Policies and Procedures Statements
OSU-CHS Institutional Biosafety Committee

1. What is an "IBC"?

The Institutional Biosafety Committee (IBC) is the cornerstone of oversight for research involving recombinant and synthetic nucleic acid molecules at the local level. Established under the NIH Guidelines specifically for the review of research involving recombinant or synthetic nucleic acid molecules IBCs are typically assigned additional review responsibilities; select agents and toxins, blood borne pathogens, xenotransplantation, stem cell research, "Dual Use" research and nanotechnology. Broader purview is a matter of institutional discretion. IBC reviews research involving recombinant or synthetic nucleic acid molecules for conformity with the NIH Guidelines for; potential risk to environment and public health, containment levels per NIH Guidelines, adequacy of facilities, SOPs, PI and lab personnel training, Institutional and investigator compliance; e.g., adverse event reports in basic and preclinical research. IBCs have authority to: lower containment levels for certain experiments in which nucleic acid from Risk Group 2-4 is cloned in non-pathogenic organisms, set containment levels for experiments involving whole plants and animals, review periodically institutional compliance with NIH Guidelines and to adopt emergency plans covering spills, contamination and other accidents.

2. IBC Chair and Membership Tenure

The roles filled by members of the IBC are directed by the *NIH Guidelines for Research Involving rDNA Molecules*. Because of the paucity of OSU-CHS employees possessing the required expertise, members will serve in their respective roles indefinitely. Unaffiliated members will serve for a term of three years. Replacement of members who decide to step down will be made as a recommendation of the IBC to the Faculty Affairs Committee.

3. Levels of Infectious Agent Pathogenicity or Molecular Biology Risk Requiring IBC Oversight

The IBC is responsible for providing oversight for all pertinent research and instructional activities conducted at the OSU-CHS. If work with infectious agents, primate-derived cell culture lines, or their products requires containment at BSL-2 (or greater), IBC oversight is required. PIs must apply for approval by providing the IBC a completed **Biological/Biohazardous Agent(s) Registration Form** which will be assigned a unique protocol number prior to evaluation. Evaluation results will be relayed to PIs and their unit supervisors in writing by the IBC Chair. Newly-hired PIs who will be conducting work with potentially biohazardous materials must provide the Office of Research personnel with a completed **Biological/Biohazardous Agent(s) Registration Form** listing all pertinent microorganisms and their biohazardous products in their possession. If work using molecular biological (i.e., recombinant DNA, molecular genetics, etc.) techniques is to be undertaken, either IBC or NIH oversight is required as directed by the *NIH Guidelines* by providing the IBC a completed **Recombinant DNA Application Form** which will be assigned a unique protocol number. If the PI considers the work exempt under the *Guidelines*, the applicant must complete a **rDNA Exemption Form** which is to be submitted to the IBC for concurrence. If not considered to be exempt, a full **rDNA Application Form** must be completed and submitted to the IBC for evaluation. OSU-CHS is not registered with either HHS or USDA to conduct research involving select agents or toxins.

4. Biohazardous Agents Inventory

All PIs who are in possession of infectious agents, primate-derived cell culture lines, or rDNA for which IBC oversight is required for their inclusion in research protocols (see Statement 3) must catalog them and maintain current inventories delineating their identities, risk group designations, and maintenance status (i.e., lyophilized *in vacuo*, cryopreserved, etc.). Inventories must be maintained using a standard **Biohazardous Agents Inventory Form** which shall be made available for inspection by the Research Office at any time. Inventories

must be kept up to date and will be expected from incoming principal investigators as well (see Statement 3) as a part of their laboratory registration process.

5. Qualification of Laboratory Workers

All personnel working in or associated with a particular laboratory (or laboratories) will be divided into two categories. **Qualified** personnel must participate in standard laboratory safety training, but have had at least 1 year of college-level chemistry and biology, and have received extensive training in a laboratory setting. Personnel who fit this category would most likely be PIs, senior technicians, postdoctoral fellows, graduate students, etc.). Qualified personnel may perform approved laboratory duties without supervision. Personnel who fail to meet these minimal criteria will be considered **non-qualified** and must participate in standard laboratory safety training and be supervised by qualified personnel at all times. Personnel who fit this category would most likely be high school students or younger, some non-science undergraduates, and non-science high school teachers. Tour groups are to be restricted to the common corridors. Medical students will be considered non-qualified if they lack hands on training in the laboratory in question. Advancement from non-qualified to qualified status may be accomplished only with the appropriate amount of training [*Ex*: high school student with three years' experience in a laboratory might be considered well trained, yet they have not taken the requisite courses].

6. Biosafety Level Registration of Facilities

Research facilities requiring containment at BSL-2 (or greater) must be registered with the IBC. PI registrants must contact the BSO or IBC Chair to schedule an inspection which will include an evaluation of routine containment practices, equipment, and the facility itself. An acceptable biosafety manual and other factors such as SOPs specifically tailored to the particular laboratory or facility must be made available. The inspection will be conducted by appropriate Office of Research personnel and at least one member of the IBC using the checklist form provided by the Office of Research. The checklist conforms to the items described in the NIH-CDC book titled *Biosafety in Microbiological and Biomedical Laboratories*, the *NIH Guidelines for Research Involving rDNA Molecules*, and pertinent OSU CHS policies. Laboratories must be registered prior to IBC evaluation of research protocol applications and registration must be renewed every three years.

7. Approval Duration Periods

All project approvals will be for a period of time not to exceed three years. Approval renewals will require completion of the appropriate application form and resubmission to the IBC.

8. Ongoing Projects Not Having Been Approved by the IBC

Failure to obtain IBC oversight to include application approvals (see Statement 3) will be referred to the Office of Research for appropriate sanctions.

9. Possession or Intent to Obtain Primate Tissues or Primate-Derived Cell Culture Lines

Principal investigators who maintain or intend to obtain primate tissue samples (including blood) or primate-derived cell lines must do so with IBC oversight. Registration requires that the appropriate Office of Research form be completed and submitted to the appropriate Office of Research personnel for submission to the IBC for approval prior to the receipt of such materials. All research with human or non-human primate tissue samples and cell culture lines must be conducted using BSL-2 containment with regard to practices, equipment, and facilities in addition to blood-borne pathogen procedures.

10. Possession or Intent to Obtain Imported Materials Requiring Federal or State Oversight (e.g., USDA APHIS)

PIs who intend to import or export materials requiring either federal or state oversight must notify the IBC in writing that all approvals have been obtained. Appropriate documentation must be included. Refer to APHIS

Plant Pathogens, HHS Select Infectious Agents, and USDA High Consequence Livestock Pathogens/Toxins for lists of materials most commonly employed which require federal or state oversight.

11. Shipping of Potentially Biohazardous Materials

The packaging and shipping of potentially biohazardous materials are regulated by the Department of Transportation, Public Health Service, International Air Transport Association, Occupational Health and Safety Administration, and the Postal Service. Noncompliance with applicable laws and regulations can result in serious penalties for both individuals and institutions. Researchers needing to ship biohazardous materials from the OSU-CHS must do so only in consultation with and after having obtained approval from the authorized certified shipping agent who is in possession of appropriate training and certifications.

12. Autoclave Utilization Policy

All members of the technical support staff will be trained in the proper use of autoclave steam sterilization and are responsible for the routine sterilization and decontamination standard operating procedures for their respective research groups. This will provide a degree of standardization by virtue of centralization of biowaste management which should insure that efficacious techniques are employed for all research laboratories. Quality control to include assessment of autoclave efficiency will be monitored on a routine basis using commercially-available kits which will be provided by the Research Office. This policy will provide both better control of sterilization and decontaminant procedures, as well as insure proper use and maintenance of all steam autoclave equipment.

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