Albert Einstein College of Medicine

Institutional Biosafety Committee Policies and Procedures

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I. Purpose

Albert Einstein College of Medicine (Einstein) is committed to conducting research in a safe and healthful manner with minimal impact on the environment. The Institutional Biosafety Committee (IBC) oversees the safe use of research involving recombinant or synthetic nucleic acid molecules and biohazards in research for Einstein. Einstein supports the endeavors of the IBC in promoting and ensuring that research is conducted in a safe and compliant manner.

The purpose of this policies and procedures document is to provide information relevant to the functions of the IBC and to assist with the consistent and efficient operation of this Committee. These policies and procedures will be revised as needed and will be approved by a majority of voting members of the IBC.

II. Scope

The Policy and the procedures outlined herein apply to all Einstein faculty, staff, and students.

III. Policy

III.A. Institutional Biosafety Committee Statement of Purpose

The IBC is mandated by the NIH Guidelines and acts on behalf of Albert Einstein College of Medicine to:

1. Review and support the activities of the Department of Environmental Health and Safety (EH&S) in providing guidance on the safe use, procurement, storage, and disposal of biohazards.
    a. Act as interface between research faculty and EH&S.
2. Serve as a forum to review, make recommendations, and raise awareness related to biosafety concerns, institutional needs, emerging biosafety issues, and new biosafety requirements.
3. Review new safety and health regulations and provide guidance on their application to Einstein.
4. Review research activities that raise safety and/or health issues.
5. Review those engineering facilities designed to protect the worker from biohazards.
6. Review the activities of the Biohazard Facilities (BSL3).
7. Review recombinant or synthetic nucleic acid molecules research to ensure compliance with the NIH Guidelines.
    a. Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecules research.
    b. Notify the Principal Investigator (PI) of the results of the IBC's review and approval.
8. Promote greater awareness and understanding by faculty and staff for the need to:
    a. Conduct all laboratory procedures and activities with attention to personal and environmental health and safety.
    b. Comply with government health and safety regulations and laws.
    c. Lower or increase containment levels for certain experiments as specified in section III-D-2-a of the NIH Guidelines.
9. Ensure that administrative controls on the use of biohazards, e.g., written guidelines, monitoring personal protection practices, etc., are available and followed.
10. Report any significant problems with or violations of the National Institutes of Health, NIH Guidelines, and any significant research-related accidents or illnesses to the appropriate

institutional official and NIH Office of Science Policy (OSP) within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator.
11. Submit an annual report to NIH OSP which includes a roster of IBC members and member roles. Inform NIH OSP of members leaving the Committee or appointed to the Committee. Biographical sketches are only sent when a new member is nominated for the Committee.
12. Recommend to the Dean (and Executive Dean) measures to decrease the exposure of the Einstein Community to biohazards.
13. Support information flow among the IBC, the Internal Review Board (IRB), and the Institutional Animal Care and Use Committee (IACUC).
14. Obtain competency training as stipulated by the NIH Guidelines.
15. Review emergent issues in biosafety.

III.B. Meetings and Structure

III.B.1. Institutional Biosafety Committee Meeting Support

The Department of Environmental Health and Safety provides the following in support of the IBC meetings:

1. Select the protocols to be reviewed by the Committee and develop the agenda.
2. Work with PIs to ensure that protocols are complete before submission to the IBC for approval.
3. Collate and distribute the IBC meeting materials at least one week in advance of meetings.
4. Prepare and submit a notice for the open meeting to Public Affairs and place it on Einstein's website.
5. Take notes during the meeting to develop an accurate record of the deliberations.
6. Facilitate discussion regarding research projects and related issues.
7. Prepare the minutes of the meetings.
8. Write memos to the PIs explaining the Committee's action on their proposal.
9. Follow up on any action requested by the Committee.
10. Draft policies for the Committee's consideration.
11. Report on incidents, such as significant laboratory accidents and laboratory-acquired infections, and violations of the NIH Guidelines and institutional policies.
12. Provide information to the IBC as needed.
13. Conduct inspections of Einstein laboratories and report any significant findings to the IBC.
14. Keep the IBC apprised of regulatory and scientific developments that pertain to biosafety.
15. Make recommendations to the IBC.

III.B.2. Structure of the Institutional Biosafety Committee

A broad array of available research and regulatory expertise is important for the IBC. The NIH requires that the IBC have at least five (5) members selected who collectively have the experience, expertise, and capabilities to assess the safety of recombinant and synthetic DNA research as well as other biological materials, agents, and organisms. The member's training and experience should enable him/her to identify any potential risks to workers, public health, or the environment.

The IBC is composed of the following members:

1. Chairperson
2. Senior Director of EH&S (Contact Person/Administrator)
3. Non-affiliated Community Members
4. Biosafety Officer
5. Occupational Health Services Member
6. Animal Institute Expert
7. Scientific Disciplines
8. Ex officio members
9. Alternate members

The Executive Dean receives the minutes and all other deliberations of the IBC as needed.

III.B.3. Appointment Process and Length of Service

III.B.3(a) Membership Appointments and Length of Service

1. Candidates can be suggested by the Chairperson, Senior Director of EH&S, Biosafety Officer, and/or Executive Dean.
2. Candidates receive a written communication from the Senior Executive Dean inviting them to serve on the Committee.
3. Candidates respond to the invitation in writing, either declining or accepting, by:
   a. Copies of all correspondence are sent to the IBC Administrator of the Committee.
   b. Administrator requests CVs from the candidates
   c. Candidates' acceptance communication and their CVs are then sent to OBA along with an updated roster of the Committee.
   d. Letter from OBA is received stating that the candidate is approved and that Einstein's Committee is in compliance.

IBC members may serve for a 3-year period; they may elect to continue for an additional 3-year term with mutual agreement or may rotate off the Committee. There is no limitation on the length of service of public members. Ex officio members serve as long as they are in their respective positions.

Alternate members are individuals who may be appointed to the Committee as Alternates for specific IBC members. Alternate members may vote in the absence of the member to whom he/she is assigned as an alternate. The alternate should attend all meetings. An IBC member and his/her alternate may not count toward a quorum or act in any official capacity at the same time. Alternates shall receive training similar or identical to the training provided to the regular IBC members. Alternate members are included in the annual report to OSP with their role and biographical sketches.

III.B.3(b) Membership Termination

Committee members may be asked to step down due to the following:

- Conflict of interest
- Lack of attendance
- Insufficient participation

III.B.4. Procedures for Defining a Quorum

In the event that the IBC Chair must be absent, he/she will request another Committee member to serve as Chair during his/her absence. Meetings will proceed with no less than 5 voting members present and can proceed with one more than the majority of the Committee membership. Attendance at meetings by voting members is critical. Committee members will be polled in advance of the meeting to ensure that there will be a quorum; otherwise, the meeting will be canceled or rescheduled. It is recognized, however, that members will not be able to make every meeting.

A quorum is declared at the beginning of each meeting and consists of the Committee members in attendance. Decisions such as approval of research projects or policies are approved when a majority of IBC members present vote for approval. The IBC may use consulting experts or establish working groups to execute its purpose. Consultants or working group members are not IBC voting members unless nominated and appointed as previously described.

III.B.5. Meeting Schedule

Meetings of the IBC are scheduled for every other month and typically last one (1) to two (2) hours. Ad Hoc meetings may be called by the Chairperson when necessary. All meetings will be open to the public unless otherwise posted. Minutes, applications, attendance records, and all IBC files will be maintained by the Department of Environmental Health and Safety.

III.B.6. Minutes Policy

In accordance with the NIH Guidelines, on request, the Institution will make available to the public, all IBC meeting minutes in consultation with Einstein General Counsel. Redaction of proprietary and private information is allowed but “must be done so judiciously and consistently for all requested documents” as cited in: Amy P. Patterson, MD IH Office of Biotechnology Activities, Minutes of Institutional Biosafety Committee Meetings, May 14, 2004.

Meeting minutes will be reviewed, approved by the members, and signed by the Chairman; if the Chairman is not present, an appointed IBC member shall sign. Minutes are submitted for approval at the next convening meeting of the IBC.

III.B.7. Institutional Biosafety Committee Voting

The following is the process for IBC voting:

1. Agenda item is presented followed by a Committee discussion
2. Motion to accept or deny approval is made
3. Motion is seconded
4. All in favor is presented; all opposed is presented
5. Majority is accepted
6. Abstentions or objections are noted.

III.C. Conflict of Interest Policy

It is the policy of this Committee that no member of the IBC may be involved (except to provide the information requested by the IBC) in the review or approval of a project in which he/she has been, or expects to be engaged, or has a direct financial interest. The member may remain in the meeting room during the deliberation but may not serve as a reviewer and must abstain from offering comments unless called upon to answer a question or provide clarification. The member must abstain from voting on the motion. Each member is expected to notify the IBC Chair in these circumstances and rescue themselves when such proposals are being discussed and are up for a vote. In addition, if the IBC Chair is PI on a project, another IBC Committee member present at the meeting will sign the approval form if the project is approved.

III.D. Protocol Reviews

The administrative function of the IBC will be handled by EH&S. Meeting materials are prepared and distributed by EH&S at least one week in advance of the meetings. Protocol copies are provided to all IBC members at this time. The agenda is also distributed to the members at least one week before the meeting.

PIs may be contacted, brought before the Committee, or placed "on call" if additional information or clarification is needed to complete risk assessments and facilitate discussion. Protocols are submitted well in advance of the IBC meeting date to allow time to address outstanding issues. Protocols that require review by the IBC cannot be expedited.

Actions by the IBC on a protocol typically involve one or a combination of the following decisions:

- Approve – The protocol is accepted as provided to the Committee
- Delegated Review – Requires the PI to take additional steps before the protocol will be approved. Typically, the protocol must be revised to the satisfaction of the BSO and/or reviewers.
- Table – The protocol has significant deficiencies that must be addressed before the Committee will reconsider it.
- Reject – This action is indicative of significant problems with the protocol.

All recombinant or synthetic nucleic acid molecules research, work involving the use of microorganisms pathogenic to humans or animals, and any work with Select Agents and Toxins at Einstein will be initially registered through EH&S. There is a special form for this registration.

III.D.1. Recombinant or Synthetic Nucleic Acids Molecules Research

All recombinant or synthetic nucleic acid molecules research, including exempt research, will be submitted to the IBC for approval. Recombinant or synthetic nucleic acid molecules research will be reviewed as follows:

1. A Document of Registration (DOR) will be completed by the Principal Investigator for their research and provided to the BSO for review.
2. The BSO will provide the project with a pending protocol number, provide a biosafety level, and enter the registration information into a computer database.

3. If the project involves Risk Group (RG) 2 agents or above, a letter or notation on the DOR will accompany the DOR sent back to the PI to let them know that the project is pending IBC approval.
4. A DOR spreadsheet is provided to the IBC members before each meeting. With a quorum present, the DORs are discussed, approved, delegated, or rejected.
5. DORs are valid for a period of three years unless there has been a change in the rDNA research in which case, the PI must complete a new DOR. DORs expire on December 31st of the third year.
6. At the beginning of each calendar year, the PI is asked to renew the signature on the DOR to verify that no changes have occurred throughout the year.
7. Once the IBC has reviewed a project, a letter or e-mail will be sent to the PI stating that the project has been reviewed by the IBC and the project is approved, delegated, tabled, or rejected.
8. No work will commence prior to the DOR being approved.

III.D.2. Pathogenic Research

Work involving the use of microorganisms pathogenic to humans or animals will be reviewed as follows:

1. A DOR that lists the microorganisms will be completed by the PI for their research and provided to the BSO for review.

2. The BSO will provide the project with a pending protocol number, provide a biosafety level, and enter the registration information into a computer database.

3. If the project involves RG2 microorganisms or above, a letter or notation on the DOR will accompany the DOR sent back to the PI to let them know that the project is pending IBC approval

4. A DOR spreadsheet listing all microorganisms is also provided to the IBC members before each meeting. With a quorum present, the DORs are discussed, approved, delegated, or rejected.

5. DORs are valid for a period of three years unless there has been a change to the research in which case, the PI must complete a new DOR. DORs expire on December 31st of the third year.

6. At the beginning of each calendar year, the PI is asked to renew the signature on the DOR to verify that no changes have occurred throughout the year.

7. Once the IBC has completed a review of a project, a letter or e-mail will be sent to the PI stating that the project has been reviewed by the IBC and that the project is approved, delegated, tabled, or rejected.

III.D.3. Select Agents and Toxins

Work involving the use of select agents and toxins will be reviewed as follows:

1. The PI will complete a form indicating their proposed plan for working with select agents or toxins.

2. The Executive Dean will be consulted, and his/her approval will be sought before proceeding with the IBC approval.

3. The IBC will review and approve, delegate, or reject registration of Select Agents and Toxins at a convened meeting

4. The PI will be notified in writing of the IBC's decision.

5. If approved, the "Application for Laboratory Registration for Possession, Use and Transfer of Select Agents and Toxins" will be initiated by the PI and EH&S.

6. No work will commence prior to approval of the "Application for Laboratory Registration for Possession, Use and Transfer of Select Agents and Toxins."

III.D.3(a) Dual Use Research of Concern

Life sciences research is essential to scientific advances that can result in improvements in Public Health and Safety, Agriculture (Plants and Animals), the Environment and National Security. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual-use research." According to *The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* articulates the practices and procedures required to ensure that dual-use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

There are many risks associated with Life Science Research such as accidental exposure of personnel or the environment to a pathogen or toxin. Many of these risks are addressed by current regulations or statutes. However, some risks related directly to the characteristics of DURC – the risk that knowledge, information, products, or technologies resulting from the research could be used in a manner that results in harm and threatens society, need closer attention.

Policy

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel (material of any kind), or national security. The United States Government's oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research. This policy addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that could generate harm.

The National Science Advisory Board for Biosecurity (NSABB) outlined a subset of dual use research which they termed "Dual Use Research of Concern" (DURC) and for which they recommended a formal process for oversight. To qualify as DURC, three conditions must be met.

Research involves one or more of the following subset of the select agents or toxins list previously regulated by the Center for Disease Control (CDC):

1. Avian influenza virus (highly pathogenic)

2. Bacillus anthracis
3. Botulinum neurotoxin (any quantity)
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Ebola virus
7. Foot-and-mouth disease virus
8. Francisella tularensis
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium botulinum
13. Variola major virus
14. Variola minor virus
15. Yersinia pestis

Research produces, aims to produce, or is reasonably anticipated to produce one of the following seven effects:

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin

Research meets the following definition: "Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security."

Principal Investigator Responsibilities

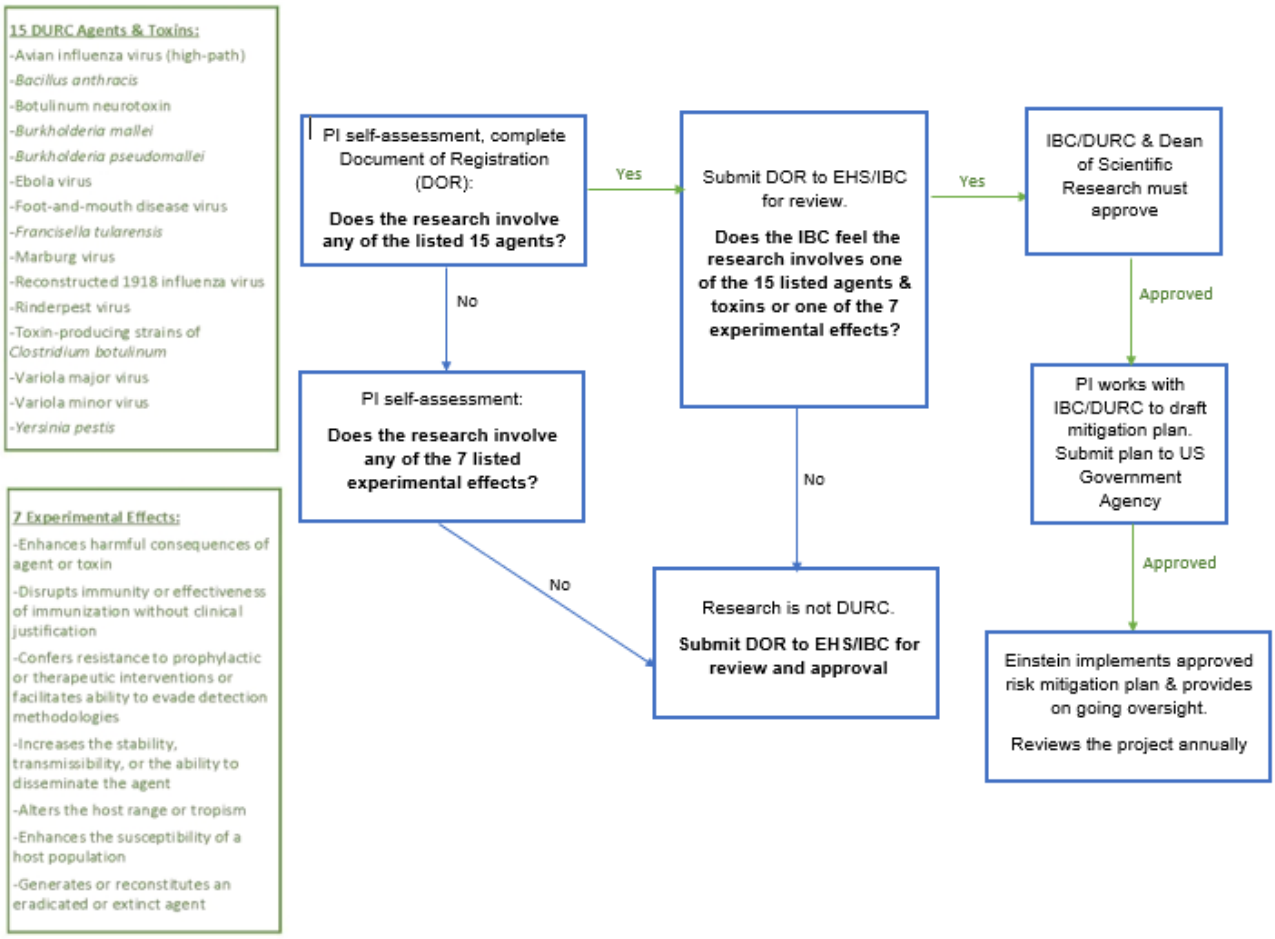
- Be knowledgeable about and comply with all Einstein and US Government policies and requirements for the oversight of DURC.
- Submit an Institutional Biosafety Committee (IBC) protocol for *any* research involving infectious agents, recombinant or synthetic nucleic acid molecules, or human materials using the Document of Registration (DOR) form. As part of the normal registration process, all protocols are reviewed for dual use potential. Clearly identify any of the 15 agents that they are planning to use in their research proposal.

- Remain vigilant for changes in the dual-use status of ongoing research projects and communicate with the biosafety officer and IBC when a change does occur.
- Ensure that no laboratory personnel conducts any research with one or more of the 15 agents listed above without approval, education, and training.
- If DURC is identified, work with the biosafety officer and the IBC to assess the dual-use risks and benefits and to develop a risk mitigation plan.
- Conduct DURC in accordance with the provisions in the approved risk mitigation plan.
- Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan.
- If changes need to be made to an approved risk mitigation plan, work with the biosafety officer and IBC committee to revise the plan (which needs to be reviewed and approved by the US Government funding agency or NIH prior to implementation of any changes).

Institutional Responsibilities

- The Biosafety Officer will provide training for DURC. Personnel working with one or more of the 15 agents or toxins listed above may be required to attend an in-person DURC training session in conjunction with EH&S and the Principal Investigator.
- Screen all IBC protocols for dual-use potential.
- If the protocol does not involve one or more of the 15 agents or toxins listed above, but does produce, aims to produce, or is reasonably anticipated to produce one or more of the seven listed effects, the IBC may require a risk/benefit analysis and risk mitigation plan as part of its approval process.
- If the protocol does involve one or more of the 15 agents or toxins listed above, the IBC will fulfill the requirements of the Institutional Review Entity for the identification of DURC and work with the Principal Investigator to draft a risk/benefit analysis and risk mitigation plan.
- The Biosafety Officer will act as the Institutional Contact for Dual Use Research (ICDUR) to communicate with the US Government funding agency (or NIH in the case of no USG funding).
- The IBC protocol of any project identified as involving DURC, along with the associated risk mitigation plan, will be reviewed by the IBC at least annually.

Dual Use Research of Concern Review Process



III.D.4. Approval of Biohazard Use in Animals

The IBC will not duplicate the work of the IACUC in dealing with animal welfare issues; instead, it is to concentrate on evaluating the risks of biohazards in research animals and associated workers.

1. If an investigator is placing biohazard agents or materials including recombinant or synthetic nucleic acid molecules into an animal, he/she must list the agent in the appropriate section of the Animal Protocol.

2. Once approved by the BSO, the PI will submit the Animal Protocol to the IACUC office where it will be reviewed by members of the IACUC and then presented for full IACUC review.

3. If the BSO does not approve the biohazard agents or material including recombinant or synthetic nucleic acid molecules work in the PI's Animal Protocol, the protocol will need to get IBC approval before the IACUC can approve.

4. The IACUC will notify the BSO of any animal hazards needing review. The BSO reviews all Animal Protocols and determines if the protocols require contain biohazards and provides the protocols to the IBC Administrator. The Administrator distributes the protocol information to all the IBC members.

5. The possible outcome of biohazards in animals are as follows:

    a. Full Committee Review – any member can call for a full Committee review. The protocol is presented and discussed at the next IBC Meeting.

    b. Clarification – requests for clarification the BSO will address all comments at the next IBC Meeting.

    c. Delegated Review – a vote by mail by our IBC members stating that the reviewer has read the Animal Protocol and they are authorizing the BSO to review and approve the protocol on their behalf. The delegated review list is then presented at the IBC meeting and entered into the minutes.

6. The IACUC Office will be notified of the IBC's protocol review via the distribution of the IBC minutes which will be supplied by EH&S.

III.E. Laboratory Containment and Safety

The PI must verify that all staff members conducting research with BSL 2 or BSL 3 organisms or biological material including recombinant or synthetic nucleic acid molecules are properly trained, have attended training, and are following all the procedures required by the regulations, i.e., his/her lab or EH&S. The PI has the immediate supervisory worker responsibility and must inform the laboratory staff of any hazards associated with their work and providing guidance on how to work safely. The PI is responsible for immediate notification to the BSO of any accidents or incidents involving viable infectious organisms.

The PI is responsible for ensuring that laboratory staff is working at the proper level of containment and with the proper personal protective equipment (PPE) at all times. The PI is also responsible for ensuring the Biosafety Cabinet (BSC) is certified on an annual basis and is operational.

III.F. Health Surveillance Program

Einstein has established and maintained a health surveillance program for personnel engaged in activities involving BSL 2 and BSL 3 activities with viable infectious organisms or recombinant or synthetic nucleic acid molecules. Further details of the health surveillance program can be obtained from Occupational Health Services.

III.G. INSTITUTIONAL BIOSAFETY COMMITTEE VOTING

The following is the process for IBC voting:

1. Agenda item is presented followed by a Committee discussion
2. Motion to accept or deny approval is made
3. Motion is seconded
4. All in favor is presented; all opposed is presented
5. Majority is accepted
6. Abstains or objections are noted.

III.H. Protecting Confidential Information

Because of the impact of disclosure on the ability to publish the information or because of patient privacy, protocols may contain information that must be patent-protected. In addition, protocols may require protection to ensure the safety and security of research facilities, materials, and personnel, or because the information is deemed patent-protected and subject to nondisclosure agreements. Every protocol is assumed to contain confidential information and release of copies to an individual outside of the Committee may be done only with the permission of the PI. Copies of protocols may be retained by Committee members and consultants, but they must be destroyed (e.g., shredded) prior to disposal.

III.I. Institutional Biosafety Committee Policies

III.I.1. General

- Approval by IBC to move intravenous infected M. tuberculosis mice from BSL 3 to BSL 2 within the Biohazard Facility [IBC Meeting, October 23, 2003]
- Approval by IBC to declassify M. tuberculosis mutants MC26030 and MC260020 from BSL 3 to BSL 2: Dr. Jacobs presented scientific data demonstrating the mutant strains to be safer than BCG. After much discussion, the IBC approved the declassification of MC26030 and MC260020 from BSL3 to BSL2 with the stipulation that all new mutants be presented to the IBC with safety data [IBC Meeting, May 17, 2004].
- The IBC offered guidance for in-servicing of the Madison Wisconsin Chamber to include:
  - Plate monitoring every six months to ensure functioning containment
  - Visual and soap solution checks of the transparent tubing to check for damage.
  - Hose markings to ensure tubing direction

  - Log book of all testing and maintenance performed on the Madison Wisconsin Chamber [IBC Meeting, August 16, 2005].
- Approval by IBC to allow Dr. Casadevall to work with Select Agent, Bacillus anthracis Sterne Strain [IBC Meeting, August 16, 2005].
- Approval by IBC to allow Dr. Casadevall to work with Select Agent, Bacillus anthracis Pasteur Strain [IBC Meeting, September 19, 2006].
- The IBC offered the following guidance in FACS sorting unfixed cells [IBC Meeting, December 9, 2008]. At a minimum, the IBC agreed that anyone entering a room where unfixed cells were being sorted must:
  - Don an N-95 respirator
  - Operators of the cell sorter are encouraged to use powered air purifiers (PAPRs)
  - All employees in the room wear gloves and disposable gowns.
- Approval to allow Dr. Kielian to continue working with Semliki Forest virus at an enhanced BSL2 containment in a biosafety hood located in a dedicated negative pressure and access-controlled room [IBC Meeting, December 9, 2008].
- Approval by the IBC to allow Dr. Fries to work with Select Agent, Staphylococcus Enterotoxin B [IBC Meeting, January 29, 2010].
- Approval by the IBC to declassify M. tuberculosis mutants H37Rv ΔeuCD and ΔpanCD from BSL 3 to BSL 2. Dr. Jacobs has found that these new strains are more attenuated than previous strains. With the previous strains H37Rv, SCID mice would succumb in 25 days at a dose of 105 CFUs. For M. bovis, the vaccine strain SCID mice would succumb in 140 days at 105 CFU and 220 days at a dose of 104. In contrast, SCID mice infected with 105 CFU of leuCD panCD double auxotroph mc26206 survival at 250 days [IBC meeting, March 11, 2010].
- Guidance provided by the IBC on appropriate precautions for work with poxviruses that can infect humans, recommendations for containment and vaccination. Approval of Vaccinia Handout "Vaccinia Virus Use and Immunization Policy for Laboratory Personnel" [IBC Meeting, March 11, 2010].

Guidelines for Exposure to XDR TB and Personnel Screening Recommendations for Exposure

- Proposal and approval to work with multiple drug-resistant and extensively drug-resistant M. tuberculosis strains in the Jacobs' Biosafety Level 3 (BSL 3) Laboratory in the Price Center.
- A major concern is expanding their work to include XDR strains
- Closer monitoring of the workers was suggested using QuantiFERON Gold and for employees to be monitored quarterly instead of bi-annually
- A surveillance and exposure plan must be developed
- Engineering controls need to be finely defined to limit exposure of personnel to the strain. No traffic should be allowed in the area other than employees working on the project.
- Animal caretakers should be part of the quarterly monitoring and should be provided with PAPRs. There should be limited access when changing animal bedding.
- PAPRs are required for entrance into the animal room
- Information should be clear regarding where PAPRs will be stored
- The Jacobs' lab should post its spill response to existing procedures.
- A post-exposure hotline must be posted in all labs using XDR TB. Post-exposure therapy will be based on the assessment of exposure by OHS in coordination with TB experts. Employees with

+PPD or other TB screening test and negative chest X-rays will have clinical assessments more frequently. Employees with HIV infection or other immuno-compromised candidates should not be working with the XDR TB.

- Dr. Jacobs and M. Larson will speak with the PAPRs caretakers before they begin work.
- There will be screening available for Engineering or any other staff who need access to the rooms. They will require PAPRs. It was felt that we will follow the standard protocol which is currently in place for additional staff entering the TB rooms.
- For any ongoing screening for TB acquisition, employees will have their symptoms checked every 3 months and a chest X-ray for active disease.
- Visiting scientists will be partnered with a senior member of the lab and will be tested and have QuantiFERON Gold available to them.
- Occupational Health Services and the BSO will be informed of any change in personnel.
- PAPRs for non-lab personnel will be provided by Dr. Jacobs. There will be a sign posted on the door stating that PAPRs are required for entry.
- Spill procedures should be reviewed by the lab workers before work begins. Spot D-con will first be considered with the option to decontaminate the entire room if needed.
- A motion was made and seconded to approve Dr. Jacobs' work to allow XDR TB strain to be used with the modification that Employee Health creates final documents. It was passed unanimously by the members present with Dr. Jacobs abstaining from voting [IBC Meetings, January 28, 2010 and March 11, 2010].

Addendum to Guidelines for Exposure to XDR TB and Personnel Screening Recommendations for Exposure

Sub-Committee made up of members, J. Nosanchuk, L. Weiss and M. Catalano provided the following:

- In a prominent space in the lab, POST sensitivities of organisms being used.
- Monitor lab workers with periodic screening
- Tuberculin test conversions will be evaluated and treatment offered in the following manner:
  - Routine conversion detected as part of the screening program will address INH and linezolid or quinolone will be offered addressing both susceptible and XDR organisms.
  - Conversion after a known laboratory exposure will address only the laboratory strain.
  - If catastrophic event occurs, i.e., massive aerosolization of XDR TB organisms, the policy will be to hospitalize those exposed and then treat them with appropriate (multiple) antibiotics including per intravenous route.
- Since baseline QuantiFERON tests have been completed the IBC unanimously agreed to change the screenings from three months to six months for workers handling XDR TB. For those employees who have a history of positive PPD and positive QuantiFERON, a signs and symptoms of TB check will be done every six months. For new workers the XDR TB lab, baseline PPD skin testing, and a QuantiFERON blood test will be performed before their being permitted to enter the lab.
- A motion was made and seconded to put this policy into effect. It was passed unanimously by the members present. [IBC Meetings, November 11, 2010.]

EINSTEIN
Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Science at the heart of medicine

Occupational Health Service
Mazer Building - Room 219H
Jack and Pearl Resnick Campus
1300 Morris Park Ave., Bronx, NY 10461
718.430-3141 fax 718.430-8827
occupational-health@einstein.yu.edu

Medical screening protocol for work with XDR TB

All approved individuals who will be either working directly with XDR TB, or who will have access to the laboratory where XDR TB is contained, MUST be medically screened prior to any possible laboratory exposure.

A designated person in the TB facility must be responsible to inform the Occupational Health Service (OHS) of those individuals who will have access to the laboratory so that pre-exposure screening can be conducted and medical clearance given BEFORE being permitted to enter the laboratory. Also, a designated person in the Institute for Animal Studies, Custodial, Engineering, Sue Golding Graduate Division, and all other appropriate departments, must be responsible to inform the Occupational Health Service of those individuals who will need medical clearance prior to any laboratory exposure.

All personnel must receive medical clearance PRIOR TO receiving respirator FIT training from the Environmental Health and Safety Office (EHS). Each person who has received medical clearance will receive written documentation from the Occupational Health Office that must be presented to the EHS Office, before respirator FIT training can be conducted.

A baseline Interferon Gamma Release Assay (IGRA) for tuberculosis will be performed on each individual prior to any laboratory exposure. Also, a voluntary HIV test will be offered to each individual prior to laboratory exposure. All results will be kept as part of the individual's confidential medical record in the Occupational Health office. Those individuals who are HIV infected should not work with XDR-TB.

For any individual who does not have a baseline medical record that includes tuberculosis screening, currently in the OHS, baseline blood tests and a physical examination will be performed in addition to the pre-exposure IGRA.

If any individual tests positive by IGRA standard, prior to any laboratory exposure, appropriate follow-up will be made and evaluation for active disease will be performed. A signs and symptoms of TB questionnaire will be completed and appropriate treatment options will be offered to the individual. The individual will be screened every six (6) months for signs and symptoms of TB.

A PPD skin test will be performed on those with a NEGATIVE PPD history every six (6) months, and a SIGNS AND SYMPTOMS OF TB QUESTIONNAIRE WILL BE COMPLETED EVERY 6 MONTHS for those with a positive history. Non-compliance will be reported to the individual's direct supervisor and EHS and a recommendation for removal from the laboratory will be made until appropriate screening is performed.

All changes in medical status i.e.- pregnancy, cancer, immunosupression, use of steroids, TNF-alpha inhibitors, chemotherapeutic agents, etc. should be reported to the Occupational Health Service immediately.

The Occupational Health Service Exposure Hotline # 1-917-729-0438 should be posted in the laboratory. This is a 24hr/7day service that should be accessed after normal business hours if an exposure is suspected. **ALSO THE LIST OF TB STRAINS CONTAINED IN THE LAB SHOULD BE POSTED IN THE LAB.**

When an individual who has worked in the XDR-TB laboratory is leaving Einstein, it is the responsibility of the individual's primary department to inform the Occupational Health Service of such, at least one week before the individual leaves Einstein, so that an exit TB exposure evaluation may be performed.

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Science at the heart of medicine

Occupational Health Service
Mazer Building - Room 219H
Jack and Pearl Resnick Campus
1300 Morris Park Ave., Bronx, NY 10461
718.430-3141 fax 718.430-8827
occupational-health@einstein.yu.edu

Post-exposure plan

Anyone who has laboratory exposure who has a change in PPD skin test from negative to positive will be notified immediately and removed from the laboratory. Also, those individuals with a history of a positive PPD skin test and negative chest x-ray who report symptoms of TB will be removed from the laboratory. In both instances, post-exposure referral for medical follow-up will be initiated immediately and appropriate treatment options will be made available to the affected individual, including completion of a signs and symptoms of TB questionnaire, chest x-ray and physical examination. Appropriate post-exposure follow-up instructions will be given. A list of sensitivities and specifics regarding drug treatment regimens will be available in the laboratory and a copy of such should be given to the individual to bring to the initial post-exposure follow-up evaluation.

Any accidental exposure that occurs in the laboratory must be reported to the Occupational Health Service (OHS) and Environmental Health and Safety Office (EHS) immediately. Appropriate post-exposure evaluation will commence immediately. If the accident/exposure happens before or after normal business hours, the Occupational Health Service Exposure Hotline should be called at 1-917-729-0438. This is a 7 day a week/ 24 hour a day service.

The affected individual should go to the Weiler ER accompanied by the list of drug sensitivities. Specifics regarding treatment regimens will be available in the laboratory.

Guidelines for PPD Conversion in a Laboratory Employee

Tuberculin skin test conversions will be evaluated and treatment offered in the following manner:

1. Routine conversion detected as part of the screening program will address both community and occupationally acquired infection. Dual therapy with INH and linezolid or a quinolone will be offered addressing both susceptible and XDR organisms.
2. Conversion after a known laboratory exposure will address only the laboratory strain.
3. If a catastrophic event occurs i.e. massive aerosolization of XDR TB organisms, the policy will be to hospitalize those exposed and treat with appropriate (multiple) antibiotics including per intravenous route.

Guidelines for Follow-up of Active TB in a Laboratory Employee

Response to therapy will be monitored by the treating physician by collecting sputum samples monthly for the course of treatment, (usually 18-24 months after cultures convert to negative.) Monitoring should continue several times a year for 2 years after the completion of therapy in order to observe for relapse.

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Anyone who has positive sputum smears and/or positive sputum cultures will be cleared to return to work only after the sensitivities of their organism are known and their medical regimen adjusted accordingly:

a) For multiple drug-resistant tuberculosis, individuals must demonstrate three (3) consecutive negative sputum cultures (final report) on appropriate therapy and clinical improvement or radiographic improvement of their pulmonary infiltrate.
b) Strong consideration should be given to enrolling all individuals with tuberculosis in directly observed therapy (DOT)
c) Whether individuals have patient contact should be considered in all cases before the decision is made to return them to work
d) All individuals with active tuberculosis will be offered HIV counseling and testing.

Exception to CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) Manual regarding ABSL-2 standards for human and non-human primate cells and tissues not experimentally infected with known infectious agents.

- The IBC was asked by Dr. Herbst to vote on whether the mice infected with human cells can remain in the current animal rooms which are not under negative pressure. A motion was made so that the mice infected with human cells can remain in the current animal rooms which are not under negative pressure.
- A motion was made and seconded to accept this policy. It was passed unanimously by those members present. [IBC Meetings, November 11, 2010].

III.I.2. Minors Working with Biohazards

III.I.2(a) Guidelines for Minors Working in Laboratories

All minors who want to/volunteer in a laboratory must:

- Register through human resources.
- Be cleared by the occupational health service.
- Be trained in all applicable regulatory and institutional guidelines for laboratory workers.
- Carry a valid ID card.

Once all this is in place, the following guidelines must be followed.

III.I.2(b) Volunteers 18 Years of Age or Older

- No restrictions

III.I.2(c) Volunteers 16 or 17 Years of Age

- Volunteers submit Student/Volunteer Release Form/Affidavit of Supervision, HR-FRM-2018-013, signed by a parent or guardian releasing Einstein from potential liability. The signed form should be submitted to Human Resources. The signed form must include a description of the work in which the volunteer will be involved and a signature of the Principal Investigator and parent or guardian of the minor.
    - Volunteers in laboratories supported by an outside entity such as Howard Hughes Medical Institute must obtain written consent from the outside entity.
- Volunteers must be continuously supervised by either the Principal Investigator or a designated competent substitute.

Prohibitions:
- Volunteers may not prepare any composition in which dangerous or poisonous acids are used unless (s)he has completed a training program given by a public school or nonprofit institution which includes safety instruction approved by the Commissioner of Labor.
- Volunteers may not work in a BSL-3 facility, or with any of the following: radiation, hazardous chemicals, animals, or exposure to silica or other harmful dust.
- Animal work, unless specific exemptions are reviewed by the Institutional Biosafety Committee and Institutional Animal Use and Care Committee.

Hours:
- When school is in session, we recommend that volunteers, consistent with New York State Department of Labor restrictions, work a maximum of:
  - 28 hours per week
  - 8 hours per day on Friday, Saturday, Sunday or a holiday
  - 4 hours per day on Monday through Thursday
- Volunteers should not work between 10:00 p.m. and 6:00 a.m.
- When school is not in session and during school vacations lasting at least one week, volunteers may work a maximum of:
  - 6 days/48 hours per week
  - 8 hours per day between the hours of 6:00 a.m. and 10:00 p.m.

III.I.2(d) Volunteers Under 16 Years of Age

- Volunteers 16 years of age and younger in high school will be considered on a case-by-case basis by the IBC or its designation. The Principal Investigator in whose lab the minor will volunteer/work should contact the Biosafety Officer (718 430-3560) for this determination.

Prohibitions:
- All the above listed restrictions as well as:
  - Any agent which is biosafety level 2 or above.
  - Any animals, unless specific exemptions are reviewed by the Institutional Biosafety Committee and Institutional Animal Use and Care Committee.

III.I.3. IBC Policy on Public Comments

In accordance with the NIH Guidelines, Einstein will, upon request, make available to the public all IBC meeting minutes in consultation with Einstein General Counsel. Redaction of proprietary and private information is allowed but "must be done so judiciously and consistently for all requested documents" as cited in: Amy Patterson, MD, IH Office of Biotechnology Activities, Minutes of Institutional Biosafety Committee Meetings, May 14, 2014.

Requests for minutes should be directed to the Biosafety Officer at the following address:

Biosafety Officer
Environmental Health and Safety
Albert Einstein College of Medicine
1300 Morris Park Avenue, Forchheimer 800
Bronx, NY 10461

If public comments are made on Institutional Biosafety Committee actions, the Chair of the IBC will forward all comments and the Institution's response to the NIH Office of Science Policy at the below address:

National Institutes of Health
Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892-1814

III.I.4. Incident Reporting Policy

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OSP within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BSL2 laboratories resulting in an overt exposure must be immediately reported to NIH OSP. Spills or accidents occurring in high containment (BSL3) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OSP.

PIs must ensure all laboratory personnel know when to seek medical attention and how to report an incident. Laboratory personnel should seek medical attention, when necessary and report all incidents to the PI and EH&S (ext. 4150).

Type of accidents to report to NIH OSP:

- Any spill or accident involving recombinant or synthetic nucleic acid molecule research that leads to personal injury or illness.
- A breach of containment.
- Skin punctures with needles containing recombinant or synthetic materials.
- Escape or improper disposition of a transgenic animal.
- Spills of high-risk recombinant or synthetic materials occur outside of a biosafety cabinet.
- Failure to adhere to the containment and biosafety practices articulated in the *NIH Guidelines*.

Minor spills of low-risk agents not involving a breach of containment that was properly cleaned and decontaminated generally do not need to be reported but should be reported to EH&S for final determination.

Any exposure of a BSL 2 or 3 agents by inhalation, inoculation, ingestion, or skin contact (including bites, cuts, and wounds) must be referred to a physician, reported to the individual's supervisor and to EH&S (718-430-4150) within 24 hours.

For Injuries involving biohazardous agents or materials including recombinant or synthetic nucleic acid molecules:

- Immediately wash the site thoroughly with soap and water, and flush mucous membranes with water/saline for at least 15 minutes.
- Notify PI and EH&S (x4150) (EH&S can be contacted after hours by calling x4111).
- If medical attention is necessary, visit:
    - Between 8AM and 4PM visit Occupational Health Services clinic, located at 1180 Morris Park Avenue, 1st floor for evaluation and treatment or go to the nearest Emergency Room.
    - All hours, go to the nearest Emergency Room for evaluation and treatment.
- Within 24 hours, contact EH&S (718) 430-4150 to fill out NIH OSP Incident Report.

- EH&S, who will report the incident, to the Institutional Biosafety Committee (IBC) and to the Office of Science Policy (OSP) immediately for overt exposure or within 30 days for others. Reports of incidents can be emailed o NIHGuidelines@od.nih.gov..

IV. Definitions

BSC	Biosafety Cabinet
BSL	Biosafety Level
BSO	Biosafety Officer
CV	*Curriculum Vitae*
DOR	Document of Registration
EH&S	Department of Environmental Health and Safety
FACS	Fluorescent Activated Cell Sorting
HIV	Human Immunodeficiency Virus
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IRB	Internal Review Board
NIH	National Institutes of Health
SP	Office of Science Policy
OHS	Occupational Health Services
PAPR	Powered Air Purified Respirators
PPD	Purified Protein Derivative
PPE	Personal Protective Equipment
RG	Risk Group
SCID	Severe Combined Immunodeficiency
TB	Tuberculosis
XDR	Extremely Drug Resistant

V. Effective Date

Effective as of: September 20, 2018

VI. Policy Management and Responsibilities

Einstein's Department of Environmental Health and Safety is the Responsible Office under this Policy. Einstein's Senior Associate Dean for Operations and Finance is the Responsible Executive. Einstein's Senior Director of Environmental Health and Safety is the Responsible Officer for the management of this Policy.

VII. Approved (or Revised)

DocuSigned by:
Jennifer Garner
D744939B0B05478...

Responsible Executive

03/26/2024

Date

Appendix A: NIH OBA Incident Reporting Template

NIH OBA Incident Reporting Template

Does this incident involve research subject to the *NIH Guidelines*?	☐ **YES** ☐ **NO** **If no, this incident does not have to be reported to OBA**	**Date of report:**
Institution name: Albert Einstein College of Medicine		
Reporter name and position:	**Reporter telephone:**	
Reporter mailing address:	**Reporter email Address:**	
Date of the incident:		
Principal Investigator (Last Name, First Name):	**Telephone Number**	
Principal Investigator email:		
Is this an NIH funded project? ☐ **YES** ☐ **NO** **If yes, please provide:**	**NIH Grant or contract number:** **NIH funding institute or center:** **NIH program officer contact information (name, email etc.):**	
What was the nature of incident?	☐ Personnel exposure ☐ Spill ☐ Loss of containment ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☐ Failure to follow approved containment conditions ☐ Other - please describe: _____	
Did the Institutional Biosafety Committee (IBC) approve this research? ☐ YES ☐ NO **If yes, please provide:**	**DOR #** **Approval date:** **Approved Biosafety level for the research:** ☐ **BSL 1** ☐ **BSL 2** ☐ **BSL 3** **Additional approval requirements:**	
What section(s) of the NIH Guidelines is the research subject to?	☐ **IIIA** ☐ **III B** ☐ **III C** ☐ **III D** ☐ **III E** ☐ **III F**	
Has a report of this incident been made to other federal or local agencies?	☐ **CDC** ☐ **USDA** ☐ **FDA** ☐ **OSHA** ☐ **EPA** ☐ **Research funding agency/sponsor: (name)** ☐ **State/Local public Health** ☐ **Federal/State/Local law enforcement** ☐ **Other -Please describe:**	

Please complete the following questions about the incident in sufficient detail to allow for an understanding of the nature and consequences of the incident. Use additional space as necessary.

1. **Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc.)**

2. **Provide the incident/violation location.**

3. **Who was involved in the incident/violation, including others present at the incident location? Include position titles (e.g., graduate student, post doc, animal care worker, etc.).**

4. **Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.**

5. **List relevant training received by the individual(s) involved and the date(s) the dates training was conducted (include training by the PI, EH&S, other online training as applicable).**

6. **Does the laboratory have standard operating procedures (SOPs) for the research? If so, was there any deviation from these SOPs at the time of the incident/violation? ❑ yes ❑ no**

7. **Was there a deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation? ❑ yes ❑ no**

8. **List the personal protective equipment in use at the time of the incident/violation.**

9. **Was there any equipment failure? ❑ yes ❑ no**

10. **Was there any injury or illness associated with the incident? ❑ yes ❑ no**

11. **What are the occupational health requirements for the laboratory personnel involved in the research?**

12. Was there any medical advice/treatment/surveillance provided or recommended after the incident? ❑ yes ❑ no

13. Are medical surveillance results available (if not available at the time of initial report please indicate when results will be available)? ❑ yes ❑ no

14. Provide a brief summary of the incident:

15. Has the IBC reviewed this incident? ❑ yes ❑ no
If yes, please provide a copy of the IBC meeting minutes which the incident was reviewed.

16. Has a root cause for this incident been identified? ❑ yes ❑ no
If yes, please describe:

17. Describe measures taken by the PI and the laboratory to mitigate any problems identified. For measures identified but not yet implemented, please include a timeline for their implementation: *(use additional space as necessary)*

Principal Investigator Signature Date