III. Risk Assessment and Research Protocols

III.1. Risk Assessment

New research or development initiatives are evaluated by the Principal Investigator in the early planning stages for the hazards that can be posed by the biological, toxic, flammable, reactive, explosive and/or radioactive materials required by the proposed work. New or inexperienced investigators are encouraged to read the Institutional Laboratory Biosafety Manual and attachments, to seek consultation with the departmental safety officers, the chair of the Institutional Biosafety Committee, the Institutional Biosafety Officer, and/or university environmental health and safety or industrial hygiene personnel, as well as to review published expert opinion regarding regulatory requirements.

The assessment of infection risks associated with the laboratory use of biohazard materials requires the proper risk classification of the material, the risk modification of the manipulations of the material, the environmental risks associated with the material, and the laboratory requirements for containment associated with those risks. Agents of Risk Group 1 or 2 can usually be assessed in consultation with the departmental safety officer but still require the submission of a research protocol to the IBC. It is required that PIs submit a research protocol for approval by the Institutional Biosafety Committee for the use of Risk Group 3 agents prior to the beginning of the research. Agents of Risk Group 3 require submissions for approval of research protocols and are best managed by early consultation with the BSL-3 Advisory Committee, the Institutional Biosafety Committee, the Institutional Biosafety Officer, and Environmental Health and Safety (OEHS) personnel.

Established, ongoing research or development initiatives should be evaluated annually by the Principal Investigator to assure that risks have not changed and that the established safety program is in compliance with the current regulatory requirements (Institutional Laboratory Biosafety Manual, latest edition). The PI has the responsibility for auditing facilities and work practices to help insure that the work of the university is completed in a safe and environmentally sound manner. New investigation
initiatives in the same laboratory that do not change the risk profile of that laboratory or its personnel only require the addition of the names of the new agents to the research protocol. New initiatives that increase the risk profile of the laboratory must be accompanied by appropriate changes in the laboratory’s research protocol (such as engineering controls, PPE, training requirements, spill containment, etc.) to reflect the increase in risk. Work at the new risk level must not begin until the appropriate research protocol is approved and in place.

The training of personnel must be documented in writing and the records kept by the Principal Investigator. All personnel must be made aware of the potential hazards associated with their work and must be trained in the designated safety procedures as well as the appropriate use of the safety equipment (including personal protective equipment and engineering controls) required and the appropriate handling of spills. It is the Principal Investigator’s responsibility to make sure that all training is completed at the required intervals by their laboratory personnel. Be aware that while allowing unpaid volunteers (both minors and adults) to work in the laboratory is a department level policy, if allowed all volunteers must take all of the required safety training prior to beginning work in the laboratory.

III.2. Risk Group Assessment

There are considerable variances in the assignment of risk to infectious agents. In order to standardize the university’s approach to this important consideration, Risk Groups will be selected according to the information in Table III.1.

Information pertaining to the assignment of agents to risk groups may be found in Appendix B of the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines)* and Section VIII of the *CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories, 5th Ed.*

This method of Risk Group (RG) assignment is the most consistent with that of the World Health Organization (WHO). While there are some variations with the assessment applied by the NIH/CDC approach in
Biosafety in Microbiological and Biomedical Laboratories (5th Edition), the RGs in the NIH Guide will be updated at least annually by the American Society of Microbiologists and be listed in Appendix B of the NIH Guidelines as published in the Federal Register. This allows a continuous update of the list of agents based on the most recent information.

Table III.1 Basis for the Classification of Biohazardous Agents by Risk Groups (RG).

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Group 1 (RG1)</td>
<td>Agents not associated with disease in healthy human adults</td>
</tr>
<tr>
<td>Risk Group 2 (RG2)</td>
<td>Agents associated with human disease that is rarely serious and for which preventative or therapeutic interventions are often available. All human source material (including blood, human cell lines and other potentially infectious materials) are considered RG2.</td>
</tr>
<tr>
<td>Risk Group 3 (RG3)</td>
<td>Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).</td>
</tr>
<tr>
<td>Risk Group 4 (RG4)</td>
<td>Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).</td>
</tr>
</tbody>
</table>

III.3. Research Protocol

The research protocol is a project-specific biological safety plan for research and teaching laboratories or common facilities shared by more than one of these activities. In each laboratory/facility, the PI/supervisor must specify the safety practices/procedures to be used in the laboratory and is responsible for the implementation of the plan. Approved practices
must be based on the risk assessment for that laboratory/project and must comply with accepted national standards. A research protocol for the containment of Risk Group 2 and 3 infectious agents and any work with recombinant or synthetic nucleic acid molecules must be submitted to the IBC prior to implementation (work with agents of RG 4 is not permitted at the university). The research protocol must address the following issues as appropriate to the individual laboratory risks:

- **Risk Group of infectious hazard:** the characteristics of infectious agents, the laboratory requirements and primary laboratory hazards of working with the agents can be found in *Biosafety in Microbiological and Biomedical Laboratories* (5th Edition), in *Physical and Biological Hazards of the Workplace*, in similar references, or by contacting the Institutional Biosafety Officer, the IBC, or EHS personnel.

- **Bloodborne Pathogens Standard (OSHA) [29 CFR 1910.1030]:** laboratory use of human or animal blood, blood components, or tissues;

- **Containment requirements/engineering controls:** for biosafety level (BSL) 2 or 3, biosafety cabinets, storage requirements, transport containers, personal protective equipment (PPE) (*i.e.*, hoods, eye protection, gloves, gowns, respirators, etc.), spill management and waste disposal;

- **University Laboratory Animal Resources:** animal husbandry matters and safety of researchers and animal facility (ULAR) personnel;

- **Exposure and Post-Exposure Follow-up:** exposure definition, prophylaxis if available (*e.g.*, Hepatitis B vaccine), and exposure follow-up coordinated through University Health Services;

- **Specific safety training requirements:** all laboratory personnel (including the Principal Investigator) must be
trained on the specific standard operating procedures to be used in the research; personnel must also be informed according to Public Employment Risk Reduction Program regulations (i.e. OSHA regulations) of the potential hazards associated with their work and must be trained in the designated safety procedures, use of safety equipment and Personal Protective Equipment, appropriate waste disposal, and availability of preventive measures such as vaccines. Examples of annually required education: standard operating procedures, bloodborne pathogens training for blood or body fluid exposure prevention, respirator training, safe animal handling, hearing conservation, laboratory chemical hazards, etc.;

- **Training records**: protocols for recording and maintaining records of initial personnel training and the annually required yearly exposure-prevention education programs must be established and in place.

### III.4. Safety Desk Book

Chemical and Biological Safety Program documents are designed to be compiled into a **Safety Desk Book**. The Safety Desk Book is intended to be the easily recognized and accessible central-safety resource for laboratory/facility safety personnel and safety officers. The chemical and biological safety program documents of the Chemical Hygiene Plans and Safety Plans are compiled and regularly updated as needed to provide clear compliance with mandated safety activities. The laboratory Safety Desk Book may be comprehensive or may be developed for individual research or development projects. The complete Safety Desk Book includes the following:

- Hazard Communication Program;
- Chemical Hygiene Plan;
- Departmental Emergency Plans;
- Radiation Safety Information;
- Annual Chemical Inventory;
Institutional Laboratory Biosafety Manual

- Annual Biohazardous Agent Inventory (if available);
- Safety Data Sheets (Safety Data Sheets) or access thereto;
- Bloodborne Pathogens Exposure Control Plan;
- Approved Research Protocols (IBC, IRB and IACUC) and Annual Reviews;
- Personal Protective Equipment (PPE) hazard assessment;
- Respirator Records (Respirator Plan) plus records of examinations and Fit Test Reports);
- Training Documentation.

Boilerplates of some of the elements of the Safety Desk Book may be found at the OEHS website at [www.ehs.osu.edu](http://www.ehs.osu.edu).

**III.6. Select Agents**

The use, possession or transfer of select agents at the University requires prior approval by the Responsible Official. For additional information on select agents please see Appendix C of this document or contact the RO or ARO at 614-292-1284.