Institutional Biosafety Committee

Policies and Procedures Manual

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The use of biological hazards in an unsafe manner has the potential to result in accidental exposures to university personnel, in liability and public relation issues for the university, and in some cases community outbreaks of disease. This document establishes policy for conducting biological research activities, defines responsibilities, and details the procedures to be used by the Institutional Biosafety Committee in the review and oversight of biological research.

General Policy

This policy applies to Oregon State University (OSU) and all affiliated facilities. Affiliated facilities are defined as those that report directly to an OSU administrative unit or receive any extramural funding through the OSU Office of Sponsored Programs.

In recognition of the necessity for conducting research utilizing potentially hazardous biological materials in a safe and secure manner, all biological research at OSU will be conducted in accordance with accepted biological safety practices and in full compliance with this and other existing university policies and all applicable federal rules and regulations relating to such activities. The OSU Institutional Biosafety Committee shall review biohazardous work conducted for any purpose by OSU personnel or in any OSU facility. The Institutional Biosafety Committee has full authority to impose containment requirements or procedural safeguards, audit programs, and inspect facilities to ensure that biohazards are handled, used, and disposed of in a safe and compliant manner.

Further, OSU will comply with the requirements set forth in the current version of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* and with Oregon Revised Statutes (ORS 431.805 and 431.810) for all work involving recombinant DNA as defined below.

Specific Policies

Policy on Public Comments

Members of the public or OSU community may comment on IBC actions by sending written comments to Biological Safety Officer, Oregon State University, Oak Creek Building, Corvallis, OR 97331 or electronically to matthew.philpott@oregonstate.edu . The IBC will review and discuss all comments at the next regularly scheduled meeting and prepare a formal response at the first opportunity. All comments received, along with IBC responses, will be forwarded to NIH / OBA.

Policy on Conflict of Interest

Members of the IBC may not be involved in the review or approval of any project or program if that member expects to be engaged in the work or has a direct financial interest, or if the protocol under review is from a spouse or close relative. Members will be asked to leave the room during discussion and voting, but may address questions or provide other information requested by the IBC.

Policy on Public Attendance of IBC Meetings

Meeting dates and times will be published on the IBC Website. Non-members of the IBC, including members of the public, who wish to attend an IBC meeting, are directed to contact the IBC administrator. Meetings or certain discussions within a meeting may be limited to members only and invited guests where select agent protocols, other sensitive or proprietary information are under discussion; the Chair shall make the final decision of what topics under discussion are appropriate for a wider audience. Principal Investigators may request that certain items in their proposals be considered for discussion only by IBC members. If a meeting or discussion is deemed sensitive, then the Chair can call an Executive Session in which the non-members will be asked to leave.

Policy for Reporting of Accidents, Exposures or Illnesses

Spills or accidents which result in possible exposures to pathogenic or potentially pathogenic microorganisms must be reported immediately by the research principal investigator to the institutional Biological Safety Officer, who shall determine and take responsibility for appropriate reporting of such incidents, following the procedures outlined in this document.

Definitions

Biohazard – any agent, toxin, or recombinant material of biological origin capable of causing infection, disease, or other detrimental effects to humans, animals, or plants.

Recombinant DNA (rDNA) – (i) molecules that are constructed outside of 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. This includes the creation or breeding of genetically modified plants or animals.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide of polypeptide product, it is exempt from review.

Pathogen – a microorganism, virus, or other infectious agent capable of reproduction within a living host, and as a consequence of that reproduction, causing persistent infection or acute disease within that host.

Biological toxin – all are poisons, predominantly proteins, of natural origin but increasingly accessible by modern synthetic methods, which may cause death or severe incapacitation at relatively low exposure levels.

Risk Groups (RG-1, RG-2, RG-3, RG-4) – microorganisms capable of causing human disease are assigned to one of four risk groups, in increasing order of their capacity to

cause disease in humans. For more information and a complete description, please see http://www.absa.org/riskgroups/index.html and, for rDNA, the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, Appendix B.

Laboratory Biosafety Levels (BSL-1, BSL-2, BSL-3, BSL-4) – a set of laboratory work practices, facility requirements, equipment, and training that may be used to ensure reasonable safety when working with biohazards. Generally, there is a rough correlation between Risk Group and Biosafety Level.

Plant Biosafety Levels – The containment levels as described in the *NIH Guidelines for Research Involving Recombinant DNA Molecules* are applicable for containment of recombinant plants (BL1-P, BL2-P, BL3-P, BL4-P).

Animal Biosafety Levels – The containment levels for housing and manipulations involving infected animals as described in the CDC Publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) (ABSL-1, ABSL-2, ABSL-3, ABSL-4) or recombinant DNA (BL1-N through BL4-N).

Exposure – Any eye, nose, mouth or other mucous membrane, parenteral or inhalation contact with potentially infectious materials.

Responsibilities

Institutional Biosafety Committee (IBC). The IBC members and Chair are appointed by the Vice President for Research. Members are (i) faculty and staff who represent broad expertise in biological science and (ii) two community representatives not affiliated with OSU. Member expertise will be in accordance with the guidance found in the CDC/NIH publication *NIH Guidelines for Research Involving Recombinant DNA Molecules*. The committee is responsible for registration, approval and oversight of all recombinant DNA and biohazard activities as described below. At its discretion, the committee may delegate certain oversight responsibilities to the institutional Biological Safety Officer (BSO). Review of recombinant DNA projects that require committee approval as stipulated in the *NIH Guidelines for Research Involving Recombinant DNA Molecules* may not be delegated.

Principal Investigators / Laboratory Directors. Instructors, Emeritus Faculty, Assistant Professors, Associate Professors, Professors, and Courtesy Faculty may serve as Principal Investigators on a proposal. Principal Investigators are responsible for directing all research and support personnel affiliated with their laboratory or research program and ensuring that all such personnel have adequate training to conduct research activities in a safe manner. The principal investigators are responsible for ensuring that all appropriate research projects are registered with the IBC; that safety recommendations and guidelines are consistently followed during the conduct of research; and that all potential releases of biohazardous agents, accidents involving biohazards or rDNA, or possible exposures resulting from the use of biological materials under their charge are reported in a timely manner to the Biological Safety Officer. Reporting to the NIH /

OBA shall be made in accordance with the policy and procedure identified in this document.

Biological Safety Officer. The Biological Safety Officer (BSO) provides technical advice and training to the IBC members and to investigators in the accepted standards for safe conduct in biological research. The BSO must be familiar with research activities, applicable state and federal guidelines and regulations, and methods for minimizing potential hazards. The BSO also is responsible for assisting with the development of campus-wide exposure control plans, emergency response plans for handling accidental spills and exposures, investigation of laboratory accidents, conducting and advising others on risk assessments for biohazards, and facility inspection audits to ensure biosafety standards are followed. The BSO also reviews occupational health programs and oversees compliance of the Select Agent regulations and OSHA Bloodborne Pathogen Standard at OSU. The BSO works with investigators to develop exposure control plans, ensure compliance with bloodborne pathogen requirements, and other biosafety guidance as needed.

Responsible Official. The Responsible Official is appointed by the institutional administration. The Responsible Official assumes responsibility for institutional compliance with all applicable federal regulations relating to access, use, and transfer of select agents and toxins (see below). The Responsible Official may appoint one or more Alternate Responsible Officials to assist with select agent oversight. The Responsible Official and / or Alternate Responsible Official shall be members of the IBC.

Research Activities Requiring IBC Registration and Oversight

Recombinant DNA. Recombinant DNA research is the use of recombinant DNA, as defined above, for any purpose, including the construction or breeding of transgenic plants and animals. All non-exempt recombinant DNA research projects must be registered with the IBC. Those projects determined to be exempt do not require registration; criteria for exempt status are restricted to those deemed exempt by the current *NIH Guidelines for Research Involving Recombinant DNA Molecules*. The IBC will have the final decision on which projects are exempt, review non-exempt projects, establish appropriate containment levels, and make other safety requirements as deemed necessary and appropriate for the protection of OSU personnel, students, and the community from potential biological hazards. The recombinant DNA oversight activities of the IBC will be conducted according to the most recent edition of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

Microbial Pathogens and Biological Toxins. All research activities involving pathogenic microorganisms of animals, humans or plants must be registered and approved by the IBC. The IBC will review projects, set appropriate containment levels, and make other safety recommendations. The IBC may delegate these activities to the BSO. Guidance for pathogen containment comes from the CDC publication *Biosafety in Microbiological and Biomedical Laboratories* (the BMBL), but requirements are established by a risk assessment process. Microbial pathogens include viruses, fungi,

protozoans, helminth parasites, and bacteria that are capable of replicating in and / or causing disease in humans, animals, or plants.

Human Pathogens. All projects which make use of human pathogens classified as Risk Group 2 or 3 organisms, or classified by the Centers for Disease Control and Prevention as organisms requiring BSL-2 or BSL-3 facilities and practices for safe handling must be registered and approved. Risk Group 1 organisms are not known to cause disease in healthy humans and registration of projects with these agents is not required unless they also fall into one of the animal, plant or select agent categories below, or they contain non-exempt recombinant DNA. The use of Risk Group 4 / BSL-4 organisms or recombinant DNA at OSU is prohibited. Research involving possible contact with bloodborne human pathogens must be conducted in accordance with the additional requirements established in 29 CFR 1910.1030 (OSHA Bloodborne Pathogen Standard) and the OSU Exposure Control Plan. Some human pathogens are select agents and must meet the additional requirements described below.

Animal Pathogens. All projects that make use of infectious agents of animals, whether zoonotic pathogens or not, must be registered and approved by the IBC. Importation or interstate movement of livestock animal pathogens requires a permit from the United State Department of Agriculture (USDA) under the authority of 9 CFR 122. Some animal pathogens are select agents and must meet the additional requirements described below.

Plant Pathogens. All research projects that make use of plant pathogens must be registered and approved. Plant pathogens include nematodes, bacteria, fungi, viruses, viroids, phytoplasmas, or any organisms similar to or allied with any of the foregoing which can directly or indirectly injure or cause disease or damage in plants. The USDA requires a permit for importation or interstate movement of plant pathogens under the authority established in the regulations 7 CFR 330. Some plant pathogens are select agents and must meet the additional requirements described below.

Biological Toxins. Research that makes use of toxins of biological origin requires registration with the BSO. If the research involves recombinant DNA expressing toxic polypeptides or non-exempt quantities of select toxins, the work must also be reviewed and approved by the IBC. Some toxins are select toxins and must meet the additional requirements described below.

Select Agents and Toxins. Research that makes use of regulated select agents or toxins must be approved by the IBC and conducted under the oversight of the institutional Responsible Official. The Responsible Official has full authority to develop and manage the university's select agent program. All select agent and toxin research must be carried out in accordance with the provisions of applicable federal regulations (42 CFR 73, 9 CFR 121 and 7 CFR 331). All research and support personnel must have authorization granted by the Responsible Official

and pass a security risk assessment. For a list of select agents and toxins, see http://www.selectagents.gov/.

Additional Requirements for Biohazard Research

Pathogen Biosecurity. All pathogens must be stored and used in a safe and secure manner that minimizes the possibility of accidental release, acts of vandalism, or the acquisition of pathogens by unauthorized persons. All pathogen laboratories and storage areas must limit access to trained research personnel and be locked when unoccupied. Doors are to remain closed while experiments are in progress. Laboratories using select agents or toxins are subject to additional security requirements.

Inspections. The BSO, IBC or Environmental Health and Safety staff may inspect laboratories and other facilities where any of the activities described above are conducted. Inspections are intended to ensure proper safety equipment and practices are in place and that research is being conducted according to the containment and safety requirements established by the IBC and/or federal recommendations and regulations. Investigators must make areas where research is conducted accessible to inspection. Inspection reports will document any identified deficiencies that must be corrected prior to a follow-up inspection.

Safety Violations. When routine deficiencies are noted during laboratory inspections, the BSO will suggest corrective action to the investigators. The BSO will serve as a resource to the principal investigator to provide him/her with whatever guidance and assistance is necessary to restore safe operating procedures to the research program. Follow-up inspections will be required after a reasonable length of time to implement corrective actions. If the principal investigator is unable or unwilling to implement corrective actions, the IBC may be asked to review the situation and suggest a remedy. In the case of investigators with repeated violations or failures to comply with corrective actions, the IBC may make recommendations for actions to the OSU Research Office. In the case of serious violations of IBC requirements or applicable guidelines that pose a danger to personnel or the community, the BSO may order that the lab be secured and activities halt for a period of 48 hours. During this time, an emergency meeting of the IBC will be called to determine a satisfactory resolution of the issue.

Registration of Projects and Programs

Investigators may register individual projects involving rDNA and / or other biohazards, or may choose the option of registering their research program. A project registration is generally quite defined in scope and may represent the work proposed in a single funded grant. The program registration requires somewhat more detailed information to be submitted than a project registration, but has the advantage of covering all expected work for the duration of the registration period (i.e., multiple sponsored projects). New project initiated with this time frame are “pre-approved” provided that they fall within the scope of the program registration submitted to the IBC. In general, investigators who have

multiple projects or areas of research emphasis will benefit from the program registration by not being required to file multiple project registrations.

Project and program registration forms and information about registration can be obtained online at http://oregonstate.edu/ehs/bio/institutional-committee. Links are provided to the biohazard / recombinant DNA registration forms which are to be completed for all projects that involve human, animal or plant pathogens, biological toxins, or recombinant DNA.

Program Registrations: Principal investigators whose research programs make use of transgenic plants are encouraged to complete the Transgenic Plant Program Biosafety Plan. The Transgenic Plant Program Biosafety Plans are reviewed by the IBC and approved; all projects that fall within the parameters of the Plan are pre-approved during the approval period. Likewise, investigators who work routinely with rDNA, transgenic animals, and / or human, plant or animal pathogens are encouraged to register their programs for review rather than individual projects. Like the Transgenic Plant Program Biosafety Plans, all work falling within the parameters of the Program Registration is approved for the duration of the approval.

Project Registrations: A project registration can be submitted for any type of project requiring registration with the IBC using the same multi-section form by completing those sections that pertain to the project. Registrations must include a narrative of the project. This narrative should provide a brief overview of the goals of the project, the methods that will be applied to achieve those goals, an assessment of the hazards of the project, and the safety procedures that will be implemented to protect workers and/or the environment from potential biohazards. Investigators may include a recommendation for the level of containment they feel is appropriate to safely conduct the proposed research.

Standard Operating Procedures: Standard Operating Procedures (SOPs) are recommended and may be required by the IBC for routine manipulations involving RG-2 or higher human pathogens, and also for high consequence animal or plant pathogens. Researchers should describe in detail the procedures they will use during manipulation of the pathogens and include all other information that is relevant to their projects. For projects that require SOPs, the safety procedures in the narrative may be referenced to the SOP to eliminate redundancy.

Where to send forms: Completed forms must be signed and should be sent to the Environmental Health & Safety biosafety office, Oak Creek Building via campus mail, or electronically to the BSO. Submission of incomplete forms or forms not signed by the principal investigator will delay the review process. The BSO provides the initial review of the proposals and will contact the principal investigator if additional information is required.

Once a project or program has been approved by the IBC, a memorandum of approval will be sent to the principal investigator.

Project Registration Duration and Annual Renewals: The duration of approval for registrations, both of individual projects and programs, is three years from the date of the memorandum of approval. Each year, the PI will be required to complete a short update to verify consistency of ongoing activities with those described in the original submission materials. If there are changes in the project / program goals, facilities, personnel, or methods, then an amendment must be filed with the IBC describing the changes to the registration. Examples of situations needing amendments would include addition of new personnel, plans to initiate work with a new rDNA construct, pathogen, animal studies, or other biohazard not currently indicated on the registration documents. If new pathogens are being added by amendment, then a Section D form for each new agent needs to be included. An amendment form can be accessed on the IBC website at http://oregonstate.edu/ehs/bio/institutional-committee.

Types of Projects and Review Procedures

The following is a general guide to the types of projects that require review by the IBC. The section numbers refer to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

1) If proposal is rDNA and falls under the provisions of Section III-A, B or C, then the full IBC must review it, and the project is also reviewed by the NIH RAC.

> Included in Section III-A, B or C are:
> A) Major actions; deliberate transfer of drug resistance to microorganisms that might compromise the use of the drug to control disease.
> B) Cloning of toxin molecules with LD_{50} of less than 100 ng / kg body weight.
> C) Deliberate transfer of rDNA (or derivatives) into human subjects.

2) If proposal is rDNA and falls under Section III-D, the project is reviewed by the IBC before the project may begin. Depending on the nature of the project, the BSO may do a risk assessment and also meet with the PI and conduct an inspection of the facilities, then provide an evaluation report with recommendations to the IBC. In some cases, outside reviews may be solicited from non-members who possess expertise in the area of the proposed research.

In reviewing proposals, the committee will make use of the guidance for appropriate containment provided by the *NIH Guidelines* and the *BMBL*, but may increase containment levels commensurate with a risk assessment of the project or the facilities in which it is to be conducted; decreases in containment level may need to be approved by NIH. Any additional safety requirements for the research should be included in the motion for approval or amendments to the motion before the final vote.

> Included in Section III-D are the following types of projects:
> a) Risk group 2 or 3 as host-vector systems (includes most animal virus vectors).

b) Introduction of DNA from RG-2, RG-3 or RG-4 organisms into non-pathogenic hosts. (Most RG-2 derived DNA is exempt if *E. coli* K-12 strains are used as host.)
c) Replication of, or helper-assisted growth of, recombinant animal viruses in tissue culture.
d) Introduction of rDNA into animals, including into the germ line (construction of transgenic animals). Construction or breeding of many transgenic *rodents* are exempt; other animals are not exempt. This section also includes review of experiments involving testing of rDNA modified microorganisms in animals.
e) Introduction of rDNA into plants, the testing of rDNA modified microorganisms or insects on plants, when these involve transmissible exotic infectious agents, serious pathogens of major U.S crops, plant pathogens with a recognized potential for serious detrimental impact on managed or natural ecosystems, or express genes for vertebrate toxins with $LD_{50} > 100$ ng / kg.
f) Experiments involving more than 10 liters of culture of rDNA modified microorganism(s) (including non-pathogenic hosts, like lab strains of *E. coli*).
g) Experiments with influenza viruses generated by recombinant methods.
Note: ***All projects falling in Section III-D may not begin until after they have been reviewed and approved by the IBC.***

3) If the proposal is rDNA and falls under Section III-E, notification of the committee at the time of the project initiation is required. These are projects determined by the NIH to have low potential for causing disease or impacting the environment. The BSO will review the project to ensure it is consistent with this expectation, and the committee will review the proposal. After review, the committee votes on whether to approve these projects. All such projects may be conducted at BSL-1 or equivalent.

Included in Section III-E are:
a) Cloning of rDNA in non-pathogenic prokaryotic or eukaryotic hosts (except as described above where rDNA codes for toxins or is derived from RG-3 or RG-4 organisms, or when the work is exempt – see below).
b) The use of animal viruses with less than ⅔ of the genome provided there is no potential for replication and spread (replication defective status must be *demonstrated* by the PI).
c) Recombinant plants and plant-associated organisms, when there is no recognized potential for dissemination or serious impact on ecosystems.

4) If the proposal involves the use of RG-2 / RG-3 human pathogens, animal or plant pathogens, or select agents (without rDNA), the BSO provides an initial review and distributes the proposal to the committee prior to the next meeting. These pathogen proposals must be reviewed by the IBC, with the BSO serving as primary reviewer and providing relevant background information to the committee. The committee may seek the input and expertise of non-members with relevant expertise for any proposal as necessary.

Exempt Recombinant DNA Projects

Note: The final determination of whether a project meets the definition of exempt status rests with the IBC Administrator, chair, or any other knowledgeable member of the IBC.

The following rDNA projects have been determined to pose no known biological hazard to researchers, the environment or the community and are exempted from review by the NIH:

1. Experiments in which DNA is not introduced into living organisms or viruses. This would include the use of PCR and electrophoresis without molecular cloning of PCR products.

2. Experiments using rDNA that consists entirely of DNA segments from a single non-chromosomal (e.g., plasmid) or viral source. Viral rDNAs that are replication competent and are RG-2 or above, or are viable animal or plant pathogens are not exempt under this category.

3. Experiments using rDNA consisting entirely of DNA from a prokaryotic host including its indigenous plasmids of viruses when propagated only in that host (same species), or when transferred to another host by well established physiological means.

4. Experiments using rDNA consisting entirely of DNA from a eukaryotic organism, including chloroplasts, mitochondria and extrachromosomal elements, but excluding viruses, when propagated only in that host (same species).

5. Experiments using rDNA that consists of DNA segments from different species that exchange DNA by known physiological processes. A current list of such exchangers is found in Appendix A of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

6. Experiments that have been determined ***by the NIH*** not to pose a threat to health or the environment, as described in detail in Appendix C of the *NIH Guidelines*.

Procedures for IBC Meetings and Documents

Meetings

IBC meetings are generally held monthly; scheduled meetings may be cancelled or additional meetings called as needed, at the discretion of the Chair. The IBC Chair, or designated alternate, calls the meetings to order and conducts the meeting business according to modified Roberts Rules of Order.

A quorum consisting of half the number of members registered with the NIH is required for regular meetings. In exceptional circumstances such as an emergency meeting, a quorum may be met with fewer than that number of members (see section on *IBC*

Procedures for Incidents or Complaints about Biohazard Use, subsection entitled *Contingency Procedures*).

Confidentiality

IBC meeting business may involve sensitive issues, proprietary information, select agent proposals, or other confidential items for discussion. Members are expected to respect the confidentiality of sensitive discussions and may not disclose any information that has been deemed confidential by request of the principal investigator or his/her agent, the Chair, University Administration, or any member of the committee. In general, all discussions not included in the official minutes are considered to be confidential.

IBC Documents

All official IBC documents are maintained by the IBC Administrator. IBC registration documents are maintained for at least the duration of project registration (3 years), along with all annual updates and associated or supporting documents. Minutes of IBC meetings are maintained for at least 10 years.

Meeting agendas, proposals and other documents are prepared, distributed to members in advance of meetings by the IBC Administrator. Minutes are recorded during meetings by the IBC Administrator or other designated person, drafted and distributed for review prior to the next meeting, and adopted by vote of the committee at the following meeting. At the time of adoption, the minutes become the public record of the committee's business. Within the minutes, proposals are referenced by tracking number, title and principal investigator. Proposals that involve recombinant DNA will contain the section(s) of the *NIH Guidelines for Research Involving Recombinant DNA* under which the research falls. The minutes shall record discussions of proposals that include but are not limited to, as appropriate, the following information: (i) agent characteristics (e.g., virulence, pathogenicity, environmental stability), (ii) types of manipulations planned, (iii) sources of insert DNA (e.g., species), (iv) nature of the inserted DNA sequences (e.g., structural genes, oncogenes, enzymes); (v) host(s) and vector(s) to be used.

Biosafety Review of Non-OSU Research Conducted in OSU Facilities

Federal rules and university policy require that all projects involving recombinant DNA or pathogens of humans, animals, or plants be reviewed for safety. A number of off-campus entities periodically conduct animal studies or other types of research involving biological hazards and/or recombinant DNA utilizing university resources or facilities on a contract basis. Often, some of the personnel involved in these projects are affiliated with the university as graduate students, animal care personnel, laboratory technicians, or senior investigators. An "off-campus entity" is defined as an organization or company that does not receive its funding from Oregon State University (OSU) or from a third party through the OSU Office of Sponsored Programs.

To ensure (i) that all biohazard and recombinant DNA research conducted at OSU conforms to current safety standards, (ii) that risks to personnel, the community, or the environment associated with these activities are mitigated by application of best practices, and (iii) that all such work has been reviewed in compliance with federal rules, the OSU Institutional Biosafety Committee (IBC) adopts the following policies and procedures for projects conducted by off-campus entities:

1) The OSU IBC will **not** serve as the compliance committee of record for the review of projects involving recombinant DNA being conducted at OSU by off-campus entities. The off-campus entity conducting the research must either form their own IBC or arrange to use a third party's IBC to meet the compliance requirements set forth in Section IV of the *NIH Guidelines for Research Involving Recombinant DNA*. Review by an external IBC must be documented, and that documentation shall be provided to the OSU IBC upon request.

2) The OSU IBC requires and reviews a standard IBC Project Registration form and appropriate supporting documents to verify that the work meets the safety requirements imposed on OSU investigators for similar projects. All projects will require a narrative addressing the goals of the project, hazardous materials or agents to be used, potential sources of risk to personnel or the environment, and procedures that will be used to minimize those risks during the conduct of the project. The narrative must also indicate in which facility or facilities the work will be conducted and the appropriate biosafety level to be used for the project. For projects which will be conducted at BSL-2 / ABSL-2 equivalent or higher containment, supporting documents should also include (i) safety SOPs for conducting hazardous tasks, (ii) documentation of appropriate training for personnel.

3) Upon completion of a review of supporting documents for a proposed project involving an off-campus entity, the OSU IBC will forward a memorandum stating that clearance for the project to be conducted in OSU facilities is either obtained or denied. If the study involves animal use, notice of approval will be provided to the IACUC; the OSU Attending Veterinarian serves as a member of the IBC.

IBC Procedures for Incidents or Complaints about Biohazard Use

Receipt of Complaints

Complaints about the misuse or unsafe use of biohazards should be referred to the IBC Chair. In the absence of the chair, the institutional biosafety officer shall act as an agent for the IBC. All complaints will be handled by the IBC as confidential to the extent possible until such time as the complaint is proven to be valid. When the complainant wishes to be openly identified, the IBC Chair will acknowledge receipt of the allegation to the complainant in writing, and direct the biosafety officer to do a preliminary investigation to determine if there is an immediate threat to personnel, environment, or the community. If so, the procedures described below for suspending research will be

followed. If the biohazardous activity in question involves the use of research animals, the University Attending Veterinarian will immediately be contacted and invited to participate in the preliminary investigation.

Investigation and Reporting

Full investigation and reporting are the responsibility of the IBC Chair, who will be assisted and supported by the biosafety officer, unless the incident or complaint involves the use of select agents, in which case the institutional Responsible Official or designated Alternate Responsible Official will coordinate. The Chair may appoint a sub-committee to conduct the investigation. Investigation of incidents or complaints may consist of inspection of facilities or laboratories where the misuse or unsafe use is alleged to occur, review of documents, and interview of persons involved. All components of the investigation process shall be documented in writing in the form of an evaluation report prepared by the biosafety officer. The report may be supplemented with photographs as appropriate. The report should include conclusion about the validity of the complaint and recommendations for further action or corrective actions, as appropriate.

A report will be made to the IBC at the next meeting, and all committee members will receive a copy of the written evaluation report at the conclusion of the investigation. The principal investigator will also receive a copy of the report. A copy of the report may also be forwarded to the Department Head, Dean, and appropriate representatives of the Research Office.

Procedures for Suspending Research

If the preliminary or full investigation determine that willful violations of safety practices have occurred which pose a threat to personnel, the environment, or the community, the biosafety officer has the authority to suspend the unsafe research activity, and to take control of any biohazardous materials present in the facility or laboratory. In the event that research is suspended for biosafety reasons, an emergency meeting of the IBC will be called as soon as possible. In this meeting, the IBC will review the available evidence and possible consequences, interview the principal investigator responsible for the research program, and take appropriate action.

If an ongoing serious hazard is posed by resumption of research, the committee may not allow research to continue until the hazard(s) have been mitigated. The committee's action may include any or all of the following requirements to be implemented before any biohazard work may continue:

- Changes in procedures used in research to make the work safer.
- Additional / different personal protective equipment to be used during tasks.
- The use of biological safety cabinets or other safety equipment.
- Training or re-training of individuals conducting research.
- Registration or review of hazardous activities not previously reviewed.

In addition, the IBC may require the principal investigator to supply documents for a full review of all research activities under their direction.

In extreme cases, the committee may decide that the risks posed by the activities are such that the work is indefinitely suspended, vote to revoke a biological use authorization, or subsequently refer the matter to the Research Office for resolution.

Contingency procedures: In the event that a quorum of IBC members cannot attend an unscheduled emergency meeting, the requirement for a 50% quorum will be waived if a minimum of three members can attend. If fewer than three members are available, the meeting will be postponed until the earliest possible time that a minimum of three members are able to meet. If the complaint or alleged misuse involves the use of select agents or toxins, the institutional Responsible Official or designated Alternate Responsible Official must be present at the meeting.

Outcomes and Follow-Up

The following are possible outcomes of the above procedures:

1. The committee may determine upon review of the investigation that there is no evidence to support the complaint or that no incident occurred.
2. If the investigation indicates the possibility that exposures or releases of biohazards has occurred, the policy and procedures for reporting of accidents or exposures described in this document shall be followed.
3. The committee may direct the biosafety officer to conduct post-monitoring of the research program through audits or unannounced inspections, with reports made to the IBC.

Procedures for Accidents, Illnesses and Recognized Exposures

Accidents, illnesses related to biohazard activities, spills or exposures to infectious or recombinant materials shall be reported to the BSO according to the policy described in this document. Different types of incidents require different responses and reporting. Exposures may require any of the following:

- Medical evaluation for any exposed persons by qualified health care professionals. If an exposure is determined to have occurred, the health care professional may indicate treatments consistent with current CDC recommendations, where applicable.
- Medical monitoring of any subsequent disease that develops as a consequence of a research-related exposure to a biohazard.
- Exposures and any subsequent illnesses shall be reported to the appropriate federal, state and local authorities as required by statute or policy:
    i. Exposures or releases that involve recombinant DNA shall be reported to NIH / OBA according the procedures detailed within the current version of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*. Exposures to infectious agents occurring in a BSL-2 or BSL-3

laboratory that involve recombinant infectious agents must be reported immediately to the IBC and to the NIH/OBA. The principal investigator is responsible for reporting to the BSO, who will report to NIH/OBA on behalf of the institution. If the BSO is not available, the principal investigator shall report the exposure directly to NIH/OBA. Exposures or accidents involving recombinant DNA that occur in BSL-1 laboratories shall be reported within 30 days to NIH/OBA. If a release involving biological materials in use under permits from the USDA / APHIS occurs, the principal investigator is responsible for reporting immediately to APHIS as required under the terms of the permit.

ii. Any exposure or releases outside primary containment that involve select agents shall be reported to the CDC according to current guidelines established by federal oversight authorities. The reporting to CDC must be done immediately by phone, by the Responsible Official or designated Alternate Responsible Official, and includes (i) the identity of the select agent or toxin, (ii) estimated quantity released or spilled, (iii) time and duration of exposure, (iv) the environment into which the release occurred, (v) the location, (vi) the number of persons potentially exposed, (vii) actions taken in response, and (vii) an estimate of the hazards. The Responsible Official or Alternate Responsible Official shall then file a completed Form 3 to CDC within seven calendar days.

iii. Any laboratory – associated or other research or clinical related infections shall be reported to the appropriate County Health Department.

Records of any accidents, exposures or illnesses shall be documented with a report and maintained by the BSO.

IACUC – IBC Coordination

The following procedure is intended to ensure appropriate review by both committees of biological research proposals involving non-exempt recombinant DNA and / or pathogens or toxins in animal studies. ***The IACUC will not grant final approval to any animal use protocols involving pathogens or recombinant DNA until the project has been reviewed by the IBC, and determined to either be exempt or has received final approval***.

1) Investigators preparing animal use research proposals that involve any of the following must register their projects with the IBC:

a) Recombinant DNA in animals, including construction or breeding of transgenic animals (the purchase, creation or breeding of transgenic / knockout ***rodents*** is exempt if it meets the criteria described in Appendix C of the *NIH Guidelines*).

b) Recombinant DNA in microorganisms or viral vectors which are subsequently introduced into animals.

c) Animal studies using bacteria, viruses, fungi, protozoa, helminthes, or other microbes or prions that are known or suspected pathogens of humans or animals.

d) The introduction of toxins of biological origin into animals.

2) For projects that involve pathogens or potentially infectious rDNA, investigators are also required to fill out the additional EH&S form entitled "*Biohazard Warning and Safety Precautions for Animal Rooms*." This form must be posted by the PI or his/her designee on the door or other entrance to the animal room or area, and appropriate hazard warning signage affixed to individual cages or enclosures to include the universal biohazard symbol. This form is available as a download from the EH&S website at http://oregonstate.edu/ehs/bio. The PI or his/her designee is also responsible for coordination and notification of animal care personnel when biological agents are to be introduced into animals.

3) Once a registration has been received, reviewed and approved by the IBC, the IACUC administrator is notified that the project has been approved. Documents relating to the project will be supplied to the IACUC upon request.

4) The BSO serves on the IACUC and provides biosafety input into animal studies as appropriate.

5) Prior to initiation of infection studies involving animals, a meeting is held with research staff, animal care staff and the BSO to discuss procedures, hazards, and address any questions relating to the safety of the study.

IRB-IBC Coordination

The Institutional Review Board has the responsibility for reviewing all OSU research that involves human subjects. When a human subject proposal involves the collection and/or use of human blood, tissues, or body fluids, it becomes subject to the requirements of the OSHA Bloodborne Pathogen Standard. The IRB administrator forwards the title of the study, name(s) of the individual(s) involved in the study, and a brief description of the project to the BSO, who ensures the requirements of the OSU Exposure Control Plan and OSHA Bloodborne Pathogen Standard are satisfied. The BSO notifies the IRB administrator when these requirements have been met.

A report to the IBC of such projects may be made during regular meetings by the BSO, unless the project also requires registration / approval of the IBC, in which case the procedures for registration and review described above apply. Examples of human subject projects that require IBC review include introduction of rDNA into human subjects, isolation and growth of human pathogens from human source materials for study, or testing of human source materials for the presence of pathogens by culture methods.