Colorado State University
Institutional Biosafety Committee
(IBC)

Policy on Biosafety and Biohazards Noncompliance

Requirement for IBC Oversight

Federal and University policies require that all research, testing, and teaching activities conducted at Colorado State University (CSU) that involve the use of biohazardous materials be overseen by the CSU Institutional Biosafety Committee (IBC). Biohazardous materials are materials of biological origin that could potentially cause harm to humans, domestic or wild animals, plants, or the environment. Examples include human, animal or plant pathogens; recombinant or synthetic nucleic acids capable of replication; transgenic animals or plants; biological toxins; human blood and certain human body fluids; and primary human or monkey cell lines. An essential element in the required IBC oversight of activities involving the use of biohazardous materials is the review and approval of a Project Approval Request Form (PARF), describing all proposed studies involving biohazardous materials, prior to initiation of the work.

A PARF is considered a contractual agreement between the investigator and the University. The IBC approves PARFs on behalf of CSU. Failure to obtain approval of a PARF prior to conducting the work constitutes noncompliance with CSU policies and federal regulations. Further, failure to report changes of an approved PARF for IBC approval constitutes noncompliance with the federal regulations and CSU policies. Depending on the nature and/or frequency of such actions, an investigator's privilege to conduct research involving biohazardous materials may be temporarily suspended or revoked entirely.

Reporting Suspected Noncompliance

To maintain the public trust in CSU's ethical and responsible use of biohazardous materials and compliance with applicable regulations, biosafety concerns and instances of suspected noncompliance should be reported. Reports can be submitted by principal investigators (PIs), laboratory staff, support staff, or the general public. They can also be reported as a result of routine laboratory audits conducted by the Biosafety Office. Individuals, whether CSU employees or members of the public, can report suspected noncompliance to the IBC Chair, University Bioethicist, University Biosafety Officer, Director of the Research Integrity and Compliance Review Office, or the Vice President for Research. The names and phone numbers of these individuals are listed on the RICRO/IBC Reporting a Biosafety Concern webpage. In addition, individuals may utilize the Colorado State University System's Compliance Reporting Hotline (anonymous online reporting or phone reporting). All claims will be treated as suspected noncompliance when initially reported. All suspected claims will be initially treated as confidential to protect all parties involved and will be investigated promptly.

Examples of Noncompliance

Noncompliance includes, but is not necessarily limited to:

- Failure to obtain IBC approval prior to initiating research that utilizes biohazardous materials
- Failure to amend an approved PARF to the IBC for approval prior to a significant change (addition of potentially biohazardous materials, change in key personnel, for example).

- Failure to report any significant problems and/or violations of the NIH Guidelines, Select Agent Regulations, Federal and State laws, or CSU policies/procedures, or work resulting in accidents/exposures and illnesses to the Biosafety Officer (BSO) and IBC
- Failure to comply with International Air Transport Association (IATA) and/or Department of Transportation (DOT) shipping or transport requirements for biohazardous materials
- Failure to provide laboratory staff with access to resources and documents describing potential biohazards and the necessary precautions (including vaccines that are available and/or serum collection monitoring processes)
- Failure to instruct, train, and document training of laboratory staff in: (i) the procedures and techniques consistent with safe microbiological practices, and (ii) the procedures for dealing with and reporting accidents
- Failure to demonstrate and document the correction of work errors and conditions that may have resulted in the release of biohazardous materials
- Instances demonstrating that biohazardous material was not appropriately contained, de-activated, or disposed of
- Allowing unauthorized individuals access to restricted areas
- Failure to adhere to CSU IBC approved Biosafety training requirements

Investigation of Suspected Noncompliance

When possible noncompliance is reported, the party receiving the report will immediately inform the Chair of the IBC, the University Biosafety Officer (BSO), and the PI. The names of the individual(s) reporting the suspected noncompliance will be held confidential to the extent possible. The BSO will promptly initiate an investigation to gather facts to allow determination of the nature and extent of the concern, whether any individuals are in immediate risk, and if the matter involves probable noncompliance with regulatory requirements or CSU policy, informing the IBC chair as needed. The Chair will advise the principal investigator (PI) that a noncompliance review has been initiated by the IBC, and that the review is being investigated by the BSO.

For more complex or serious issues, the BSO and IBC Chair may establish an investigative subcommittee to review information provided by the investigator and others. In all cases in which the investigation leads to a conclusion that noncompliance with the requirements of applicable regulations or institutional policies has occurred, or that there is a past, present, or future threat to biosafety, the BSO or subcommittee investigating will provide a report and make recommendations to the full IBC regarding the appropriate corrective action. The principal investigator (PI) may attend an IBC meeting or discuss the issue with the IBC chair or IBC in person.

The following considerations are evaluated during review of the matter:

- Whether the reported actions resulted in potential harm to the involved personnel or mistreatment (damage, or impairment?) of facilities;
- Whether any personnel, animals, plants, or the environment are still at risk;
- Whether the reported actions constitute serious or continuing noncompliance with Federal regulations and/or CSU policies;
- Whether corrective actions should be taken to avoid the noncompliance in the future, and an appropriate date by which the correction will be implemented.

If any of the above are noted, the IBC will consult with the Institutional Official (IO, the Vice President for Research) regarding the matter. If the matter is deemed to not involve noncompliance, the matter will be considered closed by the IBC. The PI shall be informed of all steps in this process.

Consultation with IO and Formal Determination of Noncompliance

Following review with the BSO, PI, and other relevant staff, the IBC will forward its findings of noncompliance and recommendations regarding any corrective action to the IO for consultation. When the IBC, in consultation with the IO, makes a determination that the matter has been deemed to be noncompliance, the IBC via RICRO shall notify the BSO and PI of the result and of the advised corrective procedures. The investigator shall have the opportunity to work with the IBC to modify the plan, as the IBC, in cooperation with the BSO, deems appropriate. Additional internal notifications may be made to the PI's Department Chair, College Dean, and the Office of Sponsored Programs, as deemed appropriate to the situation. The notification will be in writing and will include any corrective actions being required and the timeline by which they must be implemented or official notification of IBC suspension of the specific research activity, which may include, but not be limited to, removing access from restricted areas where the research is conducted (for example, removing key card access to a BSL-3 facility).

Examples of Corrective Actions After Determinations of Noncompliance

Most issues of noncompliance are minor and can be resolved administratively. For more significant issues, the IBC may recommend remedial action. Such corrective action may include, but may not be limited to:

- Requiring specific training or retraining for the investigators and/or other personnel working on the project.
- Additional monitoring by the IBC, BSO, or delegated individuals thereof, of research activities that pertain to the non-compliance citation.
- Requiring submission and approval of an amendment to the PARF (and potentially affected AARFs) prior to continuation of the research for which noncompliance was reported.
- Restricting an investigator's research practice, such as limiting the investigator to conducting studies with certain procedures, or conducting research under supervision.
- Suspending approval or terminating one or more of the investigators' project approval.

The IBC's notification to the PI regarding noncompliance and any required corrective actions will be in writing.

Procedures for Suspending Research

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

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

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

In addition, the IBC may require the principal investigator to supply documents for a full review of all research activities under his/her supervision.

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

Contingency procedures: In the event that a quorum of IBC members cannot attend an emergency meeting, the requirement for a 50% quorum will be waived if a minimum of three members, with at least one member who is a PI, can attend. If fewer than three members, or no members who are PIs, are available, the meeting will be postponed until the earliest possible time that a minimum of three members are able to meet. If the complaint or alleged misuse involves the use of select agents or toxins, the institutional Responsible Official (RO) or designated Alternate Responsible Official (ARO) must be present at the meeting.

Reporting Noncompliance to External Agencies

1) Reporting to NIH/PBBP – For research involving recombinant or synthetic nucleic acids and in accordance with the *NIH Guidelines*, Section IV-B-2-b-(7), the IBC must report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to NIH/PBBP within 30 days of the event. However, certain types of incidences must be reported on a more expedited basis. Spills and/or accidents in BSL2 laboratories involving rDNA resulting in an overt exposure must be immediately reported to NIH/PBBP. Spills and/or accidents in high containment (BSL3) laboratories involving rDNA resulting in an overt or potential exposure must be immediately reported to NIH/PBBP.
2) Reporting to CDC/USDA – For research involving Select Agents and Toxins and in accordance with the Select Agent Regulations (7 C.F.R. Part 331; 9 C.F.R. Part 121; 42 C.F.R. Part 73), sections 331.19, 121.19, and 73.19 the RO must immediately notify APHIS or CDC (by telephone, facsimile, or e-mail) upon discovery of the theft or loss or release of a select agent or toxin outside of the primary barriers of the biocontainment area. And a completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

In accordance with the *NIH Guidelines*, Section IV-B-2-a-(7), upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies with the latter required to be made available to the public. Therefore, all non-compliance activities reviewed and discussed during IBC meetings are subject to public release.

References

The following are the sources of information on regulatory and institutional requirements:

1. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
2. CDC/USDA Select Agent Program (Regulations)

3. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
4. Colorado State University – Biosafety Manual
5. CSU IBC Policy webpage

Institutional Endorsement

The "Policy on Biosafety and Biohazards Noncompliance" approved by the IBC on March 2, 2015 for recommendation to the Institutional Official supports the research, teaching and service mission of Colorado State University, and ensures that the safety of people, domestic and wild animals, and plants used therein will be protected. Therefore, as the Institutional Official, I declare the IBC-recommended policy to be the policy of the Colorado State University Program of Biosafety.

Alan S. Rudolph, PhD
Vice President for Research and
Institutional Official

4-21-15
Date