Institutional Biosafety Committee (IBC) Manual

Washington State University
Office of Research Assurances
Institutional Biosafety Committee
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I. Introduction

The Washington State University (WSU) Institutional Biosafety Committee (IBC) is a Presidential Committee charged with protecting WSU faculty, staff, students, and visitors and has the authority and obligation to stop any activity that the committee believes to be unsafe. The *WSU Institutional Biosafety Committee Manual* is your reference document detailing the policies and regulations governing research with biological materials and the requirements for submitting research proposals for review by the WSU IBC. The instructions and information contained in this handbook are set forth and adopted by the WSU IBC and are based on federal, state, county, and University 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 research activities before submitting proposals to the IBC.

The IBC operates within federal guidelines with respect to the review and approval of research protocols involving biological materials. The IBC reviews and approves many areas of biologically related activities which may include: research, teaching, diagnostic, and extension activities performed by faculty, students, visitors (including non-WSU employees working in WSU facilities), or employees of WSU involving recombinant DNA (rDNA) and/or potentially biohazardous materials. These requirements also apply to all activities in/on WSU land, facilities (owned, leased, or rented) and/or WSU designated or sponsored activities. The IBC is comprised of faculty representatives, from various academic disciplines at WSU, researchers, non-scientific members, representatives from University departments, students, and community representatives who are not affiliated with the University.

The University, investigators, their research staff, and the IBC, share the collective responsibility for the safe and ethical conduct of research including all personnel, facilities, and equipment. This collaboration must exist in a culture of trust, complete openness, and honesty by upholding the highest ethical principles in the conduct of research. By upholding the highest standards, we build public support for the pursuit of greater knowledge in a safe research environment.

Biosafety is a team effort involving the Principal Investigator (PI), WSU Biosafety Officer, laboratory research and support staff, Extension, Teaching staff and Biosafety Committee members, Environmental Health and Safety, Risk Management, Animal Care and Use, Human Subjects, and Radiation Safety, and is inextricably linked to the other aspects of laboratory safety. This handbook has been structured to reflect this approach.

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. It is the PI responsibility to become thoroughly familiar with the contents of this manual, to make sure that his or her workers become equally familiar with it, and to ensure that all work with potentially biohazardous materials is conducted in a safe and ethically sound manner, in accordance with the WSU Safety Policies and Procedures Manual (SPPMs), laboratory specific biosafety manuals and Standard Operating Procedures (SOPs).

It is essential that staff and students seek additional advice and training when dealing with potentially biohazardous agents to ensure the safety of employees, students, and the surrounding community. To assist in this, the services and resources of the WSU Biosafety Officer and the Department of Environmental Health & Safety (EH&S) are available.

II. The institutional authority under which the IBC is established

The Washington State University Institutional Biosafety Committee (IBC) is a Presidential Committee. The Institutional Official (IO) for the IBC is the Vice President for Research.

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 Washington State University who either store or carry out research or diagnostic activities involving potentially biohazardous materials must inform the Institutional Biosafety Committee via the BAF.

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 WSU 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 WSU. See the NIH Guidelines and CDC BMBL for a list of these agents. You may also reference the on-line reference provided by ABSA for assistance in determining appropriate agent risk groups.

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 extension activities.

The WSU 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. Work with materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures are provided oversight through the EH&S Blood borne Pathogen Program and, in most cases, will not require IBC oversight. 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 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 WSU employees or in/on WSU property,
  - Transgenic field trials, any genetically modified organisms to be introduced into the environment, including planting of deregulated items in the field (by WSU personnel and/or on WSU 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 Office of Research Assurances (335-7183), or WSU Biosafety Officer (335-1585).

* 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 WSU 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 which 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 WSU 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 WSU 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
- WAC 296-823 Bloodborne Pathogens
- WAC 16-752-505, 16-752-610 & 16-752-400-415 Noxious Weed Control

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 WSU 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 BAF. 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 Assurances, 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 BAF.
- 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 Washington State University. The IBC also assists EH&S in the development and review of policy (i.e. SPPMs) involving potentially biohazardous agents. The IBC is comprised of faculty representatives, from various academic disciplines and urban campuses at WSU, researchers, non-scientific members, students, and community representatives who are not affiliated with the university. The Committee typically meets monthly to review research and other activities submitted on the BAF.

The Institutional Biosafety Committee can be reached by contacting the Office of Research Assurances, at (509) 335-1585.

e. The WSU Biosafety Officer (BSO)

The BSO is responsible for developing, leading, directing, and managing a comprehensive biological safety program for Washington State University. 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, Institutional Animal Care and Use, Biohazards and Biosafety, Radioactive Materials and Radiation Devices. 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 the WSU research, teaching, diagnostic, and extension community 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 coordinates and approves facility reviews. Biosafety level one facilities are reviewed initially and at 3-year intervals by the PI (or designee) or by the BSO. Biosafety level two facilities are reviewed initially and at 3-year intervals by the BSO. Biosafety level three facilities are reviewed initially and annually thereafter by the BSO.

- 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 IBC.
- Coordinates with Facilities Operations for corrections/modifications/repairs to physical facilities,
- Review of 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.
- Per SPPM S80.12, S80.13, S80.14, 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 be inspected at least every three years and that BSL-3 facilities are inspected annually.

The BSO is responsible for assisting the PI develop appropriate Biosafety Manuals for all activities using potentially biohazardous materials. Templates can be found on our website.

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

The WSU EH&S department supports research and other activities involving biological materials in areas of laboratory biosafety, public health, and occupational biosafety.

- Maintains programs and educational materials pertaining to laboratory safety.

- Implement bloodborne pathogen standard medical surveillance program.

VII. Authority of the IBC

a. Scope of authority defined

The WSU IBC has the authority to approve, require modifications in, or disapprove all research, teaching, diagnostic, or extension activities (whether funded or non-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 WSU IBC approves protocols for up to three years. After three years the protocol (BAF) must be resubmitted. Research that has been reviewed and approved by the WSU IBC may be subject to further review and disapproval by the Institutional Official (President, Provost, or Vice President for Research and Dean of the Graduate School). However, those officials may not approve research if it has been disapproved by the WSU IBC.

The WSU IBC also functions independently of other committees and makes its independent determination whether to approve or disapprove the protocol based upon whether biological safety aspects adhere to relevant regulations, guidelines, and policies. The WSU 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 WSU IBC review and is generally reevaluated at least every three years (or more frequently, if specified by the IBC).

d. Authority to approve/disapprove amendments

All modifications to currently approved research/activities are required to have IBC review and approval prior to implementation. Modifications are submitted on an Amendment form, revised BAF, or correspondence through electronic mail.

An amendment may require full IBC review if the modification is significant. Examples of significant amendments may include the addition of potentially biohazardous materials that require a higher biosafety level, and the addition of materials or procedures that may increase the risks of the research. Administrative amendments may be approved by the Chair of the IBC and/or the WSU BSO. Examples of Administrative amendments may include the addition of very similar potentially biohazardous materials to an approved protocol (if used in a similar manner), change of laboratory room (if change is to an equivalent and approved facility), addition of personnel on the protocol, and change of PI or contact information.

The IBC modification approval is only good until the end of the original approval period. For example, if the BAF 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 WSU 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.

See last paragraph towards the bottom of page 23.
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 extension activities involving potentially biohazardous materials and rDNA commonly conducted at WSU.

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 extension 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 Washington State University and both shall represent the interest of the surrounding community with respect to health and the protection of the environment.

The BSO will be a voting member.

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.

Every effort will be made to ensure that at least two of the following fields of expertise will be represented on the IBC: pharmacy, immunology, and animal related.

Every effort will be made to include a voting member from the Office of the Campus Veterinarian (OCV).

Every effort will be made to include a voting member from EH&S.

Every effort will be made to include a non-voting member from Facilities Services.

Every effort will be made to include representation from the urban campuses on the IBC.

IX. Management of the IBC

a. The Chair

i. Selection and appointment

The Chair is appointed by the President based upon the recommendation of the IO. 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 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, the Institutional Official, the Research Assurances Officer, the IBC coordinator, the BSO, EH&S, 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 Office of Research Assurances personnel.

The Chair counts toward quorum at meetings and 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 President based upon the recommendation of the IO. WSU faculty members appointed to the IBC will serve on the board for a three-year term. Appointments to the committee typically begin August 16 of the year appointed and end August 15 three years later.

Community and/or non-affiliated IBC members will be appointed to the board for three-year terms.

At the conclusion of their terms a committee member may be appointed to an additional term and/or year(s) of service. There is no limit to the number of terms a member may serve on the IBC.

ii. **Duties**
WSU 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 or Director of ORA will hold a New Member Orientation. This orientation will introduce these new members to the federal regulations, WSU 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 or by discussing them at a full committee meeting. At a minimum, this training will occur once a year. The IBC Coordinator, BSO, and Research Assurances Officer 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 WSU IBC Manual which includes the specific WSU IBC Policies and Procedures.

d. Liability coverage for IBC members
State law offers protection for state employees and authorized volunteers who are sued for duties and actions performed in the course of their employment and in good faith.

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

f. Administrative support staff

The WSU IBC has an IBC Coordinator to coordinate the privileged and confidential institutional review and approval process of proposed research activities involving biological materials.

The IBC Coordinator

- Presents evaluations, recommendations, historical information, and precedents regarding compliance with laws, regulations, and ethical and safety standards;
- Assists in the interpretation and application of federal and state laws, regulations and institutional policies and guidelines relevant to the use of biological materials in research proposals and other activities;
- Communicates committee requests to investigators for additional Information and revisions and review responses;

- Prepares correspondence, reports, agendas, and certifications of review for funding agencies related to review and approval process;
- Independently reviews and approves administrative and procedural modifications (in consultation with the Chair, BSO, and/or Director of Research Assurances as needed);
- Facilitates approval for emergency or unique opportunity situations;
- Advises faculty, staff, and students in preparation of applications for research proposals and other activities involving biological materials;
- Maintains all records related to IBC activities.

X. Conflict of Interest policy

a. Financial Conflict of Interest

Investigators (or other project personnel) involved in a research project or other activity involving potentially biohazardous materials must disclose a potential financial conflict of interest on the BAF. The Conflict of Interest Committee will review the financial disclosure and consider the potential conflict of interest (as outlined in OGRD Memorandum No.3, *WSU Policy and Procedures for Managing Conflict of Interest in Sponsored Research and Scholarship)*.

After the Conflict of Interest Committee determines an investigator has a potential conflict of interest that cannot be eliminated, and must be reduced or managed in some way, the IBC will carefully consider the specific mechanisms proposed to minimize the potential adverse consequences of the conflict.

In all cases, good judgment, openness of process and reliance upon objective, third party oversight can effectively safeguard the integrity of the research.

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 WSU IBC is responsible for the review and approval of all projects (whether funded or non-funded) involving regulated or potentially biohazardous materials conducted under the auspices of Washington State University regardless of funding source.

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

The IBC Coordinator or 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 BAF Amendment form.

The IBC modification approval is only good until the end of the original approval period. For example, if the BAF 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 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. Investigators are required to notify the Office of Research Assurances in writing of the change, within 72 hours, and include a written description of the change and events which necessitated immediate implementation.

f. Ensuring prompt reporting to the IBC of unanticipated problems

The BSO or the Director of the Office of Research Assurances will report in writing within 10 working days to the IBC Chair, Vice President for Research and Dean of the Graduate School 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 Dean of the Graduate School) and the relevant agency (CDC or USDA/APHIS).

XII. Operations of the IBC

a. Scheduling of meetings

The full IBC will convene monthly throughout the year, unless there is no business to be conducted, in which case a meeting will not be held.

Monthly meetings will be arranged by the IBC Coordinator. IBC meetings are open to the public and meeting dates for the current

semester is published on the Office of Research Assurances' website.

b. Pre-meeting distribution of IBC review materials to members
Seven calendar days prior to a monthly meeting the IBC coordinator will send to each committee member who will attend 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 WSU IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted under the auspices of Washington State University regardless of funding source (or lack of a funding source). The IBC will consider all information presented with the BAF. The IBC may request additional information and/or clarification from the researcher.

ii. Review
Pre-Review
Upon receipt of a protocol, the IBC coordinator will pre-review the protocol for required signatures and completion. The Coordinator will contact the investigator via phone or email if any additional materials are required.

Tertiary Review
The BSO acts as a tertiary reviewer of all submitted protocols and may contact the investigator with additional questions that arise as part of this review process.

Pre-IBC Review
A week in advance of the monthly IBC meeting, a subcommittee of the IBC whose members include the IBC Chair, BSO, and Director of Research Assurances, meet to perform a review of each protocol and assign primary and secondary reviewers. Any of the Pre-IBC members may contact the PI with additional questions that arise as

part of this review process. The IBC Coordinator attends this meeting and is responsible for taking meeting minutes, providing a meeting agenda, and complete packet of information for the meeting. The IBC Coordinator may also contact the PI for additional information as assigned by Pre-IBC members at this meeting as appropriate.

Committee Review

The IBC Chair and/or BSO will assign committee members as primary and secondary reviewers. Primary and secondary reviewers should carefully review each protocol assigned and clarify any questions/discrepancies/concerns with the PI prior to the scheduled IBC meeting. Alternatively, the reviewer may ask the BSO to contact the PI on their behalf. All committee members are expected to review all protocols. All protocols will be discussed in detail at convened meetings.

The IBC will review and discuss protocols and may make one of three determinations:

i. **Approved:** The IBC may make a motion and vote to approve the protocol as submitted. The PI will then receive an approval letter.
ii. **Deferred:** When additional information or requirements must be met prior to approval. The IBC coordinator or other may contact the PI for additional information or to complete specific requirements prior to granting approval. 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 resources to assist the PI in this approval process
iii. **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 IBC Coordinator 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 protocol when extenuating circumstances warrant. If the IBC Chair agrees to expedite a review, the entire protocol will be sent (either electronically or paper) to all committee members. Committee members will return any question/comments to the IBC Coordinator to be clarified by the PI. All such communications will be shared with the entire committee membership. Committee members will return their vote to approve, defer, disapprove, or discuss at a convened committee meeting to the IBC Chair and/or Coordinator.

d. Subcommittee Review

The IBC will use subcommittees to facilitate reviews in certain circumstances. Subcommittees will be composed of 2 to 4 individuals with the appropriate expertise. When subcommittees are used for reviewing the subcommittees will report to the full committee. Subcommittees will assist in reviews requiring more specialized review or in cases where sensitive materials or information may be discussed (select agents, confidential business information).

The subcommittee will discuss and make recommendations to the IBC. The IBC considers the recommendations and can ask questions. The IBC acts as the final authority for all protocol approvals.

i. Teaching labs

A subcommittee of the IBC may be used to review teaching lab activities involving potentially biohazardous materials as requested. As time allows these BAF submittals will be considered directly by the full committee.

ii. Diagnostic labs

A subcommittee of the IBC may be used to review diagnostic lab activities involving potentially biohazardous materials. As time allows these BAF submittals will be considered directly by the full committee.

iii. Select agents and toxins

A subcommittee of the IBC will review select agent and toxin activities (above the exempt amount). They report their findings and recommendations to the IBC. The IBC asks questions and votes to approve, defer, or disapprove.

iv. Transgenic plant field trials
The BSO and/or a subcommittee of the IBC will review all transgenic field trials. The BSO and/or subcommittee reports to the IBC which reviews the information and votes to approve, defer, or disapprove these activities. Any committee member may call for additional review. The level of review will be determined by the complexity of the proposed activity. Planting of deregulated transgenic plants will may be sufficiently reviewed by the BSO while planting of transgenic plants to produce pharmaceuticals or industrial compounds may require a specialized subcommittee and/or in depth review by the full committee (in addition to the requirements found at XVI. f.).

e. 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. 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.

f. Communication from the IBC

i. To the investigator conveying IBC decisions

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

g. Appeal of IBC decisions

i. Criteria for appeal

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 and may request an opportunity to appear before the IBC.

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 WSU Institutional Biosafety Committee (IBC) Manual. For a copy of this manual, please visit the website or contact the Office of Research Assurances (509-335-1585) to request a copy.

c. Minutes of meetings

The IBC Coordinator 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

a. IBC determines the appropriate containment per NIH Guidelines
b. IBC assures that facilities, procedures, practices, training, and expertise of personnel involved in rDNA research are appropriate.
c. The IBC periodically reviews recombinant DNA research to ensure compliance with the NIH Guidelines

B. IBC Minutes must include
a. Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
b. Types of manipulations planned
c. Sources of the inserted DNA sequences (e.g. species)
d. Nature of the inserted DNA sequences (e.g. structural gene, oncogene)
e. Hosts and vectors to be used
f. Whether an attempt will be made to obtain expression of a foreign gene and if so, the protein that will be produced
g. Containment conditions to be implemented
h. Applicable section of the NIH Guidelines

d. Retention of records

All protocols reviewed and related materials will remain on file at the Office of Research Assurances (ORA) 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 ORA as a record of the committee's activities.

Policy guidance and forms will be disseminated from and stored at the RAO until replaced by new and/or revised documents.

e. Communication to and from the IBC

The BAF is available at on our website.

Any questions regarding IBC review or the content of this Handbook should be directed to the Institutional Biosafety Committee Coordinator at the Office of Research Assurances by phone (509-335-1585) or email.

The Institutional Biosafety Committee Coordinator keeps in contact with researchers regarding IBC decisions and requests for additional information.

XIV. Information the investigator provides to the IBC

a. Biosafety Approval Form (BAF)
A PI applying for IBC approval for research, or diagnostic activities need to submit a completed BAF. For the application to be processed, it must be signed by the PI and the Unit head or Dean and any supplemental materials must be included. Supplemental materials may include a more detailed abstract, copies of APHIS permit or USDA/APHIS inspection results, etc.…

b. A PI applying for approval of teaching activities involved with "potentially biohazardous material" must contact the BSO. The BSO will assist the PI in developing appropriate biosafety training for students. The PI/Instructor is responsible for ensuring that students are all trained prior to working with the agents. The BSO will also act as a resource to assist the PI in developing a Biosafety Manual and performing a facility review.

c. Requests for amendments in activities after initial approval.
All modifications to currently approved research and diagnostics activities 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 BAF Amendment form along with copies of the BAF sections to be modified/changed (as appropriate).

For changes in Teaching activities simply send the changed information to the IBC Coordinator in an email. These changes will be entered in the data base and will only be brought to the teaching subcommittee if they increase the risk. IBC Coordinator will notify the BSO and the BSO will work with the IBC Chair to make this decision.

The IBC amendment approval is only good until the end of the original approval period. For example, if the original BAF 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.

d. 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) {part of NIH} within 30 days.

e. Notification

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 BAF and returning it to the IBC office in time for review before the expiration date. The investigator is responsible to keep BAFs 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 does not 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 finished/discontinued.

f. Student research

Research conducted by students involving 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 (reviews, manuals, and OSHA BBP Exposure Control Plans ECP)

a. Biosafety laboratory reviews
The WSU Environmental Health and Safety Department (EH&S) reviews biosafety labs (BSL-2 and 3, ABSL-2 and 3) utilizing checklists and reporting results and recommendations to the BSO and IBC. The IBC requires that BSL-2 facilities be inspected at least every three years and that BSL-3 facilities are inspected annually. The BSO reviews biosafety facilities used for recombinant DNA activities at BSL-1.

b. Biosafety manuals
The WSU Biosafety Officer works with the PI and WSU Environmental Health and Safety Department (EH&S) to review biosafety manuals. The IBC considers the status of the laboratory specific biosafety manual when reviewing and approving protocols. The Biosafety Manual is reviewed by the BSO every 3 years.

c. OSHA Blood Borne Pathogen Standard (ECP)
EH&S is responsible for assisting the PI in adhering to this standard.

d. Teaching Activities
For teaching activities, the PI/Instructor works with the BSO as a resource to develop student training for the course, the biosafety manual and the BSO will perform a facility review for BSL-1 facilities. EH&S performs BSL-2 facility reviews.

XVI. Materials and activities requiring additional permits or approvals

Many biological materials and activities require additional federal permits. These permits may be necessary for a wide range of activities. In general, any biological material that requires a federal permit should be registered with the WSU IBC via the BAF.

XVII. Copies of the permits must accompany the BAF.

The following permits require the signature of the Institutional Official (the Vice President for Research and Dean of the Graduate School or his/her designee)

a. APHIS permits
The United States Department of Agriculture (USDA) through the Animal and Plant Health Inspection Service (APHIS) issues permits for

many biological materials and activities. Additional information can be found at the APHIS website.

b. CDC permits

The United States Department of Health and Human Services (DHHS) through the Centers for Disease Control (CDC) regulates many biological materials and activities. The CDC regulates the interstate transport of etiological agents. Additional information can be found at the CDC website.

c. FDA permits

d. EPA permits

e. American Type Culture Collection (ATCC)

Researchers ordering materials from ATCC for the first time may be required to complete a new account application. The ATCC account application requires the signature of an Institutional Official or the BSO.

f. Field trials of genetically modified organisms

Field trials of genetically modified organisms always require permits from the USDA Animal and Plant Health Inspection Service (APHIS). At WSU only the IO (the Vice President for Research and Dean of Graduate School or his/her designee) may sign permits for field testing of genetically modified organisms.

Additional requirements may be needed if the proposed field trials include transgenic plants expressing molecules of pharmaceutical intent ("bio-pharming"). There are specific regulations and requirements for the "Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds" (7 CFR Part 340). Additional information can be found on the APHIS website. All permits and field testing of plants designed to produce pharmaceuticals must be signed by the WSU IO (the Vice President for Research and Dean of the Graduate School or his/her designee).

XVIII. 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 comply the PI will work with EH&S directly to develop the Exposure Control Plan (ECP). A BAF does NOT need to be submitted to the IBC unless the EH&S department determines that the activities are beyond the scope of the ECP and require the IBC's 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

At WSU, the bloodborne pathogen program and training are administered by the EH&S department. Information can be found at the EH&S website.

c. Biosafety level

In general research 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 WSU Bloodborne Pathogen Program. Work with unfixed primary human cell lines requires:

- Registration with the IBC via the BAF.
- 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.
- An abbreviated bloodborne pathogen exposure control plan (for established human cell lines without characterized agents) is provided by EH&S. For established cell lines with RG-2 or above characterized agents the BSO can provide an abbreviated bloodborne pathogen exposure control plan and assist the PI in developing a BSL2 biosafety manual.
- Lab personnel training should include review of the biosafety manual and or ECP.
- If established cells or tissues were NOT derived from human or primate liver, Hepatitis B virus immunization need not be offered but will be considered for workers who request it.

XIX. 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. 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.

XX. Definitions

Potentially Biohazardous Material –

The Institutional Biosafety Committee reviews and approves many areas of biologically related research which may include, teaching, diagnostic, and extension activities.

The WSU IBC defines potentially biohazardous materials to include all 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 WSU employees or in/on WSU 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 WSU personnel and/or on WSU 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 WSU 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 whom 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 (OPIM) 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) is an organism whose genetic material has been altered using techniques generally known as recombinant DNA technology.

HIV: Human immunodeficiency virus.

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, 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 an employee 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: Defined in Washington Administrative Code, Biomedical Waste; any 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 can release these materials during handling; and
- Contaminated sharps and pathological and microbiological wastes containing blood or other potentially infectious materials.

Responsible Official: A facility official who has been designated the responsibility and authority to ensure that the requirements of 42CFR73, 9CFR121, and 7CFR331 are met, as appropriate, for the pathogen/toxin in use.

Risk: A measure of the potential loss of a specific biologic agent of concern, based on 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. In this document, "*Select Agents (SA) pathogens*" and "*SA pathogens*" refer to both select agent pathogens and toxins for all biosecurity purposes.

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 RO.

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.