Institutional Biosafety Committee (IBC) Handbook

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I. Acronyms

ABSA:	American Biological Safety Association
ATDs:	Aerosol Transmissible Diseases
BBPs:	Bloodborne Pathogens
BSC:	Biosafety Cabinet
BSL:	Biological Safety Level
BSO:	Biological Safety Officer
BUA:	Biological Use Authorization
DNA:	Deoxyribonucleic Acid
DURC:	Dual Use Research of Concern
ECP:	Exposure Control Plan

EH&S:	Environmental Health and Safety
IACUC:	Institutional Animal Care and Use Committee
IATA:	International Air Transport Association
IBC:	Institutional Biosafety Committee
IRB:	Institutional Review Board
LAI:	Laboratory Acquired Infection
NIH:	National Institutes of Health
OBA:	Office of Biotechnology Activities
ORED:	Office of Research and Economic Development
PI:	Principal Investigator
PPE:	Personal Protective Equipment
rDNA:	Recombinant Deoxyribose Nucleic Acid
RMW:	Regulated Medical Waste
UCM:	University of California, Merced (also, UC Merced)
USDOT:	United States Department of Transportation
USG:	United States Government

II. Definitions

Biosafety team:
The Biosafety team is an integral part of the UC Merced EH&S department and includes the Campus Biological Safety Officer (BSO), Assistant Biological Safety Officer (ABSO), and IBC Coordinator.

Biosafety admin:
The term biosafety admin refers to biosafety team personnel with BUA technical knowledge and IBC membership, who are responsible for conducting BUA prereviews.

Conditional BUA Approval:
BUA protocols that require additional technical justifications, amendments (e.g. adding required or desired personnel training) or clarification of method protocol from the PI(s) shall receive conditional approval from the IBC standing committee.

Dual Use of Research of Concern (DURC)

Dual Use of Research of Concern (DURC) is defined by the US Government (USG) as research that has legitimate purposes for improving various aspects of life but may also be utilized to cause harm. In order to minimize harmful use of such research, the USG has adopted a set of regulations regarding agents and research outcomes that are perceived to be high-risk.

IBC administrators
The IBC Chair, IBC Vice-Chair, and the Campus BSO are considered the IBC administrators.

Minor changes
Changes in the BUA that do not alter the risk factor of the research work are considered minor changes.

Quorum
When greater than fifty percent (50%) of the voting members are present in an IBC meeting, a quorum is achieved, and voting may be confirmed.

Significant changes
Changes in the BUA that alters (increases or decreases) the risk factor of a research work is considered significant changes.

Tabled BUA Protocol
BUA protocols that do not provide enough critical information to make a reasonable risk assessment by the IBC are voted on by the IBC voting members to be tabled until the next IBC meeting, with the expectation that the PI will provide additional information.

III. Purpose

The University of California, Merced Institutional Biosafety Committee (IBC) shall serve the academic research community as the cornerstone of oversight for university-related research involving recombinant and synthetic nucleic acid molecules, microorganisms, biological toxins, animals, and human/non-human primate substances. To continue to receive research funding from the NIH (National Institute of Health)- implementation of the IBC at an academic research institution is a mandatory requirement.

IV. Scope

The IBC functions as the UCM review body responsible for approval and oversight of activities involving the use, storage and handling of biohazardous materials in accordance with the NIH's Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Medical Waste Management Act, and the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) document. The IBC may choose to implement additional guidelines based on risk assessments.

A. Recombinant/synthetic nucleic acid molecules and genetically-modified organisms, as covered by the NIH Guidelines

B. Potentially infectious organisms (typically Risk Group 2 or greater organisms) such as viruses, bacteria, fungi, or prions that can cause disease in humans or cause significant environmental or agricultural impact

C. Select agents and select toxins, as covered by the CDC's Division of Select Agents and Toxins (DSAT) regulations

D. Human and nonhuman primate materials (including established cell lines), as covered by the Cal/OSHA Bloodborne Pathogen Standard

E. At its discretion or upon IACUC request, the IBC may also review protocols involving animals or animal specimens known to be reservoirs/vectors of zoonotic diseases

F. Dual Use Research of Concern (DURC)

G. Materials not within the IBC purview by regulation, that UCM may add to IBC oversight:

1. Plant infectious agents or other infectious agents with potential environmental impact, exotic arthropods, exotic microorganisms, BSL-1 microorganisms, biological material requiring an APHIS, CDFA, EPA or other governmental permit

V. Roles and Responsibilities Related to IBC

The IBC, Principal Investigator, Biosafety Office, and Occupational Health Provider all have specific roles and responsibilities that contribute to a functioning IBC program.

A. The roles and responsibilities of the UCM IBC include:

1. Review and approval or rejection of research conducted at or sponsored by the University for compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*) and any additional requirements for materials listed within the committee's scope. This review shall include:
    a. Independent assessment of containment levels
    b. Assessment of agents or materials including their modifications/manipulations and characteristics
    c. Assessment of facilities, procedures, practices, and training and expertise of personnel
    d. Ensuring compliance with human gene transfer protocols
    e. Verification of any additional notifications, approvals, or permits that have been obtained or are required as a condition of approval
    f. Review of health surveillance requirements

    Note: To ensure adequate review and oversight, the IBC may seek external expertise on an ad hoc basis for BUA protocols containing research with which IBC members have limited knowledge or familiarity.

2. Notifying the PI of the results of the committee review and approval, including any special conditions or stipulations that deviate from standard containment measures.
3. Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH OSP within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator.

B. The roles and responsibilities of the Principal Investigator (PI) include:

1. Complying with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research and any additional guidelines set by IBC's risk assessment.
2. Obtaining IBC approval for research involving recombinant and synthetic nucleic acids by submission of a Biological Use Authorization for review and, if required, additional approval from the UCM Institutional Animal Care and Use Committee (IACUC) and/or the UCM Institutional Review Board (IRB).
    a. The PI must not initiate or modify recombinant or synthetic nucleic acid molecule research which requires Institutional Biosafety Committee approval prior to

initiation until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the *NIH Guidelines*

3. Maintaining updated copies of the following documents:
    a. *UCM* Biosafety Manual
    b. *UCM* Laboratory Safety Plan
    c. *UCM* Laboratory Safety Plan Supplement*(s)*
        1. *Form 1: Principal investigator information*
        2. *Form 2: Lab safety plan supplement*
        3. *Form 3: Lab self-assessment form*
        4. *Form 4: lab safety plan training form*
    d. Exposure Control Plan (for bloodborne pathogens only)

Note: It is the PI's responsibility to ensure that all the above referenced documents are kept up to date, stored in a folder/binder and placed at an easily accessible location inside the laboratory. All laboratory users shall be trained on the information contained in these documents and their implementation in the execution of laboratory research.

4. Enrolling staff, students, technicians in the OHSS (Occupational Health Surveillance System) when appropriate (currently for Bloodborne Pathogen research protocols).
5. Conducting mandatory self-inspections and performing risk assessments with regard to the following:
    a. All possible research hazards to human health and the environment
    b. High risk activities that can result in potentially hazardous exposure to personnel
    c. Preventing potential laboratory acquired infections (LAI) to laboratory personnel
6. Taking all necessary steps to mitigate identified health risks, including:
    a. Supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed
    b. Correct work errors and conditions that may result in release or exposure
    c. Ensuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics)
7. Ensuring all laboratory personnel are trained and aware of research hazards and mitigative controls including:

a. The PI's emergency contact information
b. Laboratory safety manual emergency response information
c. Information regarding potential health hazards (chemical, biological, radiological) present in the lab and hazard controls including engineering controls, administrative controls, work practices and the use of personal protective equipment (PPE).
d. Reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection)

8. Reporting accidents/near misses to Environmental Health & Safety
9. Awareness of and adherence to the UCM Dual Use of Research of Concern policy and report any concerns to the IBC or biosafety office
10. Maintaining an updated Biological Use Authorization (BUA) throughout the conducted research work, making amendments as needed
11. Working with the UCM BSO to investigate any safety or research compliance critical applications in the course of laboratory research work and compliant resolution regarding any concerns.
12. Complying with shipping requirements for recombinant or synthetic nucleic acid molecules and any other infectious materials.

C. The Roles and Responsibilities of the UC Merced Biosafety Office (within the Dept. of Environmental Health and Safety) include:

1. Maintaining and filing all compliance oversight documents (agendas, meeting minutes, protocols, etc.) and reference materials (biosafety manual, lab safety plan, etc.) in accordance with the most recent NIH guidelines along with federal, state and local regulations as well as UC policies, plans and procedures
2. Developing and updating emergency procedures that involve any potential laboratory accidents, material spills, and personnel exposures to recombinant and synthetic nucleic acids or any biological agents
3. Responding immediately to notification of any accidents or incidents involving releases or exposures related to biological agents and working with the PIs to conduct post incident investigations
4. Providing technical advice to PIs and the IBC on research safety and security procedures
5. Working with the UCM IBC members to mitigate any potential risks associated with the approved research

6. Addressing and investigating any biological safety related issues reported by any academic or non-academic personnel
7. Reporting to the IBC and the institution any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the BSO becomes aware unless the BSO determines that a report has already been filed by the PI
8. Acting as a liaison between the UCM IBC and the NIH OBA
9. Reporting any regulatory required incidents including exposures to the NIH on behalf of the IBC

D. The Roles and Responsibilities of the Occupational Health Service Provider include:
1. Providing medical assistance and vaccinations
2. Providing post-exposure prophylaxis and medical follow-up
3. Maintaining medical records as required by Occupational Health and Safety Administration (OSHA) 29 CFR 1910.120 and 29 CFR 1910.134 and Title 42 CFR Part 73 and the NIH Guidelines for recombinant or synthetic nucleic acids.

VI. Composition and Membership of the IBC

A. The UC Merced IBC membership composition is in compliance with the requirements of Section IV (B)(1) of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). The Office of Research and Economic Development (ORED) appoints both the chairperson and members for the IBC. A traditional IBC appointment term length is two years and has the option to be renewed.
1. The Institutional Biosafety Committee must comprise no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment
2. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment.
3. At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix L, *Physical and Biological Containment*

for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants, require prior approval by the Institutional Biosafety Committee.

4. At least one scientist with expertise in animal containment principles when experiments utilizing Appendix M, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals,* require Institutional Biosafety Committee prior approval.
5. When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee.
6. When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that the Institutional Biosafety Committee has adequate expertise and training.
7. Additional members can include persons with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment; persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and at least one member representing the laboratory technical staff.
8. Additional professionals with specific expertise related to the BUA in review may be brought in as guests on an ad hoc basis to provide input and recommendations.

B. Ex-officio:

Ex-officio members are non-voting members within IBC who provide administrative advice based on the positions they hold within the institution, unrelated to technical expertise.

C. Quorum:

When greater than fifty percent (50%) of the voting members are present in an IBC meeting, a quorum is achieved. In absence of quorum, voting on BUAs cannot be conducted. No member of an IBC may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a BUA in which they have been or expect to be engaged or have a direct financial interest. Any member in that circumstance must recuse themselves from the review, and their presence in IBC does not count toward quorum for that BUA.

D. Member Removal:

The following events may result in removal of an IBC chair/member initiated by an IBC administrator:

1. Regular absence from meetings
2. No response to BUA protocol review assignments
3. An unresolved conflict of interest

The process is initiated during the IBC meeting and the decision to remove is contingent upon receiving a majority vote by IBC members.

VII. Dual Use of Research of Concern (DURC)

Dual Use of Research of Concern (DURC) is defined by the US Government (USG) as research that has legitimate purposes for improving various aspects of life but may also be utilized to cause harm. In order to minimize harmful use of such research, the USG has adopted a set of regulations regarding agents and research outcomes that are perceived to be high-risk.

A DURC sub-committee sits under the IBC and if/when a BUA falls under the DURC category, the sub-committee will review it and provide their input.

VIII. BUA Management and Review Process

A. BUA Program Management:

BUAs are housed online within the Biosafety Program of the Risk & Safety Solutions (RSS) Platform. The IBC Coordinator, as part of the EH&S biosafety team and ex-officio IBC member, administratively manages all BUAs, including:

1. Following up on and assisting PIs with draft submittals
2. Assigning biosafety admins for BUA prereview and IBC members as primary/secondary reviewers for IBC review
3. Communicating revision requests to PIs and monitoring completions of conditions for approvals (if applicable)
4. Notifying PIs of BUA approval on behalf of IBC
5. Processing personnel amendment forms

6. Sending BUA renewal reminders thirty (30) days prior to expiration and assisting with renewal or deactivation process

Note: BUA Approval and Expiration Dates are exclusively set by the Campus BSO.

B. Review Process Prior to IBC Meeting

Note: See Appendix A for a visual BUA Process Chart.

When a PI initially submits a BUA to Biosafety Review, an assigned Biosafety Admin will complete a prereview before the BUA is sent to IBC Review. This prereview is composed of the following items:

1. Confirm that Project Title reflects the proposed work
2. Confirm that that Project Overview is complete
3. Review Project Overview and listed Biological Materials for any inconsistency
4. Check each section for completeness, with all information reasonable and coherent
5. Determine if any agents/toxins fall under the ATD Standard or Select Agent Program, determine select agent toxin exempt quantity if applicable
6. Determine if PI makes transgenic animals or plants
7. Verify all locations with space containment level (BSL) are listed
8. Verify overall BSL for any shared room
9. Verify BSL is listed on all materials and is consistent with BSL of listed locations
10. Verify necessary attachments are included (i.e. article references, agent references, BBP ECP, SOPs, vector maps, etc.)
11. Consider engineering controls during review: Is research in an appropriate location? Is all work done in a biological safety cabinet (BSC)? If not in a BSC, why?
12. Verify ventilation is efficient and appropriate at all research stations
13. Verify list of personnel is current
14. Check completion of personnel training (all standard applicable requirements met)
15. Verify laboratory inspection history for patterns/unresolved items of non-compliance
16. Determine if any health consults or vaccinations are recommended or required
17. If recombinant or synthetic nucleic acids are to be used, verify or help determine the applicable section of the NIH Guidelines that applies to the research
18. Schedule laboratory visit for new applications, renewals, and amendments with increased risk to check for any deviations from the protocol

The biosafety admin adds any questions or requests for changes/additions to the comment sections within the BUA and notifies the IBC Coordinator of the prereview completion. The

IBC Coordinator will set the BUA to PI Revise status and follow up with the PI until all comments have been addressed to the satisfaction of the biosafety admin. When revisions are complete, the IBC Coordinator sets the BUA status to IBC Review and assigns the BUA to two IBC members (primary and secondary reviewers) for review.

IBC Reviewers perform similar reviews to the biosafety admin, with a specific focus on performing a risk assessment. This review includes, but is not limited to the following:

1. Determine if the Project Title adequately reflects the proposed work
2. Read all sections for continuity
3. Review any attachments
4. Determine if additional information is needed
5. Complete a Biohazard Risk Assessment
    a. **Biosafety**:
        i. Agent Classification:
            a. Review the Risk Group for each agent: (ABSA website https://my.absa.org/Riskgroups)
            b. Determine if changes were made to the organism that increase or decrease risk (Ex. addition of an oncogene or toxin gene; attenuation of organism)
        ii. Biological Containment/BSL Determination:
            a. Secondary Barriers: What administrative controls, work practices and personal PPE shall be used?
            b. High Hazard Activities: Determine if rDNA work will increase risk to humans, animals or environment (BSC use, sharps use, potential inhalation and potential transmission to research personnel)
            c. Health Assessment: Are there any populations at increased risk? Are Occupational Health screenings/vaccinations recommended or required?
            d. Staff Proficiency: Does any work require verification of proficiency?
            e. Disinfection and Disposal: Any additional disinfection procedures (Ex. Prions)
    b. **Biosecurity**:
        i. Are any select agents being used/handled?
        ii. Any risk for nefarious use? Did the PI answer "Yes" to any of the DURC questions?

The primary and secondary reviewers present their reviews at the IBC meeting, opening the discussion of the BUA among the full committee.

IX. Full Committee Review and Approval for New, Renewed, or Amended Protocols

New BUAs, BUA renewals, and amendments to active BUAs that involve significant changes are all subject to full committee review. Committee members shall be given adequate time, a minimum of five business days, to review and provide comments on new, renewed, or amended protocols.

The assigned primary and secondary reviewers shall briefly describe the new, renewed or amended BUA during the IBC meeting and lead the IBC committee members in discussion and risk assessment of the submitted protocol. Any comments, concerns, requests, and/or suggestions by committee members shall be documented in the meeting minutes. Following this discussion, the IBC chair shall initiate a motion for approval or tabling of the submitted BUA, to be seconded by another voting member. The number of responses from voting members (yea, nay, and abstention) shall be recorded in the meeting minutes.

The IBC Coordinator shall document any review comments received from IBC members in the relevant comments sections of the online BUA and shall return the protocol to PI Revise status. The IBC Coordinator shall also email the PI to notify them of the outcome of the IBC discussion and to request feedback and/or modification on the protocol.

When all submitted comments, questions, and clarifications have been adequately addressed by the PI and are to the satisfaction of the primary and secondary reviewers, the new/renewed/amended BUA protocol shall be approved by the IBC administrator (Campus BSO) and are valid for one to three years based on risk determined by IBC, after which a renewal or deactivation is required. This approval is limited to the IBC and does not function as approval from any other administrative bodies that may be required (e.g., IACUC, IRB).

X. Types of BUA Approval

A. Administrative Approval

The Campus BSO can administratively approve minor changes to IBC-approved BUA protocols such as changes in location (with the same approved space containment level), and additions or deletions of laboratory personnel, biological materials, or experiments that do not affect the risk to human health or the environment, or compliance with regulatory requirements.

The IBC is notified of all administrative approvals and their reasoning during the IBC meeting. Administrative approvals do not change the expiration date of the BUA and are still subject to renewal at the expiration date set after initial IBC approval.

B. Full Approval:

BUA protocols (new, renewed or amended) that receive unconditional approval from a quorum of the IBC standing committee are considered approved. Once BUA protocols receive full approval under the auspices of the IBC, the PI(s) can officially begin research work unless the protocol requires approvals from additional oversight committees.

C. Provisional Approval:

Proposed BUA experimental work that falls under the category of Section III-A through Section III-D (mentioned below) can be considered for provisional approval wherein the release of research grant money is contingent upon IBC BUA approval. <u>However, no research work must be initiated until full approval is granted by the full IBC committee.</u>

III-A- Experiments that require Institutional Biosafety Committee approval, RAC Review, and NIH Director approval before initiation

III-B- Experiments that require NIH OSP and Institutional Biosafety Committee approval before initiation

III-C- Experiments that require Institutional Biosafety Committee and Institutional Review Board Approvals and RAC Review (if applicable) before research participant enrollment

III-D- Experiments that require Institutional Biosafety Committee approval before initiation

D. Conditional Approval:

BUA protocols that require additional minor technical justifications, amendments (e.g., adding required or desired personnel training) or clarifications of method protocol from the PI(s) shall receive conditional approval from the IBC standing committee. Once the PI addresses all comments from reviewers and personnel listed in the BUA complete all training, the IBC Coordinator will forward the revised protocol to the same assigned reviewers (primary and secondary) for their final comments. Upon the reviewers' satisfaction that all comments have been adequately addressed, the Campus BSO approves the BUA and sets the expiration.

E. Tabled Protocol

BUA Protocols that do not receive the necessary IBC majority votes from a quorum of the IBC voting members shall be considered tabled. The committee may also motion and vote to table the BUA if there are high risk concerns or if significant information and additions to the protocol are needed to allow for a full risk assessment. Tabled BUAs are revisited at the next IBC meeting if timely response is received by the PI. The IBC Coordinator and/or biosafety admin forwards all comments of the IBC standing committee to the PI to address within the BUA and, if invited, the PI may be in attendance at the following meeting to answer any questions related to the revised BUA protocol. IBC can vote in favor of full or conditional approval if all questions are addressed and an adequate risk assessment is performed, but IBC may retain the tabled status if high risk concerns are still present.

XI. BUA Non-Compliance and the Role of IBC

A. Non-Compliance Regarding BUA Review and Approval

The most common scenarios of BUA non-compliance are:

1. PI(s) conducting BUA-required research work without any BUA submittal

   Or

2. PI initiating the work under the following circumstances-
   a. Failure to meet conditions of approval
   b. Research work being conducted outside the scope of the approved BUA
   c. Research work being conducted with an expired BUA

PIs conducting BUA-required research without a BUA or outside the scope of their current approved BUA will have ten (10) calendar days to initiate a new BUA or an amendment, respectively. If a BUA or amendment is not submitted for review within ten calendar days, escalation to the PI's department chair and IBC will immediately occur. Failing to comply may result in serious repercussions as determined by IBC in consultation with departmental and academic leadership.

The biosafety office will offer in-person/Zoom assistance to the PI for resolving any BUA-related issues. If the PI remains unresponsive to the biosafety office's follow-ups, the IBC coordinator will escalate to the Biosafety officer. If still unresponsive, the PI will be added to the IBC non-compliance list, initiating:

a. Pause on BUA-related order approvals
b. Department Chair notification
c. IBC notification and discussion

IBC discussion may result in further escalation and failing to comply with IBC requirements may result in suspension of the BUA by the IBC.

Note: See Appendix B for the escalation timeline for Administrative/IBC Conditional Approval Non-compliance.

All BUAs approved by the IBC are valid for a period of one to three years from the date of the initial approval, contingent upon the PI(s) approved research work demonstrating compliance with all terms and conditions of the IBC-approved BUA. System-generated notifications shall be sent to the PI(s) for renewal of the BUA(s) in addition to personal reminders (at least 30 days before expiration) from the Biosafety office. If a BUA is not renewed prior to expiration, the biosafety office will notify IBC and appropriate measures will be taken, including adding the BUA to the non-compliance list and potentially further escalation.
All BUA issues regarding non-compliance shall be subject to escalation through the EH&S department to the appropriate departmental authorities for notification and further action. Continued or repeat non-compliance could result in the suspension of research work being performed.

B. PI Occupational Health Non-compliance

The failure of the PI(s) to enroll/renew laboratory research personnel in the occupational health surveillance system prior to the personnel conducting lab work shall be subjected to escalation through the EH&S department to the appropriate departmental authorities for additional action. There shall be no tolerance for laboratory research team members performing research work without being enrolled in the UCM occupational health surveillance system.

C. Medical Waste Management Non-compliance

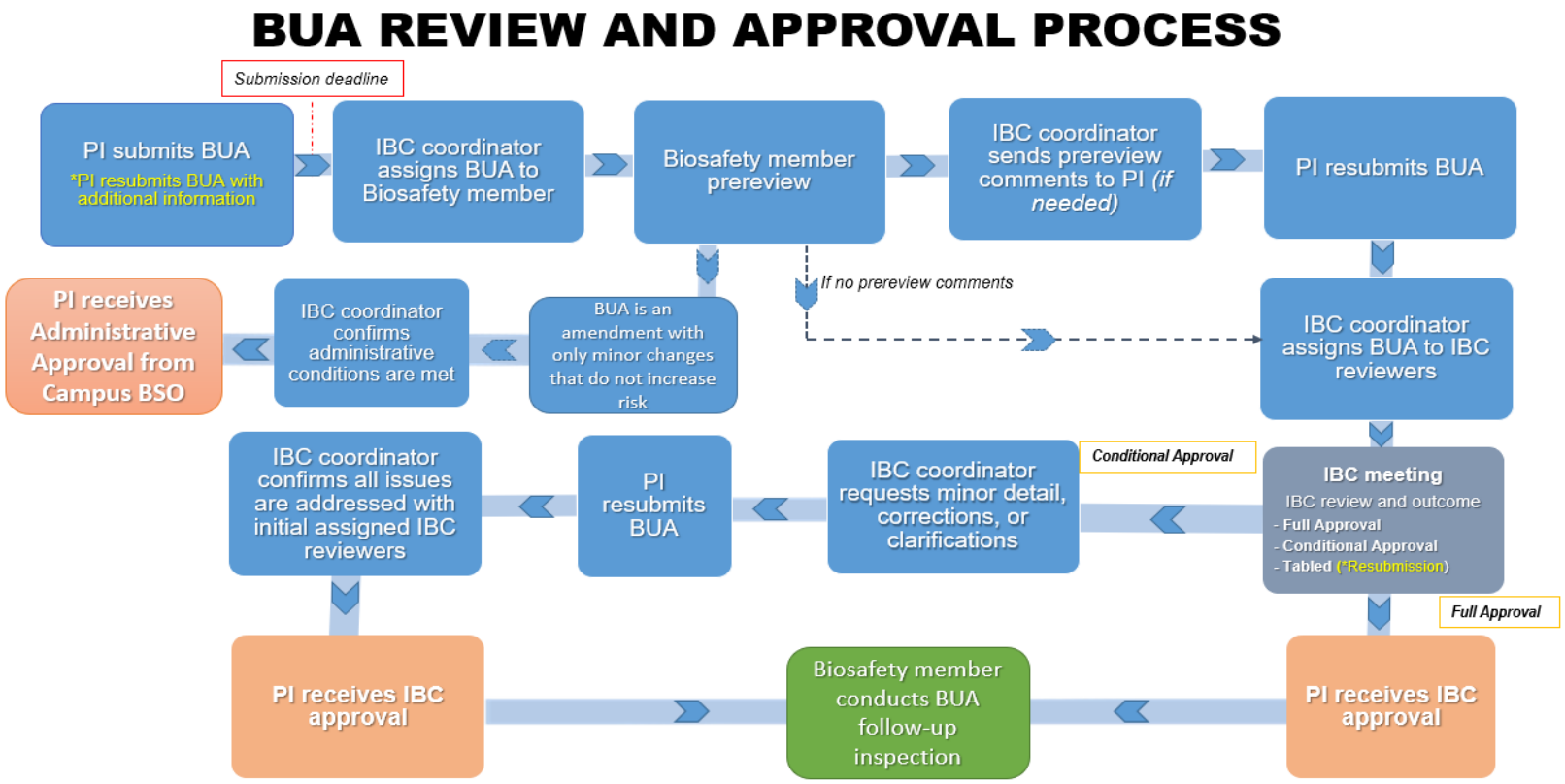
Non-compliance issues regarding laboratory regulated medical waste (RMW) management shall be subjected to escalation through the EH&S department to the appropriate departmental authorities for review and possible further action. All laboratory personnel from the non-compliant laboratory must complete and provide documentation of completion (regardless of previous training records) of the following training courses within seven (7) days discovery of non-compliance:

1. Laboratory Safety Fundamentals Training
2. Biosafety Training
3. Medical Waste Management Training
4. Bloodborne Pathogens Training (If the non-compliant lab handles BBPs)

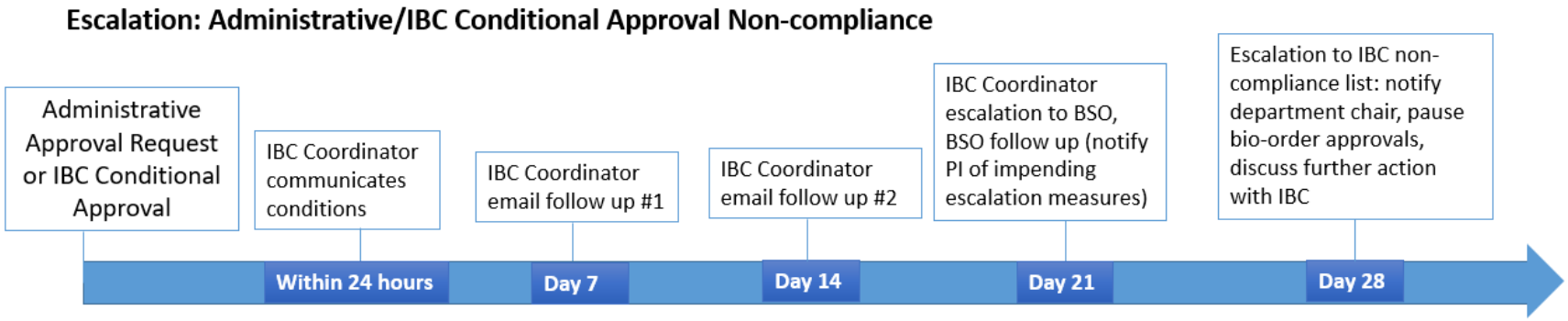
D. Non-Compliance with Regulated Shipping of Infectious or Biological Materials

Any non-compliance regarding shipping regulated biological materials, including but not limited to infectious agents, shall be subjected to escalation through the EH&S department to the appropriate departmental authorities for further action. All personnel from the non-compliant laboratory shall be required to complete and document the completion of applicable Hazardous Material Shipping training (regardless of previous training records) within seven (7) days of the discovery of non-compliance. For repeated/intention violations, additional escalations may occur including revoking of access to research materials and/or laboratory spaces.

Appendix A: BUA Review and Approval Process Chart



Appendix B: Escalation Timeline for Administrative/IBC Conditional Approval Non-compliance



Days in this timeline refers to calendar days

Note: This timeline assumes initiation of research or of administrative changes at the time of IBC conditional approval or administrative request submittal. If no research has been initiated, or if no administrative changes have occurred by the date of escalation, escalation measures may be adjusted.

Appendix C: Occupational Health Provider Information

UC Merced does not currently have an in-house Occupational Health Center for employees. The contracted occupational health physician reviews the health file of the individual online through the Occupational Health Surveillance System (OHSS) and clears them for their respective work. Upon recommendation by the physician, any medical procedures are conducted by:

Patients First Medical Center
394 E Yosemite Ave, Merced, CA 95340
Monday to Friday 8:00 am – 8:00 pm
Saturday and Sunday 9:00 am – 5:00 pm
Phone: 209-383-3990