to ensure safety performance and practices during activities employing biohazardous materials and/or rDNA.
f. Ensure that all rules and regulations of EHS regarding the safe use of biohazardous materials including the reporting of any significant problem regarding operations and implementation of containment practices and procedures, biological spills, accidents, containment failure or deviations from practice which results in the release of biohazardous material and/or exposure of lab occupants or the public to biohazardous material are adhered to by all users under his/her supervision.
g. Restrict access to lab to qualified individuals per regulations.
h. Develop and implement written lab specific Biosafety procedures and containment practices to ensure that all persons who have potential to be exposed are informed in advance of potential risk and safety procedures.
i. Ensure all maintenance work is conducted only after equipment and laboratory area is thoroughly decontaminated.

j. Complete all training as required by IBC/EHS.

J Workers with Biohazardous Materials including rDNA
a. Any person working with biohazardous materials including rDNA at UNF or under funding provided by or through UNF will work under the direction of a Principal User, complete all required training, follow lab specific Biosafety practices and procedure, inform the Principal User of personal health requirements that may require further safety precautions and report to all problems, deviations and spills safety and security concerns to the Principal User and if necessary to the BSO/IBC.

POLICIES AND PROCEDURES FOR RECOMBINANT DNA ACTIVITIES AT UNF

Recombinant DNA Definition

The "NIH Guidelines" provides a list of covered experimental uses of recombinant DNA that are considered biohazardous and a separate list of exempt experimental uses of recombinant DNA that are not considered biohazardous. These lists are found in Section III of the "NIH Guidelines".

In the context of the NIH Guidelines, recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above. Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

IBC Responsibilities

In order for the IBC to review, approve, and oversee practices and procedures related to all activities involving rDNA, the IBC in conjunction with EHS will

a. Review and/or approve rDNA research and teaching projects for compliance with the NIH Guidelines and notify the investigator or instructor about the outcome of the review before the work commences. The review will entail examination of a number of matters, including

- Assessment of [1] potential risks to health and the environment for the activity, contingency plans for handling accidental spills and personnel contamination, [2] containment levels required by the NIH Guidelines for the proposed activity (IBC will lower 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. IBC will set containment levels as specified in Sections III-D-4-b, Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants), [3] of facilities, procedures, practices, and training/ expertise of personnel involved in rDNA activities;
- Description of how work will comply with all aspects of NIH Guidelines Appendix M;
- Assurance 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), Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained; 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; Final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, RAC Review Requirements).

- Compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines.

b. Notifying the applicant of the outcome of the IBC review.

c. Formulate, monitor and enforce campus policy and procedures for the safe use and handling of recombinant molecules including procedures for handling spills and contamination.

d. Advise the Assistant Vice President for Research on all matters relating to the safe use of rDNA.

e. Assist PIs to meet their teaching and research responsibilities when using recombinant DNA materials.

f. Recommend to the BSO and Assistant Vice President for Research modifications, suspension or termination of projects to assure compliance with regulatory policies.

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

h. File an annual report with NIH/OBA which includes [a] A roster of IBC members with clear indication of Chair and BSO and contact person, Plant, Animal or Human Gene Therapy expert or ad hoc member if applicable. [b] Biographical sketches of all IBC members.

i. Annually review rDNA research conducted at UNF to ensure compliance with the NIH Guidelines.

j. Approve EH&S emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

k. Ensure that all IBC protocols, minutes, agenda and related correspondence (including that with regulatory agencies) will be housed in ORSP.

PROCEDURES FOR APPLICATION AND APPROVAL AND CONTINUATION OF APPROVAL OF rDNA ACTIVITIES AT UNF INCLUDING BOTH TEACHING AND RESEARCH.

A UNF registration is required for all activities that involve the storage, possession and use or manipulation of rDNA on the UNF campus or in activities funded by or through UNF. The Principal User (UNF faculty member or research scientist) will make application but all users are responsible for full compliance with the NIH Guidelines in the conduct of rDNA activities including reporting requirements, and will be held accountable for any reporting lapses. Student researchers and technical staff must work under the direction of a Principal User.

INITIATION OF rDNA PROJECTS

[1] All UNF persons (faculty, research scientist, technical staff, and students) using or proposing to use rDNA in any activity must successfully complete UNF’s Biosafety Training Program and read the relevant portions of the current NIH Guidelines and UNF’s Biosafety Guidelines (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) prior to initiation of any rDNA work and on an annual basis.

[2] Any protocol utilizing humans or animals must receive IBC or IACUC approval respectively prior to initiation of work. IBC approval must be obtained prior to final IRB or IACUC approval.

[3] Protocols for rDNA activities must be completed by the primary investigator or instructor using specific forms (IBC website). Protocols will be submitted as a hard copy and efile to ORSP for initial review and disposition.

[4] Prior to submission of proposals for internal or external funding for any new or substantially changed existing protocols using rDNA, the applicant must gain approval from the BSO that the appropriate facilities and expertise are available for such work.

[5] The review process will be as follows:

- The BSO can approve rDNA applications that are exempt (NIH Guidelines III-F). Approved exempt applications are presented at the next IBC meeting.
Applications for non-exempt projects (III-E, D, C, B, A) will be reviewed by the IBC at a regular or convened meeting after initial review by the BSO in a timely manner. Review by the IBC will include an assessment provided by the BSO of the proposed Biosafety Level and facilities, procedures, training and other factors deemed necessary for the safe conduct of the project.

ANNUAL REVIEW AND THREE YEAR RESUBMISSION

[1] Exempt Protocols. An annual report (reviewed by BSO and presented at next IBC meeting) and a resubmission every three years.


[3] The IBC may require more frequent review of protocols in the case of an adverse events or near-misses etc.

SUBSTANTIAL CHANGES TO PROTOCOLS

Any substantial modification of a non-exempt or exempt project will require prior approval of the BSO and if the BSO deems necessary IBC approval. The investigator must report a significant change in the research protocol prior to initiation of the change via a letter of modification addressed to the IBC. Significant changes include, but are not limited to the following:

a. Change in review category
b. Change in biosafety level
c. Change requiring additional approvals (e.g., IRB, ACC, etc)
d. Change in infectious agent
e. Any change involving a select agent
f. Any change involving research in review category I of IBC Form A- Use of rDNA in Research.

POLICIES AND PROCEDURES FOR THE USE OF BIOHAZARDOUS MATERIALS

Definition of Biohazardous Materials

Biohazards are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or the environment. The risk can be direct through infection or indirect through damage to the environment.

Biohazardous materials include certain types of recombinant DNA; organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia); and biologically active agents (i.e. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment or community.

Biological materials you may not consider to be biohazardous maybe regulated by regulations and guidelines as biohazardous materials.

Organisms

The CDC, NIH and other government agencies and professional organizations provide listings and information on organisms and viruses considered to be biohazardous or infectious agents. Any organism or virus listed in Risk Group (RG) two, three, four or that requires Biosafety Level (BL) two, three or four containment is considered biohazardous.

IBC Responsibilities

In order for the IBC to review, approve, and oversee practices and procedures related to all activities involving rDNA, the IBC in conjunction with EHS will


[2] Review and/or approve research and teaching projects involving biohazardous materials prior to their implementation.
[3] Inspect laboratory space where the proposed use of biohazardous materials will take place to ensure that requested containment levels are adequate.

[4] Advises the Assistant Vice President for Research on all matters relating to the safe use of biohazardous materials on campus.


[6] Recommends modifications, suspension or termination of projects to assure compliance with regulatory policies.


[8] Ensure that all IBC protocols, minutes, agenda and related correspondence (including that with regulatory agencies) will be housed in Office of Research and Sponsored Programs.

PROCEDURES FOR APPLICATION AND APPROVAL AND CONTINUATION OF APPROVAL OF USE OF BIOHAZARDOUS MATERIALS AT UNF INCLUDING TEACHING AND RESEARCH.

A UNF registration is required for all activities that involve the storage, possession use or manipulation of biohazardous materials including any activities supervised and or conducted on campus by any persons. UNF staff and faculty using of campus and by funds provide by or through UNF.

[1] Prior to initiation of any protocol using biohazardous materials in any activity including teaching and research, all users must read UNF’s current Biosafety Manual, and complete UNF’s biosafety program and lab-specific training. All persons utilizing infectious agents for any activity must read the relevant portions of Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition from the CDC and NIH accessed at http://www.cdc.gov/od/ohs/pdffiles/4th_BMBL.pdf. All training must be repeated annually.

Prior to submission of proposals for internal or external funding for any new or substantially changed existing protocols using biohazardous material, the applicant must gain approval from the BSO that the appropriate facilities and expertise are available for such work.

[2] Student researchers and technical staff must work under the direction of a Principal User who must be a UNF faculty member or research scientist. The Primary User will submit applications as hard copies and efiles to ORSP for the use of biohazardous materials, animal or plant etiologic agent, select agent, and cultures of tissues, organs or cells of human origin using forms available at ORSP (IBC website). ORSP will send applications to the BSO for initial review and disposition.

[3] The BSO can approve applications at BSL-1 (exempt biohazardous protocols) and which do not use rDNA but applications at BSL-2 or higher will be reviewed by the IBC at a convened meeting. The initial review by the BSO will include an assessment of the proposed Biosafety level and facilities where the work will be undertaken. The BSO may consult at her/his discretion with members of the IBC or any other sources of expertise as is deemed appropriate.

[4] Both exempt and non-exempt protocols will be subject to annual review by the IBC and require resubmission every three years. The IBC may require more frequent review of protocols. For example, an adverse events or near-misses will require a review of the protocol. Forms are available from ORSP.

[5] Any substantial modification of a non-exempt or exempt project will require prior approval of the BSO and if the BSO deems necessary IBC approval. The investigator must report a significant change in the research protocol prior to initiation of the change. Proposed changes can be reported to the IBC via a letter of modification addressed to the Chair of the IBC. Significant changes include, but are not limited to the following:

a. Change in review category
b. Change in Biosafety level
c. Change requiring additional approvals (e.g., IRB, ACC, etc)
d. Change in infectious agent
e. Any change involving a select agent
SPECIFIC POLICIES FOR USE OF SELECT AGENTS

All investigators contemplating the use of any agent or toxin on this list must contact the UNF Environmental Health and Safety Office at 904 620-2019 and abide by the rules of DHHS and USDA. Prior approval is needed from both the BSO and the IBC.

APPENDIX A

SUMMARY OF SECTION III of the NIH GUIDELINES for rDNA RESEARCH

Adapted from Section III of the 2002 NIH Guidelines. Please review the criteria listed in the full version of the NIH Guidelines to ensure that your study meets the criteria of the summarized versions listed below.

**Note:** If an experiment falls into Sections III-A, III-B, or III-C and one of the other sections, the rules pertaining to Sections III-A, III-B, or III-C shall be followed. If an experiment falls into Section III-F and into either Sections III-D or III-E as well, the experiment is considered exempt from the NIH Guidelines.

**SECTION III-A:** Experiments that Require Institutional Biosafety Committee Registration, RAC Review, and NIH Director Approval Before Initiation

III-A-1-a: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

**SECTION III-B:** Experiments That Require NIH/OBA and Institutional Biosafety Committee Registration Before Initiation

III-B-1: Cloning of Toxin Molecules with LD<sub>50</sub> of <100ng/kg of body weight.

**SECTION III-C:** Experiments that Require Institutional Biosafety Committee Registration and Institutional Review Board and RAC Approval Before Research Participant Enrollment

III-C-1: Deliberate transfer of rDNA, or DNA or RNA derived from RDNA into human subjects.

**SECTION III-D:** Experiments that Require Institutional Biosafety Committee Registration Before Initiation

III-D-1-a: Introduction of rDNA into Risk Group 2 agents conducted at BL-2 or ABL-2N.

III-D-1-b: Introduction of rDNA into Risk Group 3 agents conducted at BL-3 or ABL-3N.

III-D-1-c: Introduction of rDNA into Risk Group 4 agents conducted at BL-4 or ABL-4N.

III-D-1-d: Introduction of rDNA into restricted agents at BL4 or BL4-N not permitted except on a case-by-case basis following NIH/OBA review and USDA permit.

III-D-2-a: DNA from Risk Group 2 or Risk Group 3 agents transferred into nonpathogenic prokaryotes or lower eukaryotes or exempt from the NIH Guidelines (see Section III-F).

III-D-2-b: DNA from Risk Group 4 and restricted agents transferred into nonpathogenic prokaryotes or lower eukaryotes not permitted except on a case-by-case basis following NIH/OBA review and FDA permit.
III-D-3-a: Infectious or defective (defective eukaryotic viruses contain < 2/3 of the genome) Risk Group 2 viruses in the presence of helper virus in tissue culture may be conducted at BL-2.

III-D-3-b: Infectious or defective Risk Group 3 viruses and prions in the presence of helper virus in tissue culture may be conducted at BL-3.

III-D-3-c: Infectious or defective Risk Group 4 viruses in the presence of helper virus in tissue culture may be conducted at BL-4.

III-D-3-d: Infectious or defective restricted poxviruses in the presence of helper virus in tissue culture not permitted except on a case-by-case basis following NIH/OBA review and USDA permit.

III-D-3-e: Infectious or defective viruses in the presence of helper virus in tissue culture not covered in III-D above may be conducted at BL1. IBC reserves right to determine Risk Group Classification for novel agents.

III-D-4-a: rDNA, or DNA or RNA molecules derived from DNA except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism. Animals with sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly under BL1 or BL1-N. Introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-D-4-b. Modified Risk Groups 2 and higher see Sections V-A, V-G, and V-L.

III-D-4-b: rDNA, or DNA or RNA derived from DNA involving whole animals not covered in Sections III-D-1 or III-D-4-a. Containment determined by the Institutional Biosafety Committee.

III-D-4-c: Exceptions under Section III-D-4: Generation of transgenic rodents that require BL1 containment are described under Section III-E-3 and the purchase or transfer of transgenic rodents is exempt from the NIH Guidelines under Section III-F.

III-D-5-a: Recombinant techniques with exotic infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants. BL3-P

III-D-5-b: Plants with cloned genomes of readily transmissible exotic infectious agents that may reconstitute by genomic complementation.

III-D-5-c: Readily transmissible exotic infectious agents, such as the soybean rust fungus, maize streak or other viruses in the presence of their specific arthropod vectors. BSL-4P

III-D-5-d: Sequence encoding vertebrate toxins introduced into plants or associated organisms. BL-3P

III-D-5-e: Microbial pathogens of insects or small animals associated with plants if the rDNA-modified organism has a recognized detrimental impact on ecosystems.

III-D-6: Experiments involving more than 10 liters of culture. IBC determines containment level (See Appendix K)

SECTION III E: Experiments Requiring IBC Registration Before Initiation

III-E-1: Formation of rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus in tissue culture. BL-1 with no helper virus. IBC classifies retroviral vectors with packaging system capable of infecting human cells as BL-2.

III-E-2-a: rDNA-modified plants and rDNA-modified organisms not in section III-E-2-b. BL-1-P.

III-E-2-b: Plants modified by rDNA that are noxious weeds or can interbreed with noxious weeds. Plants with rDNA that represents the complete genome of a non-exotic infectious agent. Plants associated with rDNA-modified non-exotic microorganisms with and rDNA-modified exotic microorganisms with no recognized potential for serious
impact on ecosystems. rDNA-modified arthropods or small animals associated with plants or with arthropods or small animals associated with them if the rDNA-modified microorganisms have no serious impact on ecosystems. BL-2-P.

III-E-3: Generation of rodents with stable introduction of DNA into the animal’s genome if BL-1. Otherwise see Section III D-4.

SECTION III-F: Exempt Experiments (require IBC registration before initiation)

III-F-1: No organisms or viruses.

III-F-2: DNA segments from a single nonchromosomal or viral DNA source.

III-F-3: DNA from a prokaryotic host when propagated only in that host or when transferred to another host by well established physiological means.

III-F-4: DNA from an eukaryotic host when propagated only in that host.

III-F-5: DNA segments from different species that exchange DNA by known physiological processes.

III-F-6: Those that do not present a significant risk to health or the environment as determined by NIH & RAC.

Appendix C: Exemptions under III-F-6
Appendix C-I rDNA (not virus sector) in tissue culture. (See C-IV for exceptions)
Appendix C-II E.coli K-12 host-vector systems. (See C-II-A for exceptions)
Appendix C-III Saccharomyces host-vector systems (See C-III-A for exceptions)
Appendix C-VI Purchase or transfer of transgenic rodents