Mission and Oversight

The mission of the Duke University IBC is to:
1) ensure that all recombinant DNA research conducted at the institution or sponsored by the institution is conducted in compliance with the National Institutes of Health Recombinant DNA Guidelines, and
2) ensure that all research protocols involving Select Agents (defined by 42 CFR 73) are reviewed and found to comply with all national, state, and local requirements
3) ensure that all laboratory work conducted at Biosafety Level 3 containment or Animal Biosafety Level 3 is reviewed and found to comply with all national, state, and local requirements
4) respond to requests from other institutional entities (e.g., Employee Occupational Health and Wellness, Division of Laboratory Animal Resources) or individuals for other types of biosafety review

The Duke University IBC has responsibility for such research throughout the entire Duke University enterprise. IBC members are jointly appointed by the Chancellor of Health Affairs and the Provost of Duke University. The Duke Occupational and Environmental Safety Office (OESO) staff will support the IBC in carrying out its mission. The IBC is authorized to inspect research facilities, approve research practices and procedures, and to take actions, such as enforcement of cessation of laboratory or clinical research activities, in the event of an unsafe workplace situation.

Structure and Function of the IBC

I. Membership

a. The committee consists of at least five members appointed by Duke authorities (see above), including the Biological Safety Officer (BSO), and at least two members external to the institution (community members). Membership and qualifications are in compliance with Sections IV-B-2-a and –b of the NIH Guidelines. In addition, there is representation from the medical faculty for review of Gene Transfer or Therapy protocols. Other ad hoc members may be called upon for specific expertise needs,
depending on the research involved (ex., plant experts for plant protocols).
b. Members are appointed for a five year term that may be extended based on specific IBC or institutional needs.
c. Membership may be suspended by a majority vote of the IBC for members or their alternates who attend less than 50% of those IBC meetings for which their expertise is relevant over a one-year period.

II. Staff, Meeting Schedules, and Voting

a. The Office of the Biological Safety Division of OESO (BSD) will be responsible for keeping records, recording minutes, and scheduling meetings for the IBC. This will include review of submitted protocols for completeness of information required for IBC review.
b. The IBC will meet every month, and when necessary, to expedite the approval process. The IBC will follow the following procedures:
   i. All proposals will be due in complete form in the BSD 14 calendar days in advance of the IBC meeting.
   ii. The BSO will request protocol modifications and corrections by Email, identifying a deadline for corrected protocol submission 7 calendar days prior to the IBC meeting.
   iii. Applications received after day 14 or incomplete after day 7 prior to a meeting will be held over until the next month. Exceptions to this policy will require approval by the BSO and one of the two IBC co-chairs.
   iv. The BSO will finalize the protocols and agenda 5 days prior to the IBC meeting, and send an Email notification to all members. No changes will be accepted after this date.
   v. IBC Core members (IBC co-chairs, BSO, and a DLAR representative) will review protocols in advance to identify protocols requiring specialized expertise; the co-chairs will assure appropriate expertise is available for review of the protocols.
   vi. A quorum for the meeting is defined as at least 5 IBC members, at least one of which must be an external (community) member.
   vii. The IBC approves protocols by a majority vote of the membership at a designated meeting. Although information regarding protocols may be communicated by e-mail, voting must occur at a designated meeting.
   viii. No member of the IBC will vote on a protocol with which he or she has any connection or in which he or she has a personal or professional interest other than as a member of the IBC. [See “Principal Investigator (PI) presence and
participation in Duke Institutional Biosafety Committee (IBC) meetings” Policy]

ix. The final result of the voting for each protocol will be recorded, along with any comments and recommendations, and will be communicated to the PI of the protocol. Any recommendations for other committee review (i.e., Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)) will be communicated by the BSO on behalf of the IBC chair.

x. The IBC will provide NIH OBA any public comments on the IBC actions, along with the IBC response to the comments, within 30 days of such public comment.

c. No project requiring IBC approval will commence prior to IBC approval of the protocol.

d. PIs will be notified annually and asked to complete an annual update form for continuing projects to document that information regarding gene constructs, work procedures, locations, animal use, new personnel training, or other significant changes are current with the IBC records. Any problems associated with the work, including violations of guidelines, accidents or illnesses associated with the protocol, or adverse events (in the case of human clinical trials) must be reported to the IBC, and, after review, may require a significant change or amendment to the protocol, re-review of the protocol by the IBC, and/or reporting to the NIH Office of Biotechnology Activities (OBA).

III. IBC Minutes

a. The BSO will develop meeting minutes for approval at the subsequent meeting of the IBC.

b. The minutes will include the date of the IBC meeting, location, meeting attendees, rDNA or IBC business, a list of protocols that includes for each the IBC number, the PI name, title of the protocol, a brief description of whether the work involves human, animal, or plant; rDNA information (viral vector, plasmids), the approved biosafety level of containment, and the applicable section of the NIH rDNA Guidelines.

c. Sensitive identifiers, such as PI name or specific animal information, will not be included in the minutes describing rDNA review so that these minutes can be posted on an IBC website after final approval.

d. The Minutes will reflect the final deliberation of the IBC for each protocol with the following status terms:

   i. Approved: Exempt. The protocol was determined by the IBC to be exempt. No further requirements.

   ii. Approved: No modifications necessary
iii. **Approved contingent on receipt of the following modifications and/or additional materials within 21 days of notice:** Requested modifications or clarifications that are sent within the time frame can be reviewed and final approval given by the BSO without subsequent review at an IBC meeting.

iv. **Pending.** PI must respond with the following modifications and/or additional materials within 21 days of notice: Requested modifications are to be received within the time frame for subsequent review at an IBC meeting.

v. **Protocol review terminated by IBC, reapplication is required.** Administrative termination when the PI does not provide a responsive reply within 21 days of request. A new registration is required, and will be provided a new IBC number.

vi. **Rejected.** Protocol is rejected because the IBC feels the work cannot be conducted safely, the risks outweigh the benefit, or other reasons.

e. Members of the public requesting copies of the IBC minutes will be directed to that web-site or provided with printed copies if desired.

**General Policy for IBC Oversight**

All work involving rDNA that is not exempt from the NIH Guidelines must be registered with the Safety Office. In addition, the following types of rDNA experiments must be **reviewed and approved** by the IBC prior to initiation of work:

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 drug to control human, animal, or plant diseases,

b. The cloning of toxin molecules with LD50 of Less than 100 nanograms per kilogram body weight, and

c. The deliberate transfer of rDNA into humans.

**NOTE:** The 3 types of experiments above must also be approved by the NIH RAC and/or OBA.

d. The use of Risk Group 2, 3, or 4 or restricted organisms as Host-vector systems,

e. The cloning of DNA from Risk Group 2, 3, or 4 or restricted organisms into non-pathogenic prokaryotic or lower eukaryotic host-vector systems,

f. The use of infectious or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems,
g. The involvement of rDNA with whole animals,
h. The involvement of rDNA with whole plants,
i. The involvement of more than 10 liters of culture involving rDNA,
j. Those not included in the above categories in which all components are derived from non-pathogenic prokaryotes and lower eukaryotes,
k. Those involving the formation of rDNA molecules consisting of no more than two-thirds of the genome of any eukaryotic virus,
l. Any work with the CDC Select Agents (PI must be registered with the CDC, as well as receive approval from the IBC)

The following experiments are EXEMPT from the NIH Guidelines and only require registration with the Biological Safety Office:

a. rDNA molecules that are not in organisms or viruses,
b. Those that consist entirely of a single DNA segment from a single nonchromosomal or viral DNA source, though one or more may be a synthetic equivalent,
c. Those that consist entirely of DNA from a single prokaryotic host (including its plasmids or viruses) when propagated only in that host (or closely related strain) or when transferred to another host by well established physiological means,
d. Those that consist entirely of DNA from a single eukaryotic host (including chloroplasts, mitochondria, or plasmids) when propagated only in that host (or closely related strain),
e. Those that consist 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 (see NIH Guidelines for a list of these exempt exchangers),
f. Those that do not present a significant risk to health or the environment (see NIH Guidelines for this list).

Procedure for IBC Protocol Registration and Review:

i. Principal Investigators must submit a rDNA registration form for all protocols involving non-exempt experiments involving rDNA to the BSD at least two weeks prior to the IBC meeting.
ii. After initial review of the protocols by the IBC Core members (IBC co-chairs, BSO, and a DLAR representative), investigators may be asked to modify or correct protocols. All modifications and corrections must be submitted to the Safety Office at least 7 days prior to the IBC meeting.
iii. The BSO will finalize the protocols and agenda 5 days prior to the IBC meeting. No changes will be accepted after this date.
iv. IBC registration deadlines and meeting dates will be posted on the IBC website.
v. An electronic rDNA survey tool has been developed to assist PIs in understanding their responsibilities under the rDNA Guidelines. (See
OESO training website courses: rDNA Survey. The survey communicates requirements for additional review of some types of research. The survey must be completed by all Principal Investigators once a year. PIs remain responsible for making the determination of whether their work is exempt from the NIH Guidelines. PIs are also responsible for understanding and complying with the NIH Guidelines.

vi. Experiments involving deliberate transfer of rDNA into human subjects must also be reviewed by the NIH OBA (Appendix M of the NIH Guidelines) and the Duke IRB. The PI must also notify the Duke Clinical Research Pharmacy for approval of a process for handling the material for patient delivery and Duke Hospital Infection Control for proper patient care precautions when a viral vector is used in a clinical trial.


viii. Experiments using any Select Agents as defined by 42 CFR 73 must be registered by the CDC or USDA. The BSO will coordinate the registration process. Research protocols using Select Agents must also be approved in advance by the IBC.

ix. A “Standard Operating Procedure” (SOP) must be submitted for any work using viral vectors or requiring BSL2, ABSL2, BL2-P, BL2-N, BL2-LS, or higher containment. This would include any work that uses human blood, body fluids, or cell lines. The BSO or the IBC may also require an SOP for other types of work.

x. Protocols will expire 3 years after the approval date.

Specific Responsibilities

I. IBC:

a. Reviews protocols for compliance with the NIH rDNA Guidelines including the following

   i. Assessment of the containment levels required by NIH, OSHA, and CDC Guidelines for the proposed activity
   ii. Assessment of the laboratory facility, practices and procedures, and training as presented for the protocol
   iii. Assessment of the emergency plan covering spills and personnel exposures resulting from such activities

b. Periodically reviews guidelines for activities involving rDNA to ensure compliance with all federal agencies

c. Reports to NIH on an annual basis:

   i. A roster of IBC members and noting the chair
   ii. Biographical sketches of all IBC members, including community members
d. Reports incidents involving rDNA to NIH OBA:
   i. Any significant problems with rDNA research, significant violations of the NIH Guidelines, or significant research-related accidents and illnesses will be reported to NIH OBA within 30 days of the notification of the IBC. The following are examples of reportable incidents:
   - Skin puncture with a needle containing recombinant DNA
   - The escape or improper disposition of a transgenic animal
   - A spill of high-risk recombinant materials occurring outside of a biosafety cabinet (BSC).
   
   ii. The following incidents will be reported to NIH OBA immediately upon notification:
   - Spills or accidents resulting in an overt exposure to microbes containing rDNA that are assigned to BL2 containment
   - Spills or accidents resulting in overt or potential exposure to microbes containing rDNA that are assigned to BL3 containment
   
   iii. The NIH OBA will be consulted if there is uncertainty as to whether reporting is warranted.

e. Reports any public comments or questions received regarding rDNA or IBC business to the NIH OBA.
   a. Establishes procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities.
   b. Insures that all DNA research involving human subjects be addressed by requirements in Appendix M of the NIH Guidelines, consider the recommendations made by the NIH RAC review, insure that research participants are not enrolled in the proposed study until the RAC review process has been completed and approval has been given by the IBC, IRB, and any other applicable regulatory authorizations.

2. Biological Safety Division Office (BSD)
   a. Keeps a database of Duke IBC registered and approved protocols
   b. Receives protocol applications and prepares them for IBC review and/or approval
   c. Ensures that all laboratories submitting IBC registrations for approval have been audited for compliance with the proper safety levels, and conducts annual laboratory audits to ensure compliance with the NIH Guidelines
   d. Keeps records of IBC registrations, viral vector registrations, any correspondence with PIs and the IBC members, and minutes of IBC meetings.
e. Annually records the renewals of continuing projects, or discontinues completed ones.
f. Communicates decisions of the IBC with the PIs

3. Principal Investigator:
a. Makes an initial determination of the required levels of physical and biological containment, and practices and procedures in accordance with the NIH Guidelines; determines if the protocol is exempt or requires IBC approval
b. Submits the appropriate paperwork for the proposed work (see procedure above)
c. Is responsible for adherence to all requirements of the NIH Guidelines, including required safety practices
d. Submits an annual update of the continuing protocols to the IBC
e. Trains all laboratory workers regarding the potential hazards of the work and precautions to be taken
f. Investigates and reports any significant problems or illnesses pertaining to the operation and implementation of containment, or any adverse reactions occurring during clinical studies to the BSD for review by the IBC
g. Ensures that all lab workers experiencing occupational exposures to rDNA material will report such exposures to EOHW and the IBC.
h. Complies with any shipping requirements for rDNA molecules
i. Insures that laboratory workers who work with animals involved in the work participate in the Duke Health Surveillance for Animal Handlers

4. Employee Occupational Health and Wellness:
a. Medical surveillance recommendations or requirements are described in each protocol safety Standard Operating Procedure (SOP).
b. Occupational exposures to rDNA material will be reported to EOHW, and subsequently, to the NIH OBA if applicable.