



UNIVERSITY OF
SOUTH DAKOTA

**Institutional Biosafety
Committee (IBC) Manual**

**Environmental Health & Safety
and the Institutional Biosafety Committee**

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I. Introduction

The University of South Dakota (USD) Institutional Biosafety Committee (IBC) is a committee appointed by the Vice President for Research. The IBC has the authority and obligation to stop any activity using biological materials, including but not limited to recombinant DNA and infectious organisms, that the committee believes to be unsafe. The *USD Institutional Biosafety Committee Manual* is your reference document detailing the policies and regulations governing research, teaching and outreach activities with biological materials and the requirements for submitting protocol proposals for review by the USD IBC. The instructions and information contained in this handbook are set forth and adopted by the USD IBC and are based on federal, state, and local regulations and guidelines. Sections of the manual describe and explain the various aspects of the review process and regulatory requirements. Investigators and IBC committee members should familiarize themselves with the contents of this handbook. In addition, investigators should carefully review the sections of the manual that address their specific activities before submitting proposals to the IBC.

A successful biosafety program depends on investigators who are committed to a safe working environment and who are knowledgeable of the intricacies of laboratory safety. To assist, the services and resources of the USD Biosafety Officer (BSO) and the Department of Environmental Health & Safety (EH&S) are available.

II. The Institutional Authority under Which the IBC Is Established

The University of South Dakota Institutional Biosafety Committee (IBC) is a university committee, reporting to the Vice President for Research, who serves as the Institutional Official (IO).

III. Purpose of the IBC

The IBC oversees and establishes University policy for review and approval of all activities involving the use of recombinant DNA and potentially biohazardous materials (see section IV for complete list of potentially biohazardous materials) to assure compliance with current regulations and guidelines. PIs and/or laboratory supervisors at University of South Dakota who either store or carry out research or diagnostic activities involving potentially biohazardous materials must inform the Institutional Biosafety Committee via the Biosafety Protocol Registration Form. It is the policy of the University that all activities involving potential biohazards be conducted in a safe manner in order to protect laboratory workers, students, other persons, our community and the environment from potentially biohazardous agents and in such a manner that projects conducted by one faculty member will not have an adverse effect on adjacent projects conducted by other scientists. The USD IBC will maintain all related records for 3 years after the completion of the activity.

Further, it is University policy that no Risk Group (RG) 4 Agents may be used or stored at USD. See the NIH Guidelines and CDC BMBL for a list of these agents.

IV. Research and Activities Requiring Review and Approval from the IBC

The IBC reviews and approves many areas of biologically related activities which may include: research, teaching, diagnostic, and outreach activities.

The USD IBC defines potentially biohazardous materials to include all infectious organisms (bacteria, chlamydiae, fungi, parasites, prions, rickettsias, and viruses) which can cause disease in humans, animals, or plants, or cause significant environmental or agricultural impact. The IBC will also capture information on materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures. Oversight is provided only for cell cultures and tissues of human and non-human primate origin that contain characterized agents at RG 2 or above. Potentially biohazardous materials* include (but are not limited to) all of the categories below. Projects involving material(s) included in any of these categories must be submitted for IBC approval prior to initiating the project.

- Recombinant DNA (rDNA),
- Genetically modified organisms. Including, but not limited to:
 - Animals, plants, invertebrates, and/or other organisms created by USD employees or in/on USD property,
 - Transgenic field trials, any genetically modified organisms to be introduced into the environment, including planting of deregulated items in the field (by USD personnel and/or on USD property),
 - Field testing of plants engineered to produce pharmaceutical and industrial compounds,
- Any organisms, or agents requiring federal permits (including but not limited to, APHIS, CDC, EPA, FDA),
- Pathogens/infectious agents (human, animal, plant, and other),
- Select/Biological Agents and Toxins (CDC and USDA). Please note that possession, use, or transfer of Select/Biological Agents and Toxins entails additional requirements – contact the Office of Research Assurances for additional information,
- Human & non-human primate cells (including all cell lines), tissue, blood and potentially infectious fluids. (see section XVII.c for more information),
- Work with animals or vectors known or suspected to be reservoirs of RG2 or RG3 infectious agents when such work increases potential exposure risks to personnel or other animals,
- Oncogenic viruses used in conjunction with animals

The IBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these areas. When it is unclear whether a material constitutes a potential biohazard, the IBC should be consulted. Questions should be directed to the USD Biosafety Officer, who is the Director of Environmental Health and Safety (phone: 605-677-6265; ehs@usd.edu). The phrase potentially biohazardous material is used throughout this manual to indicate all biological materials that the IBC oversees. The list includes materials that are not included in the NIH Guidelines and materials that may not traditionally be considered biohazardous. In addition to regulation of activities with potentially biohazardous materials, the USD IBC also oversees work with some organisms not viewed as biohazardous, including genetically modified whole plants which are commercially available and do not require APHIS permits.

V. Principles that govern the IBC

The IBC developed this manual and operates based upon the following regulations/guidelines:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), most current edition.
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), most current edition, developed by the Center for Disease Control (CDC) and the National Institutes of Health (NIH).

- USDA/APHIS 7 CFR Part 340, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering and all APHIS Permit regulations/guidelines.
- 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins.
- All non-exempt select agent work being performed under one of USD protocols at another institution will require an assurance that the work is being performed in an approved select agent lab and that the user is an authorized, registered user. This written assurance from the other institution's IO would be required before USD IBC can approve this work.
- 7 CFR Part 331 and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins.
- USDA/ARS Facilities Design Standards, Chapter 9. Biohazard Containment Design (<http://www.afm.ars.usda.gov/ppweb/242-01m.htm#H304>).
- Sanford School of Medicine of the University of South Dakota procedures for bloodborne pathogens (<http://www.usd.edu/medical-school/medical-doctor-program/upload/Bloodborne-Exposure-Checklist.pdf>)

No work should be considered so important that it jeopardizes the well-being of the worker or the environment. The planning and implementation of safety protocols to prevent laboratory-acquired infections and to eliminate the spread of contamination must be part of every laboratory's routine activities and biosafety manual. The handling of biological agents and recombinant DNA requires the use of precautionary measures dependent on the agents involved and the procedures being performed. It is the purpose of this manual to provide background information and guidelines to be used in conjunction with other resources for the evaluation, containment and control of potentially biohazardous materials in laboratories.

VI. Duties and Responsibilities

a. Principal Investigators and Laboratory Supervisors.

The PI is primarily responsible for the people and activities in their laboratories. They are responsible for implementing an appropriate biological safety program specific for their projects (including having a current Biosafety Manual for the individuals and activities under their purview). They should evaluate all their operations, perform risk assessments, and develop plans for all activities accordingly. They are responsible for establishing the appropriate biological safety containment levels in consultation with the USD Biosafety Officer and ensuring adherence to these levels. They must also ensure strict adherence to biological safety practices and techniques for all work involving potentially biohazardous materials. Individuals are responsible for their own safety and that of others potentially affected by biohazardous agents or substances, and for the protection of the environment.

Prior to the commencement of any activities involving the use of potentially biohazardous materials, the PI must register the potentially biohazardous agents they propose to use with the IBC via the Biosafety Protocol Registration Form. It is also the responsibility of the PI to ensure that personnel receive the appropriate training on the potential hazards and precautionary measures applicable to the potentially biohazardous materials. This includes instruction in specific practices and techniques required for safely handling the agents.

b. Laboratory Workers, Postdocs, Students, Individuals

Individuals must adhere to biological safety practices and techniques. This includes working with potentially biohazardous agents using the appropriate containment and personal protective equipment as directed by the supervisor and PI. Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a laboratory worker, whether the person is a faculty member, student, intern, visiting scholar, or volunteer. Laboratory workers are the most critical element in maintaining a safe working environment. Each person must look out for her/his own safety and that of their co-worker. If individuals do not follow the university and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working environment. It is the laboratory worker's responsibility to:

- Conscientiously follow lab-specific biosafety practices and procedures.
- Inform the PI of any health condition that may be a result of or complicated by their work in the lab.
- Report to the PI or the lab supervisor all problems, procedural discrepancies, spills, or accidental releases as soon as they occur.
- Report to the Office of Research Assurances any significant violations in biosafety policy, practices, or procedures that are not resolved by the PI.
- Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the PI, the Office of Research and Sponsored Programs or members of the Institutional Biosafety Committee.

c. Unit Leaders (Deans, Chairs, and Directors)

Unit leaders (Deans, Chairs, and Directors) have the following responsibilities:

- Require that prior to initiation of research, each investigator or laboratory director using recombinant DNA, microbial pathogens or human blood and tissues with characterized agents at Risk Group 2 or above, completes and submits the IBC Biosafety Protocol Registration Form.
- Require that students receive instruction in safety procedures in teaching laboratories or field situations where the potential for exposure to a potentially biohazardous agent or material exists.
- Determine that appropriate facilities and safety equipment are available for proposed research or instruction involving potentially biohazardous agents.
- Provide leadership and support in laboratory safety at the management level in the unit.

d. The Institutional Biosafety Committee (IBC)

The IBC is responsible for reviewing and approving practices and protocols for the handling of recombinant DNA and potentially biohazardous materials at all research facilities under the auspices of University of South Dakota. The IBC also assists EH&S in the development and review of policy involving potentially biohazardous agents. The IBC is comprised of faculty representatives, from various academic disciplines at USD, researchers, non-scientific members, and community representatives who are not affiliated with the university. The Committee typically meets monthly to review research and other activities submitted on the Biosafety

Protocol Registration Form. The Institutional Biosafety Committee can be reached by contacting the Office of Research and Sponsored Programs at (605) 677-5370 or orsp@usd.edu.

e. The USD Biosafety Officer (BSO)

The BSO is responsible for developing, leading, directing, and managing a comprehensive biological safety program for University of South Dakota. The biological safety program must meet NIH, CDC, USDA, OSHA, any other granting agency, Federal, State and local requirements. The program includes close cooperation and interaction with faculty committees approving research protocols and procedures for the use of human subjects, animal subjects, radioactive materials and devices, and for chemical hygiene and physical safety. Participation of the IBC in the USD Research Safety Committee enables cooperation and coordination. The BSO will provide guidance and consultation to assess the risk of working with potentially biohazardous materials (see section IV for complete list). The BSO interacts with USD faculty, staff and students engaged in research, teaching, and outreach to inform and ensure compliance with state and federal reporting or audit requirements, and effect actions to inspect and correct deficiencies when noted. The BSO performs facility reviews initially and annually for facilities working at BSL-1 and 2. The BSO is responsible for assisting the PI develop appropriate Biosafety Manuals for all activities using potentially biohazardous materials.

f. The USD Department of Environmental Health and Safety (EH&S)

The USD EH&S department supports research and other activities involving biological materials in areas of laboratory biosafety, public health, and occupational biosafety. The Director of EH&S is the BSO, who carries out the following activities:

- Reviews (initial and at regular intervals) physical facilities and containment equipment for compliance with general CDC guidelines for Biosafety Level (BSL) and Animal Biosafety Level (ABSL) laboratories for research and diagnostic work in accordance with laboratory inspection checklists developed in coordination with the BSO and the IBC.
- Coordinates with Facilities Operations for corrections/modifications/repairs to physical facilities,
- Reviews laboratory biosafety manuals and standard operating procedures (SOPs) for compliance with guidelines for BSL and ABSL procedures,
- Provides general guidance about health and safety standards, and assists the IBC in reviewing research proposals.
- Helps ensure that biohazard, sharps and glass wastes are properly transported outside of laboratory buildings and are treated and disposed of properly after leaving these buildings per applicable state and federal regulations,
- Maintains list of approved biosafety laboratories with review dates and results. The IBC requires that BSL-2 facilities are inspected at least annually.
- Maintains programs and educational materials pertaining to laboratory safety.
- Assist with bloodborne pathogen program.

VII. Authority of the IBC

a. Scope of authority defined

The USD IBC has the authority to approve, require modifications in, or disapprove all research, teaching, diagnostic, or outreach activities (whether externally or internally funded) that fall within its jurisdiction as specified by both the federal regulations and Institutional policy.

b. Authority to approve, modify, or disapprove studies based upon consideration of biological safety aspects

The USD IBC approves protocols for up to three years, with annual reviews (section VIIIc). After three years the protocol (Biosafety Protocol Registration Form) must be resubmitted. Research that has been reviewed and approved by the USD IBC may be subject to further review and disapproval by a senior institutional official (President, Provost, Vice President for Health Affairs, or Vice President for Research). However, those officials may not approve research if it has been disapproved by the USD IBC.

The USD IBC also functions independently of other committees and makes its independent determination whether to approve or disapprove the protocol based upon whether or not biological safety aspects adhere to relevant regulations, guidelines, and policies. The USD IBC has jurisdiction over all research involving regulated or potentially hazardous biological materials, thereby providing broader protection than required by the regulations.

c. Authority to require progress reports from investigators and oversee the conduct of the study

Any approved research or protocol is subject to continuing USD IBC review. Each protocol will undergo an annual review to ensure that no substantive changes to the protocol have occurred. Protocol resubmission will occur every three years or more frequently if specified by the IBC.

d. Authority to approve/disapprove amendments

All modifications to currently approved research and other activities are required to have IBC review and approval prior to implementation. Modifications are submitted on an Amendment form. The IBC modification approval is only good until the end of the original approval period. For example, if a protocol's original approval is issued on January 1, 2013 it will have an expiration date of December 31, 2015. If a modification is approved during this time, the approval still lasts only until December 31, 2015.

e. Authority to suspend or terminate approval of a study

The USD IBC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IBC's requirements or that has been associated with unexpected serious consequences. Any suspension or termination of approval shall include a statement of the reasons for the IBC's action and shall be reported promptly to both the PI and unit head. Information concerning noncompliance or perceived noncompliance with the NIH Guidelines or University policies or procedures may be brought forward by any person and the IBC must recommend appropriate action.

VIII. Membership of the IBC

a. Number of members

The IBC will have no less than five members with varying backgrounds to promote complete and adequate review of research, teaching, diagnostic, and outreach activities involving potentially biohazardous materials and rDNA commonly conducted at USD.

b. Qualification of members

The IBC will have sufficient expertise among its members to be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, recognized guidelines, applicable laws, and standards of professional conduct and practice.

c. Diversity of members

The IBC will be sufficiently qualified through the experience, expertise, and diversity of the members, to promote respect for its advice and capability to assess the safety of recombinant DNA research, teaching, diagnostic, and outreach activities and to identify any potential risk to workers, public health, or the environment. The IBC will include at least two members from the surrounding community. Neither of these members will be affiliated with University of South Dakota and both shall represent the interest of the surrounding community with respect to health and the protection of the environment. The BSO and the attending veterinarian of the Animal Resource Center will be voting members. As appropriate at least one member whose primary expertise is in plants, plant pathogens, and plant pest containment principles and one member with expertise in animals and animal containment principles will be appointed to the IBC Committee.

IX. Management of the IBC

a. The Chair

i. Selection and appointment

The Chair is appointed by the Vice President for Research (Institutional Official). The Chair serves as chair for at least one year and may be reappointed. The Chair is also a voting member. If the Chair is unavailable for a scheduled meeting any member may be asked by the Chair to be a substitute. If a Chair is unavailable for a period of time exceeding 3 months the Institutional Official may appoint a temporary Chair.

ii. Duties

The Chair directs the IBC meetings in accordance with institutional and federal requirements. S/he works closely with IBC members, Institutional Official, BSO, Research Safety Committee members, and investigators to ensure that research and other activities involving regulated or potentially biohazardous materials are conducted safely and in accordance with all applicable federal, state, and Institutional regulations, policies, and procedures. The chair is the designated signatory for the IBC and conducts all IBC meetings.

The Chair may delegate signatory duties to the BSO. The Chair counts toward quorum at meetings and also votes.

iii. Removal

The Chair may be removed or replaced by the IO.

b. The IBC members

i. Selection and appointment

Members are appointed by the Vice President for Research. USD faculty members appointed to the IBC will serve on the board for a three-year term, and may be reappointed for an additional three-year term. Appointments to the committee typically begin with the beginning of the academic year (fall semester) and end with the beginning of the academic year three years later. Community and/or non-affiliated IBC members will be appointed to the board for three-year terms, and may be reappointed for an additional three-year term. There is no limit to the number of terms a member may serve on the IBC, however, IBC members must take at least a one-year hiatus after a second consecutive term.

ii. Duties

USD IBC members are responsible for ensuring that all research and other activities utilizing regulated or potentially hazardous biological materials are reviewed and approved in a manner consistent with federal, state, and local laws, regulations, guidelines and institutional policies.

iii. Removal

IBC members may be removed or replaced by the IO.

c. Training of IBC Chair and members

i. Orientation

When a new member or chair is appointed to the IBC, the BSO will conduct an orientation to introduce these new members to the federal regulations, USD IBC meeting procedures, review process, and the IBC forms.

ii. Continuing Education

Continuing education of the IBC member is done through special training meetings as well as educational information distributed to members through newsletters, on-line courses, or by discussion at a full committee meeting. At a minimum this training will occur once a year. The BSO may attend professional development conferences throughout the year to keep current on IBC issues.

iii. Reference Materials

Each IBC member is provided with the URL of the USD IBC Manual which includes the specific USD IBC Policies and Procedures. IBC members will receive one printed copy of the NIH Guidelines (the most recent version available at the time they join the committee); the URL for the current NIH Guidelines will be available on the EH&S page in the USD Portal.

d. Use of consultants

The USD IBC is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be USD faculty or staff, or may be unaffiliated with USD. The consultants may present their assessments in writing or in person.

X. Conflict of Interest Policy

a. Financial Conflict of Interest

By university policy, investigators or other personnel with decision-making roles must disclose to the university potential financial conflicts of interest. Disclosure occurs routinely with contract renewals each year, when submitting proposals for external funding, and when financial interests change so as to create a perceived conflict. The Faculty Senate Committee on Conflict of Interest Committee will review the financial disclosure, and consider the potential conflict of interest. After the Conflict of Interest Committee determines an investigator has a potential conflict of interest that cannot be eliminated, it will recommend a plan to reduce or manage the conflict. When the conflict of interest involves work with biohazardous materials, the IBC will be consulted in development of the proposed plan to minimize the potential adverse consequences of the conflict. The IBC may impose conflict management strategies more but not less stringent than recommended by the Faculty Senate Committee on Conflict of Interest.

b. Non-Financial Conflict of Interest

i. No selection of IBC members by investigators

The PI cannot select which IBC member will review their protocol. Additionally, any IBC member must recuse himself or herself from a review if s/he has any real or apparent conflict of interest.

ii. Prohibition of participation in IBC deliberations and voting by investigators

Reviews of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IBC on actions concerning projects or activities in which they have an active role or conflict of interest. Failure to abide by these provisions may be cause for removal of a member from the IBC. IBC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol. The IBC member must make any conflict of interest known to the IBC Chair. The member may provide information to the IBC if requested. The fact that a protocol is

submitted by another investigator from an IBC member's Unit or Section does not, in and of itself, constitute a conflict of interest.

XI. Functions of the IBC

a. Conducting initial and continuing reviews

The USD IBC is responsible for the review and approval of all projects (whether funded externally or internally) involving regulated or potentially biohazardous materials conducted under the auspices of University of South Dakota regardless of funding source.

b. Reporting findings and actions of the IBC to the investigator

The BSO will report findings and actions of the IBC to the investigator.

c. Determining which studies require review more often than every three years

The IBC requires that all active protocols be resubmitted every three years, unless the IBC has determined the nature and/or risk of the research requires more frequent renewal. All field trials that require an APHIS permit or notification require an annual submittal of the current USDA permit or notification to the IBC.

d. Reviewing and approving changes/amendments to research activities

All modifications to currently approved research/activities are required to have IBC review and approval prior to implementation. Modifications are submitted on a Biosafety Protocol Amendment form. The IBC modification approval is only good until the end of the original approval period. For example, if the Biosafety Protocol original approval is issued on January 1, 2013 it will have an expiration date of December 31, 2015. If a modification is approved during this time, the approval still lasts only until December 31, 2015.

e. Ensuring that changes in approved research are not initiated without IBC review and approval except where necessary to eliminate apparent immediate hazards

There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to relieve an apparent immediate hazard. In these situations, the PI may implement a change necessary to protect humans or the environment. Investigators are encouraged to contact the IBC if this type of situation arises prior to implementation of the protocol change.

f. Ensuring prompt reporting to the IBC of unanticipated problems

The BSO will report in writing within 10 working days to the IBC Chair, Vice President for Research, relevant Unit or Agency Head (sponsor), any applicable regulatory body, any report of adverse events as mandated in the Federal Regulations. Select Agents and Toxins require immediate notification of the Responsible Official (the Vice President for Research) and the relevant agency (CDC or USDA/APHIS).

g. Facility planning and construction

A representative of the IBC will be included as an advisory member of planning and construction committees that are constituted for individual building projects that include laboratories.

XII. Operations of the IBC

a. Scheduling of meetings

The full IBC will meet quarterly, typically September, December, March, and June, unless there is no business to be conducted, in which case a meeting will not be held. Meetings will be arranged by the BSO or designee. IBC meetings are open to the public (unless proprietary information is discussed, which will occur in executive session) and meeting dates for the current semester are published on the Environmental Health & Safety website.

b. Pre-meeting distribution of IBC review materials to members

Seven calendar days prior to a meeting the BSO will send to each committee member who will be in attendance at the next meeting:

1. Meeting agenda
2. Minutes from the previous meeting
3. All new protocols to be reviewed
4. Modification Requests
5. Renewal Requests
6. Continuing Education Materials

c. The review process

i. Description of the review process

The USD IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted under the auspices of University of South Dakota regardless of funding source (external or internal). The IBC will consider all information presented with the Biosafety Protocol forms. The IBC may request additional information and/or clarification from the researcher.

ii. Review

Pre-IBC Review: Upon receipt of a protocol, the BSO will check the protocol for completeness of non-technical information, such as name, department, etc. Approximately one week in advance of the IBC meeting, the IBC chair and BSO will pre-review the protocol, and contact the investigator via phone or email if any additional materials are required or for information likely to be requested during the IBC review.

Committee Review: The IBC chair will present the proposed protocols to the convened IBC, though s/he may delegate responsibility for presentation to other IBC members. All committee members are expected to review all protocols. All protocols will be discussed in detail at convened meetings. The IBC chair will not approve protocols on behalf of the IBC

without review and approval by the IBC. The IBC will review and discuss protocols and may make one of three determinations:

Approved: The IBC may make a motion and vote to approve the protocol as submitted. The PI will then receive an approval letter.

Deferred: Approval will be deferred when additional information or requirements must be met. The IBC chair or BSO will contact the PI for additional information or to complete specific requirements prior to granting approval.

If the information or requirements constitute a major change to the protocol, the IBC may require review at a convened IBC meeting prior to granting approval.

If the information or requirements are minor, then once the additional information or requirements have been met the PI will receive the approval letter.

The IBC will maintain deferred protocols for 6 months for the PI to meet the requirements for approval. After 6 months the protocol may need to be resubmitted to the IBC. The BSO acts as a resource to assist the PI in this approval process

Disapproved: In certain cases research activities may be proposed that are deemed too hazardous or for which the proper expertise or facilities are not available. In such cases the IBC may vote to disapprove the research.

The BSO will notify the researcher of the decision of the committee and, in the case of approved protocols, issue written approval on behalf of the committee.

Emergency Review: The IBC Chair may agree to expedite the review of a particular protocol when extenuating circumstances warrant. To do so s/he will convene an *ad hoc* meeting of the IBC after the entire protocol is sent to all committee members.

d. Voting requirements

i. Quorum required

A quorum of more than half of the voting membership is required to conduct business.

ii. Full voting rights of all reviewing members

Each member has one vote.

iii. No proxy votes

No proxy votes are allowed.

iv. Prohibition of conflict-of-interest voting

IBC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol.

v. Alternates

Each IBC member may have designated alternates, who are appointed by the IO. Alternates may attend all meetings, however, they vote only when the primary member is absent. Alternates attending meetings (when the primary member is present) do not count toward quorum and may not vote. Alternates are encouraged to review all protocols and participate in all discussions.

e. Communication from the IBC

IBC actions that occur during meetings are promptly conveyed (usually within 5 working days) to the PI in writing by the BSO. Communications include approval or, for deferred protocols, all requirements that must be met for the committee to grant approval.

f. Appeal of IBC decisions

If an IBC application is disapproved, the reasons for disapproval will be conveyed to the PI in writing. The investigator may request the IBC to reconsider by responding in writing within 10 working days, and may request an opportunity to appear before the IBC. The IBC's decision upon appeal is final.

XIII. IBC record requirements

a. IBC membership roster

Each year the IBC coordinator will submit to NIH-OBA (Office of Biotechnology Activities) a copy of the membership roster and curriculum vitae demonstrating the qualifications of each committee member.

b. Written procedures and guidelines

Written IBC procedures and guidelines are contained in the USD Institutional Biosafety Committee (IBC) Manual. For a copy of this manual, please visit the EH&S website in the USD Portal or contact the Director of Environmental Health & Safety (605-677-6265, ehs@usd.edu) to request a copy.

c. Minutes of meetings

The BSO or designee will take minutes at each meeting of the IBC. The minutes will contain:

- 1) Members present
- 2) Others present (guests/consultants/researchers)
- 3) Summary of discussions
- 4) Motions made and seconded

- 5) Record of voting
- 6) Assurances that the current OBA Guidelines are adhered to
 - a) Per February 23, 2007 Guidelines
 - i) IBC determines the appropriate containment per NIH Guidelines
 - ii) IBC assures that facilities, procedures, practices, training and expertise of personnel involved in rDNA research are appropriate.
 - iii) The IBC periodically reviews recombinant DNA research to ensure compliance with the NIH Guidelines
 - b) IBC Minutes must include
 - i) Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
 - ii) Types of manipulations planned
 - iii) Sources of the inserted DNA sequences (e.g. species)
 - iv) Nature of the inserted DNA sequences (e.g. structural gene, oncogene)
 - v) Hosts and vectors to be used
 - vi) Whether an attempt will be made to obtain expression of a foreign gene and if so the protein that will be produced
 - vii) Containment conditions to be implemented
 - viii) Applicable section of the NIH Guidelines

d. Retention of records

All protocols reviewed and related materials will remain on file in the Environmental Health & Safety department for three years after the completion of publication (or conclusion of the research). The IBC maintains a database of all proposed and active projects and activities involving rDNA and potentially biohazardous material. Files may be paper or electronic. Meeting minutes and IBC rosters will remain on file at EH&S as a record of the committee's activities. Policy guidance and forms will be disseminated from and stored at EH&S until replaced by new and/or revised documents.

e. Communication to and from the IBC

The Biosafety Protocol forms are available from EH&S or on the USD website Portal access at www.usd.edu. Any questions regarding IBC review or the content of this manual should be directed to the BSO at 605-677-6265 or ehs@usd.edu. The BSO keeps in contact with researchers regarding IBC decisions and requests for additional information.

The public may address comments to the IBC by clicking on a link on USD's public EH&S website (<http://www.usd.edu/research/research-and-sponsored-programs/environmental-health-and-safety.cfm>), which opens an email dialog box, or use the telephone number at the bottom of the EH&S public webpage to call the EH&S director (BSO). If these communications include comments on IBC actions, those comments (and IBC response) will be forwarded to NIH Office of Biotechnology Activities as specified in Section IV-B-2-a-(7) of the *NIH Guidelines*.

f. Public access to IBC meeting minutes

The pertinent state statute governing open records is South Dakota Codified Law Chapter 1-27 (Public Records and Files). The public may request copies of meeting minutes by emailing or writing to the BSO. The BSO will provide a written copy of minutes within 5 working days. If the

records request cannot be fulfilled within that time period, the BSO will reply to the request within 5 working days to explain the situation and provide a target day for compliance with the request. The State of South Dakota Open Records Law exceptions (1-27-1.5) will apply, and minutes may be redacted as permitted in the exceptions. Redacted items include but are not limited to personnel records, details of bona fide or applied research, and proprietary information as described in 1-27-1.5(3).

XIV. Information the investigator provides to the IBC

a. Biosafety Protocol Registration Form

A PI applying for IBC approval for research, teaching, diagnostic, or outreach activities needs to submit a completed Biosafety Protocol Registration Form.

b. Biosafety Protocol Forms for rDNA, infectious agents, animal studies, and toxins

In addition to the Biosafety Protocol Registration Form, and depending upon the nature of the work, the PI will complete forms requesting information on recombinant DNA, infectious organisms, studies with animals, or toxins and select agents.

c. Annual Review Form

Unless the IBC requires more frequent and in-depth review, PIs with approved protocols will submit a completed annual review form to update their protocol for minor changes such as personnel changes, training updates, etc. Major changes are not requested on the annual review form, but rather are submitted through the usual IBC review process. The BSO will send reminders for annual review form submission one month prior to the first and second anniversary date of protocol approval. After three years, resubmission of the Biosafety Protocol form is required.

d. Requests for amendments in activities after initial approval.

All major modifications to currently approved protocols are required to have IBC review and approval prior to implementation. Minor changes that do not increase the risk to workers, the community, and/or the environment may be processed as an administrative approval performed by the IBC Chair or the BSO. Significant modifications to approved activities will be forwarded to the full IBC for review. Amendments should be submitted on the Biosafety Protocol Amendment Form along with copies of the original protocol sections to be modified/changed (as appropriate). The IBC amendment approval is only good until the end of the original approval period. For example, if the original Biosafety Protocol approval is issued on January 1, 2013 it will have an expiration date of December 31, 2015. If a modification is approved during this time, the approval still lasts only until December 31, 2015.

e. Reports of unexpected adverse events

All unanticipated/adverse events should be reported to the IBC in writing as well as any actions taken on the part of the researcher as a response to the adverse event. NIH Guidelines require that the PI report any significant events to the IBC & OBA (Office of Biotechnology Activities)

within 30 days. The Emergency Response Plan should be consulted for urgent situations, and the BSO notified as soon as possible.

Appendix G of the *NIH Guidelines* specifies certain types of accidents that must be reported on a more expedited basis:

- Spills and accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to the IBC and the OBA (*NIH Guidelines* Appendix G-II-B-2-k)
- Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to IBC, BSO, and OBA (Appendices G-II-C-2-q and G-II-D-2-k)

Further information on reporting of incidents, accidents, or violations to NIH OBA can be found on the OBA website at:

http://oba.od.nih.gov/oba/ibc/FAQs/IBC_Frequently_Asked_Questions7.24.09.pdf.

f. Notification of protocol expiration

Two months prior to the expiration of an approved protocol, the PI will receive an e-mail notifying them that their approved protocol is about to expire. Investigators desiring to continue their research are responsible for completing a new Biosafety Protocol form and returning it to the IBC office in time for review before the expiration date. The investigator is responsible to keep Biosafety Protocol forms current regardless of whether they receive an expiration notice or not. One month prior to the expiration a second notification will be emailed. If the PI doesn't respond at the end of two months the last notification will indicate that the protocol is expired. At this time all work on this project must be discontinued.

g. Student research

Research conducted by students and that involve biological materials, whether dissertation, thesis, or other research projects, should be supervised by a faculty advisor and submitted to the IBC for review. IBC review and final approval should take place during the proposal stage of the dissertation or thesis.

XV. Biosafety laboratories

a. Biosafety laboratory reviews

The BSO reviews biosafety labs (BSL-2, ABSL-2) annually and reports results and recommendations to the IBC. The BSO reviews biosafety facilities used for recombinant DNA activities at BSL-1.

b. Biosafety manuals

Biosafety manuals including this IBC manual and biosafety manuals created by PIs are reviewed by the BSO. The IBC manual is reviewed by the BSO, IBC, and IO every 3 years.

c. Blood Borne Pathogens

EH&S is responsible for assisting the PI in adhering to best practices.

d. Teaching Activities

For teaching activities the PI/Instructor works with the BSO as a resource to develop student training for the course, including a biosafety manual for the course as appropriate. The BSO will perform a facility review for BSL-1 and BSL-2 facilities.

XVI. Materials and activities requiring additional permits or approvals

In general any biological material that requires a federal permit should be registered with the USD IBC via the Biosafety Protocol Registration Form. Copies of the permits must accompany the Biosafety Protocol Registration Form. Permits that require the signature of the IO include:

a. Federal permits

Many biological materials and activities require additional federal permits. These permits may be necessary for a wide range of activities.

- i. APHIS permits (<http://www.aphis.usda.gov/>).
- ii. CDC permits (<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>).
- iii. FDA permits
- iv. EPA permits
- v. Field trials of genetically modified organisms (<http://www.aphis.usda.gov/brs/pharmaceutical.html>).

b. Other permits

- i. Material Transfer Agreement (Forms, under Research and Sponsored Programs in the USD website Portal)
- ii. American Type Culture Collection (ATCC)

XVII. Bloodborne pathogens

Activities utilizing human and primate tissues, cells blood and other potentially infectious body fluids must comply with Federal and State requirements. These materials are always considered to be potentially infectious agents and must be treated as a pathogen.

a. Activities whose only exposure to potentially biohazardous material is through work with agents that fall under the OSHA BBP Standard

For this work to be in compliance, the PI will work with the BSO directly to develop an exposure control plan. A Biosafety Protocol Registration Form should be submitted to the IBC for USD's inventory of biological materials, but IBC review and approval are not required unless the BSO determines that the activities are beyond the scope of the exposure control plan and require IBC

oversight. An example of this would be work with INT-407 cell line that contain characterized Human Papilloma Virus and are classified by ATCC as a BSL-2 cell line.

b. Bloodborne pathogens program and training

Researchers should contact the EH&S director (605-677-6265, ehs@usd.edu) for information and assistance. Students in the medical doctor program should refer to the bloodborne exposure checklist for assistance (<http://www.usd.edu/medical-school/medical-doctor-program/upload/Bloodborne-Exposure-Checklist.pdf>).

c. Biosafety level

In general research and teaching activities with blood and other body fluids should be performed using BSL-2 practices.

d. Human cell lines

Requirements for working with unfixed human cell lines are based upon whether the human cell line is primary explants, derived from these explants (typically those collected by a researcher or a colleague) or established, transformed human cell line lines well characterized by rigorous techniques (such as those obtained from ATCC). When tissue from human cell lines is fixed with material to render it incapable of carrying an infectious agent these requirements no longer apply.

i. Primary Human & NHP Cells/Tissues

Work with primary human cell lines requires adherence to the USD Bloodborne Pathogen Program. Work with unfixed primary human cell lines requires:

- Registration with the IBC via the Biosafety Protocol Registration Form.
- Work with unfixed primary human cell lines must be performed in a BSL2 facility following BSL2 practices.
- A bloodborne pathogen exposure control plan must be in place.
- Bloodborne pathogen training is required.
- Individuals working with human cell lines should be offered hepatitis B immunization, unless information is available to indicate that hepatitis B is not reasonably expected to be present in the cell line.

ii. Established Human & NHP Cell Lines

Even established or transformed cell lines (such as those obtained from the ATCC) may not be pathogen free as they can be adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures or physically contaminated by other cell cultures handled in the same lab. Work with unfixed established human cell lines requires:

- Work with unfixed established human cell lines should generally be performed following BSL2 practices.

- Some established cell lines must be worked with in a BSL-2 facility. The cell line source and BSO should be consulted in establishing the appropriate biosafety level.
- Contact EH&S director for training and assistance with bloodborne pathogens
- Lab personnel training should include review of the biosafety manual and or exposure control plan.

XVIII. Biosecurity

The security of biological materials is of significant concern and importance. The PI and all laboratory personnel must be conscientious with respect to the control of biological materials. Questions about export controls should be addressed to the Vice President for Research. Access to laboratories and materials must be limited to the greatest extent possible. PIs should identify the risk that a material may pose (i.e., low, medium, high) and perform a vulnerability assessment of the use and storage of the material. The protection and security of the material should be based upon the risk. Security for biological materials to be considered includes (but is not limited to):

- Additional locks (padlocks and electronic access cards) on laboratories, freezers, etc. where biological agents are used or stored.
- Chain-of-custody forms within laboratories to track materials.
- Inventories of biological materials.
- Logs of access to areas where biological materials are in use.
- Conduct a threat and/or vulnerability assessment.

XIX. Definitions

Potentially Biohazardous Material: The Institutional Biosafety Committee reviews and approves many areas of biologically related research, teaching, diagnostic, and outreach activities. The USD IBC defines potentially biohazardous materials to include all of the categories below. Projects involving material(s) included in any of these categories must be submitted for IBC approval.

- Recombinant DNA (rDNA),
- Genetically modified organisms. Including, but not limited to:
 - Animals, plants, invertebrates, and/or other organisms created by USD employees or in/on USD property,
 - Genetically modified whole plants (even those commercially available and not requiring APHIS permits; to include planting of USDA deregulated commercially available seed in the field)
 - Transgenic field trials, any genetically modified organisms to be introduced into the environment (by USD personnel and/or on USD property),
 - Field testing of plants engineered to produce pharmaceutical and industrial compounds,
- Any organisms requiring federal permits such as; APHIS, CDC, FDA, EPA, etc.,
- Pathogens/infectious agents (human, animal, plant, and other),
- Select/Biological Agents and Toxins (CDC and USDA),
- Human and primate tissues, cells and cell lines, blood and blood products, and potentially infectious body fluids.
- Work with animals or vectors known or suspected to be reservoirs of RG2 or RG3 infectious agents when such work increases potential exposure risks to personnel or other animals,
- Oncogenic viruses used in conjunction with animals.

The IBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these areas. When it is unclear as to whether a material constitutes a potential biohazard, the IBC should be consulted. Questions should be directed to the Office of Research Assurances, IBC Coordinator, or USD Biosafety Officer.

Biosecurity: Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.

Biologic Terrorism: Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) for terrorist purposes.

Blood: Human and primate blood, and blood components that include plasma, platelets and wound exudates, and products derived from this blood.

Bloodborne pathogens: Pathogenic microorganisms present in human blood, which can cause disease in humans. Includes the hepatitis B virus (HBV), hepatitis C virus (HCV) and the human immunodeficiency virus (HIV).

Chain of Custody: The serial holders of a pathogen, each of who is responsible for securing the pathogen and are accountable for its documentation.

Contaminated: Presence or reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Decontamination: Use of physical or chemical means to remove, inactivate or destroy bloodborne pathogens or other biohazardous agents on a surface or item to the point where they are no longer capable of transmitting infectious particles and the item or surface is rendered safe for handling, use, or disposal.

Engineering controls: Controls such as sharp disposal containers or self-sheathing needle that isolate or remove the hazard from the workplace.

Genetic Engineering: Genetic engineering refers to the process in which genes or other genetic elements from one or more organisms are inserted into the genetic material of a second organism using molecular biology methods. Moving a new gene or genes in this way allows researchers to introduce new traits into an organism from individuals of the same species or from unrelated species.

Genetically Modified Organism (GMO): An organism whose genetic material has been altered using techniques generally known as recombinant DNA technology.

HIV: Human immunodeficiency virus.

Institutional Official (IO): The facility official who has been designated the responsibility and authority to ensure that the requirements for compliance with federal, state and local regulations are met.

Other potentially infectious materials (OPIM): Including the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood and all

body fluids where it is difficult or impossible to differentiate between body fluids; any unfixed tissue from human and HIV/HBV containing culture medium.

Parenteral: Entry into the body by other means than through the digestive tract, such as by piercing mucous membranes or the skin by needle sticks, human bites, cuts and abrasions.

Personal protective equipment (PPE): Special clothing/equipment worn by a worker to protect against a hazard. General work clothes (uniforms, pants, shirts, blouses) not intended to function as protection against a hazard are not considered personal protective equipment.

Regulated waste: Solid or liquid waste that may present a threat of infection to humans. Examples include:

- Non-liquid or semi-liquid tissue and body parts from humans and other primates; laboratory and veterinary waste which contain disease-causing agents; discarded sharps; and blood, blood products and body parts from humans and other primates;
- Other potentially infectious materials; contaminated items that would release blood;
- Other potentially infectious materials in a liquid or semi-liquid state if compressed;
- Items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; and
- Contaminated sharps and pathological and microbiological wastes containing blood or other potentially infectious materials.

Risk: A measure of the potential loss of a specific biologic agent of concern, on the basis of the probability of occurrence of an adversary event, effectiveness of protection, and consequence of loss.

Select agent: Specifically regulated pathogens and toxins as defined in Title 42, CFR, Part 73, including pathogens and toxins regulated by both DHHS and USDA (i.e., overlapping agents or toxins) and plant pathogens regulated by USDA alone.

Select Agent Access: The ability to take physical possession of select agents/toxins. Such access includes areas where unlocked freezers, small unsecured, yet locked, containers, and cabinets contain select agents/toxins.

Select Agent Area: An area where select agents/toxins are used or stored, regardless of whether they are in locked containers. Such an area would be a laboratory room or connecting rooms where select agents are used or stored. Corridors outside the laboratory room where select agents are used or stored may or may not be declared a select agent area, depending upon the biosecurity plan approved by the IO.

Threat: The capability of an adversary, coupled with intentions, to undertake malevolent actions.

Threat assessment: A judgment, based on available information, of the actual or potential threat of malevolent action.

Vulnerability: An exploitable capability, security weakness, or deficiency at a facility. Exploitable capabilities or weaknesses are those inherent in the design or layout of the biologic laboratory and its protection, or those existing because of the failure to meet or maintain prescribed security standards when evaluated against defined threats.

Vulnerability assessment: A systematic evaluation process in which qualitative and quantitative techniques are applied to arrive at an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interest.