Institutional Biosafety Committee

Charter and Procedures

Version 5.0

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Cal State University, Fullerton

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I. Policy Statement

Bodies having regulatory oversight hold California State University, Fullerton (CSUF) accountable for meeting official internal guidelines, policies and procedures. The Institutional Biosafety Committee (IBC) of CSUF has voted to accept this document as its Charter. Therefore, investigators should anticipate that regulatory bodies evaluate compliance against this document posted on the CSUF IBC website (https://www.fullerton.edu/doresearch/compliance/ibc.php). It is CSUF IBC policy that the Principal Investigator (PI) is responsible for the safe handling of biological materials, including recombinant and synthetic DNA molecules, in their facilities. The policies of CSUF follow guidelines and regulations set forth by National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Environmental Protection Agency (EPA) and California Occupational Safety and Health Administration (Cal/OSHA).

II. Purpose

This document describes current policies of the CSUF IBC and outlines role of the IBC in ensuring research involving biological materials is conducted in a manner that is safe for faculty, staff, students, research subjects, general public and the environment. This document is intended to help administrators, PIs, and IBC members comply with University guidelines and applicable federal, state and local regulations. A Biological Safety Officer (BSO) assists the IBC, research and instructional community in meeting compliance requirements of the NIH Guidelines. The BSO is also responsible for the development, implementation, and maintenance of a comprehensive Biosafety Program. The IBC and its policies will complement and support the objectives of this Biosafety Program.

III. Responsibilities

A. Institutional Biosafety Committee (IBC)

The IBC provides recommendations to the Director of Environmental Health and Safety (EHS) and BSO in the EHS Office which is a part of the Division of Administration and Finance. Administrative tasks of the IBC are processed by staff of the Office of Research Compliance (ORC).

Provisions of this Charter apply to all research projects and instruction conducted in CSUF facilities or on CSUF property, including all rented or leased facilities or properties on the Main Campus, Desert Studies Center, Grand Central Arts Center and Tucker Wildlife Preserve. Hereafter these units will be collectively designated as CSUF. This Charter also applies to all projects and instruction carried out by faculty, staff, or students in connection with University responsibilities, regardless of location. If work is being done off site, the IBC may accept the approval of another institution's IBC.

The IBC establishes, recommends, and/or approves policies on the proper use of biological materials including:

- recombinant/synthetic DNA,
- creation of transgenic animals and plants,
- agents infectious for humans, animals or plants (including bacteria, viruses, parasites, fungi, prions),
- materials sourced from humans or non-human primates, including human and primate tissue culture cell lines, blood, serum, plasma, unfixed cells and other potentially infectious materials (OPIM per Cal/OSHA),
- animals exposed to infectious agents or infected with recombinant/synthetic molecules.,
- biologically active agents (i.e. toxins,) that may cause disease in other living organisms or cause significant impact to the environment or community,
- other biological materials, as determined necessary by the Biosafety Officer or IBC Chair.

Policy objectives are to protect faculty, staff, students, research subjects, general public, and environment from exposure to these materials. In the unlikely event that a laboratory persists in following procedures in violation of compliance regulations and IBC policies, the Committee will recommend the imposition of sanctions by Department Chairs, Deans, etc.

The IBC shall:

1. Establish and monitor policy, practices and procedures for work involving the above listed biological materials at CSUF.

2. Ensure that adopted policies, practices and procedures for work with such materials meet applicable regulatory standards and guidelines.

3. Review biological research and instruction conducted at or sponsored by CSUF for compliance with adopted policies, regulations and guidelines. This review shall include an independent assessment of the biological containment required, and a risk assessment which considers the facilities, equipment, laboratory activities, quantities/titer of material to be handled, training and expertise of personnel involved in the research and/or instruction.

4. The IBC shall ensure PI is provided with results of the review and approval status in a timely manner.

5. Assess proposed containment facilities and practices for research projects and instructional activities. The IBC will use the biosafety levels (BSL) established by the CDC, NIH, and USDA as the usual standards of containment to be set for work with a given biological material. To the extent allowed by federal law and regulation, the IBC may, at its discretion and based on a risk assessment process, increase or reduce the BSL depending on the circumstances presented by a specific activity.

6. Screen all Biological Use Authorization (BUA) applications for potential Dual Use Research of Concern (DURC), utilization of Select Agents and Toxins (SAT) and biological materials that have risk of Aerosol Transmissible Disease (ATD).

7. When an IRB or IACUC protocol also requires review by the IBC, the work described in the protocol may not commence until approval has been obtained from both committees.

8. Review any findings of the BSO and/or ORC in investigating any significant violation of policies, practices and procedures; participate in an investigation of any significant research or instructional related accidents or illnesses; and recommend to the EHS Director and/or Department Chairs/Deans appropriate disciplinary action if an investigation reveals significant violations.

9. Perform other functions as may be delegated to the IBC by the ORC, EHS Director, Department Chairs, and/or Department Deans.

10. In conjunction with the ORC, BSO, and other parties as appropriate (e.g., Director of Animal Care), responsibilities of the IBC include:

    a. Review design specifications and criteria for laboratory and animal facilities.

    b. Review and assessment of compliance with permit-related requirements for work with materials from USDA Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), Plant Protection and Quarantine (PPQ), Biotechnology Regulatory Services (BRS), and Environmental Protection Agency (EPA).

Protocols are reviewed by members of the Committee. **However, it is not the responsibility of the IBC to critique technical merit or overall goals of a PI's research or instructional program. Applications are reviewed for biological containment, biological safety, and biosecurity concerns only.**

B. Office of Research Compliance (ORC)

The ORC, through the BSO and the IBC, implements a program to help ensure that research and instruction are conducted in full conformity with the provisions of the references as set forth in this document. To fulfill this responsibility, the Associate Vice President of the Office of Research and Sponsored Projects (ORSP) shall serve as the Institutional Official for the IBC. The ORC shall oversee:

1. Preliminary review of BUA applications for completeness.

2. Maintenance of an IBC email account, IBC web pages, repository of all IBC documents including minutes, agendas, correspondence with PIs or department heads, disciplinary recommendations, etc.

3. Compliance with specified IBC-related training requirements for PIs and IBC members.

4. Invitations to new members for the IBC, with input from the BSO, IBC Chair, EHS Director, Department Chairs/Deans, etc.

5. With the BSO, generate and send the annual report to NIH.

6. With the IBC Chair, prepare IBC meeting agenda and BUA submission package.

7. Distribute the IBC meeting agenda and BUA submission package to IBC members in advance of the IBC meeting.

8. Communicate to the BSO and IBC Chair if a scheduled IBC meeting will meet quorum requirements.

9. Finalize IBC meeting minutes and distribute to the IBC members.

10. Coordinate annually with PIs for any updates to approved BUA(s).

C. Biological Safety Officer (BSO)

The BSO serves as the Biosafety Program representative for all regulatory compliance inspections. The BSO shall:

1. Manage the Biosafety Program and support implementation of IBC policies and procedures.

2. Ensure compliance with specified biosafety-related training requirements for PIs and laboratory personnel.

3. Assist laboratories in conforming to pertinent regulatory guidelines and IBC policies by providing training, facility inspections, and communication of Biosafety Program and related regulatory requirements.

4. Perform annual inspections of BSL-1 and BSL-2 laboratories for compliance with NIH Guidelines, the CDC-NIH "Biosafety in Microbiological and Biomedical Laboratories" guidelines, and the Cal/OSHA Bloodborne Pathogens Standard as applicable.

5. Perform technical review of protocols to determine level of review/approval needed.

6. Review and approve BUA applications involving human/primate-sourced materials.

7. Prepare reports as needed for institutional management regarding IBC activities and Biosafety Program status.

8. If flagged by the Institutional Animal Care and Use Committee (IACUC) during protocol review, screen protocols submitted for identification of biological materials; consult with the Director of Animal Care, campus Veterinarian, and PI regarding appropriate containment procedures for biological materials.

9. Monitor federal, state, and local regulatory trends, and communicate any changes to the IBC.

10. With the ORC, generate annual reports to NIH.

11. Work closely with EHS Director to coordinate all aspects of compliance.

12. Assist the ORC with maintenance and updates for the IBC webpage.

13. Review and revise the IBC Charter at least annually, in consultation with the IBC Chair and the ORC.

14. Coordinate (with the PI, IBC Chair, EHS Director, as appropriate) **immediate** reporting to the IBC and NIH Office of Science Policy (OSP) of any spills and accidents in a BSL-1/2 laboratory involving recombinant/synthetic DNA that result in an overt exposure. While this report must be immediate, care must be taken to ensure that multiple reports are not made and there is a single point of contact for the University with the OSP.

15. Coordinate (with the PI, IBC Chair, EHS Director, as appropriate) reporting any significant problems, violations, or any significant research-related accidents and illnesses (involving recombinant/synthetic DNA) to the OSP and the appropriate institutional official within 30 days in accordance with the *NIH Guidelines*. The OSP expects a preliminary report when the incident/illness occurs, and a final report within 30 days. Although NIH Guidelines allow reporting by the PI, it is recommended that notification of OSP be coordinated with the IBC Chair, BSO, etc. so that multiple, perhaps conflicting, reports are not made.

16. Attend IBC, IACUC and IRB meetings as required.

D. Director of Environmental Health and Safety (EHS)

The EHS Director supplements the program to help ensure research and instruction are conducted in full conformity with the provisions of the references as set forth in this document. In order to fulfill this responsibility, the EHS Director shall:

1. Establish and implement policies that provide for the safe conduct of research and instruction involving biological materials.

2. Through the IBC and the BSO, assess compliance with the regulations and guidelines by PIs conducting research and instruction at CSUF.

3. Review the adequacy of resources for the dissemination of information on biological materials and biosafety procedures, including training programs and workshops.

4. Review resources for medical surveillance measures to protect the health and safety of personnel.

E. Principal Investigator (PI)

The PI is defined as a CSUF full-time faculty member having assigned space where research or instructional activities are conducted. The PI is responsible for full compliance with the policies, practices and procedures set forth by CSUF. This responsibility extends to all aspects of biosafety involving all individuals who enter or work in the PI's laboratory or collaborate in

carrying out the PI's research or instruction. Although the PI may choose to delegate aspects of the Biosafety Program in his/her laboratory to other laboratory personnel (laboratory directors, supervisors, graduate students, etc.) or faculty, this does not absolve the PI of his/her ultimate responsibility. The PI remains accountable for all activities occurring in his/her laboratory. Documentation of training and compliance with appropriate biosafety practices and procedures is essential. The PI is responsible for ensuring the appropriate safety training of personnel, provision of appropriate personal protective equipment (PPE), and for correcting errors and unsafe working conditions.

As part of her/his general responsibilities, the PI shall:

1. With the help of the BSO and standardized forms, develop and implement written laboratory-specific biosafety procedures that are consistent with the nature of current and planned research or instructional activities and make available copies of the specific biosafety procedures in each laboratory facility. These documents should be kept in the Laboratory Biosafety Manual. The PI shall ensure that all laboratory personnel, including other impacted faculty members, understand and comply with these laboratory-specific biosafety procedures.

2. Ensure all personnel who are working on an approved BUA are listed on that BUA and have read and understood the approved BUA. The current/approved BUAs shall be included in the Laboratory Biosafety Manual.

3. Delay initiation of research or instruction until BUA(s) has been approved by the IBC.

4. Ensure all approved laboratory personnel and visitors who may be exposed to any biological materials are informed in advance of their potential risk and of the behavior required to minimize that risk. It is essential that everyone who may have potential exposure to biological materials be informed of any hazards and appropriate safety practices before entering or working with such materials.

5. Ensure contaminated equipment is thoroughly decontaminated by the laboratory staff, PI, or EHS before maintenance is performed. Refer to Disinfectant SOP and/or call EHS for decontamination guidance if needed.

6. Ensure research and instructional materials are properly decontaminated before disposal and all personnel are familiar with the appropriate methods of waste disposal. Refer to Disinfectant and BSL 2 Waste Disposal SOP for additional information.

7. Report any significant problems, violations of the policies, practices and procedures to the BSO as soon as possible. Report all laboratory spills outside of containment to the BSO, as well as potential exposures (possible aerosols, intact skin contamination, etc.).

8. Notify the BSO immediately if:

    a. An overt exposure has occurred. An overt exposure is one that is known to have happened, such as an eye splash or a cut/needle stick involving infectious/recombinant materials, etc., or

b. A laboratory-acquired infection is known or suspected, or

c. A spill of any quantity involving recombinant/synthetic DNA or an agent infectious to humans, plants, or animals that occurs in a public area.

9. Ensure all personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed. The PI should contact the BSO for assistance with all biosafety training needs.

10. Coordinate with the BSO and develop emergency plans for handling accidental spills and personnel contamination.

11. Create and foster an environment in the laboratory that encourages open discussion of biosafety issues, problems and violations of procedure. The PI will not discipline or take any adverse action against any person for reporting problems or violations to the IBC, BSO, Risk Management, local, state or federal agencies.

12. Comply with shipping requirements for biological materials and select agents. This includes requirements set forth by the US DOT, IATA, and the USDA. EHS provides shipping training as required for all lab personnel. The PI should contact EHS to ensure that all applicable transportation safety regulations have been met prior to shipping microbiological cultures, tissues (human or animal) or body fluids, and whole plants and insects. These materials are often regulated and may require special permitting for shipment, and must only be shipped by personnel who have been properly trained and authorized by CSUF to ship such materials on its behalf.

In submitting a BUA application to the IBC, the PI shall:

1. Make an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth by NIH Guidelines and CDC "Biosafety in Microbiological and Biomedical Laboratories" document as applicable. **BSL-3, BSL-4, ABSL-2, ABSL-3 and ABSL-4 facilities are not available at CSUF at this time.**

2. Select appropriate microbiological practices, safety equipment, personal protective equipment and laboratory techniques to be used for the research or instruction.

3. Complete and submit applications, also known as Biological Use Authorization (BUA), to the IBC using Cayuse online application system located on the IBC website (https://www.fullerton.edu/doresearch/compliance/ibc.php)

4. Submit any significant changes in a given project to the IBC for review and approval utilizing BUA online application system.

5. Certify that the protocol does not involve DURC, SAT, or ATD.

Prior to initiating research or instruction, the PI shall coordinate with the BSO as needed to:

1. Make available to all laboratory personnel and involved facilities staff (such as animal care staff) the protocols that describe the potential risks from biological materials and the precautions to be taken.

2. Instruct and train all personnel in:

    a. Identification of the biological materials present,

    b. Practices, equipment and techniques required to ensure safety and reduce potential exposure,

    c. Procedures for dealing with accidents, spills and exposures.

3. Inform laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

4. Ensure that collaborators are made aware in advance of any biological materials sent to them, and comply with all applicable packaging and shipping requirements. These materials are often regulated for shipment and must only be shipped by personnel who have received IATA/ICAO/DOT (Regulatory) Hazardous Material/Dangerous Goods Specific Shipping training offered by CSUF EHS and are authorized by CSUF to ship such materials on its behalf. See BSO and EHS for training.

5. Maintain a formal inventory of all biological material received and sent. Logs should include the approximate quantity of the materials and where it is stored in the laboratory.

During the conduct of the research or instruction the PI shall:

1. Supervise the safety performance of laboratory personnel to ensure required safety practices are employed.

2. Investigate and report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures.

3. Immediately notify the BSO of any laboratory spills, accidents, containment failure or violations of biosafety practice which result in the release of biological materials and/or the exposure of laboratory personnel (or the public) to biological materials. The IBC may be consulted by the BSO if necessary. Near misses must also be reported to the BSO.

4. Correct work errors and conditions that may result in the release of biological materials.

5. Ensure the integrity of all containment systems used in the project or instructional activity.

6. Restrict access as required by the laboratory-specific biosafety practices and procedures, and by the biosafety containment level approved by the IBC.

IV. IBC Policy and Procedures

A. IBC Membership

Membership of the IBC will include scientists, clinical investigators, animal care and use representative, occupational health/medical representative, administrators from CSUF, and community representatives as applicable. Based on NIH Guidelines (section III-B-2-a), the minimum number of IBC members is five. Members are appointed by the Department Chairs/Deans, the ORC or the EHS Director for a renewable term of 2 years. An effort is made to represent all major units served and to have a mix of technical expertise (e.g. recombinant DNA; agents infectious to humans, animals or plants; acute toxins of biological origin) representative of the protocols being reviewed, and to represent the diversity of the University community. Committee composition will be maintained in accordance with NIH Guidelines.

Special membership requirements:

1. *Community representation*: NIH Guidelines stipulate that at least two (2) members of the IBC ("non-affiliated members") not be affiliated with the institution (CSUF), but be representative of the interests of the local general population and reside within 50 miles of the institution. Community members may include officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community. While the NIH Guidelines do not stipulate a particular educational background for a non-affiliated member, this person(s) must be able to understand the basic concepts of the BUA requests submitted to the committee.

   The Non-affiliated Member has the following responsibilities:

   a. Attend IBC meetings;

   b. Be up-to-date on relevant biosafety protocols administered by CSUF (this will be facilitated through the BSO);

   c. Represent the interests of the surrounding community with respect to the environment and public health;

   d. Review all applications submitted to the committee;

   f. Must not have an affiliation (financial or otherwise) with the University; and

   g. No conflict of interest

The IBC and ORC should be able to justify its selection of non-affiliated IBC members should the independence and qualifications of those individuals ever be called into question.

Community members will serve a term of two (2) years, which can be renewed by mutual agreement of both CSUF and the community member.

2. *Ex-officio members*: By virtue of their administrative or regulatory positions, the Associate Vice President of the Office of Research and Sponsored Projects (the Institutional Official of the IBC), EHS Director, NSM Dean, and any other designated CSUF personnel responsible for compliance (e.g., CSUF legal representative) are all ex-officio members of the IBC. All Ex-officio members **are not** voting members.

3. *Subject Matter Expertise*: If a BUA application is outside the area of expertise of IBC members, the IBC is authorized to seek counsel from an individual knowledgeable in the subject matter. This person(s) can be someone external to CSUF if necessary and would not be a voting member.

4. *Consultants:* Consultants will be used as needed to enhance transparency of larger campus/community concern such as public relations and incident response. These consultants would not vote nor count towards quorum.

B. IBC Member Training

All new members are required to complete training on the regulatory responsibilities and functions of the IBC. This training must be completed before participation in voting activities of the committee. All IBC members must also complete retraining as needed (e.g., significant changes to NIH Guidelines, BMBL, etc.), covering topics that will enhance the committee's understanding of Biosafety-related issues and institutional review policies. Retraining will be administered during discussions in regularly held meetings.

C. IBC Member Responsibilities

The IBC Chair shall:

1. Moderate/conduct the IBC meetings and discussion of each BUA application.

2. If the IBC Chair cannot be present or must take a leave of absence to their duties, they can designate their responsibilities to the Vice Chair or Chair-Elect.

3. Remain current on required IBC training. Complete retraining as needed, covering IBC-related topics.

4. Remain current on other training, as required by ORC or EHS.

5. Remain current on all relevant biosafety guidelines and regulations as set forth by CSUF, local, state and federal government. Designate IBC Members as primary reviewers to BUAs and communicate these assignments to the ORC.

6. With the ORC, prepare the IBC meeting agenda.

7. Communicate to the ORC if a scheduled meeting will not reach quorum due to IBC Member absences.

8. Be involved in any discussions/notifications to the OSP about spills, releases, exposures, laboratory associated infections, etc.

The IBC members shall:

1. Attend scheduled meetings or notify ORC if attendance is not possible.
2. Remain current on required IBC training. Complete retraining as needed, covering IBC-related topics.
3. Remain current on other training, as required by ORC or EHS.
4. Complete IBC training before participating in voting activities of the Committee.
5. Serve as Primary Reviewer of a BUA application as required and as assigned by the IBC Chair.
6. Be prepared to discuss each application, even those not assigned as a Primary Reviewer.

D. IBC Schedule and Meetings

Currently, IBC meetings will normally be scheduled once a month unless otherwise indicated, excluding summer intersession. Meetings are open to the public and are announced on the ORC website calendar. However, the IBC, at its discretion, may close the meeting, or part of a meeting, and not post meeting materials on the website consistent with protection of privacy; proprietary interests; health and safety of University employees, the environment, and the community; or as required by law or regulation.

All meeting materials will be provided to IBC members at least ten (10) days before the regularly scheduled meeting.

1. *Agenda*. The agenda will be made available to the public upon request.
2. *Minutes*. Minutes of each IBC meeting will be kept per guidance issued by the NIH Office of Science Policy (OSP). Draft minutes from the previous meeting will be provided to IBC members pending IBC approval. Once approved by the IBC, minutes will be made available to the public upon request.
3. *BUA Applications*. All BUA applications must be submitted to ORC at least three (3) weeks before the scheduled IBC meeting. BUA application deadlines are posted on the IBC website (https://www.fullerton.edu/doresearch/compliance/ibc.php)

E. Quorum

A quorum is defined as 50 percent plus one of the voting members. Non-voting members are not counted when determining a quorum. Written proxies do not count toward a quorum. If a quorum is not met, BUA applications cannot be voted upon, but can be discussed and recommendations provided to the PI for improvement, if necessary.

F. Proceedings

Meetings will be conducted in accordance with Robert's Rules of Order. The IBC Chair will issue all points of order, summarize BUA requests as necessary, moderate discussion, and call

for motions. Motions, seconds, and/or other propositions may be made by any voting member of the IBC. Motions pass by a simple majority of the voting members present, assuming a quorum is present.

G. Charter Acceptance and Modification

Acceptance of the Charter and any future modifications must be approved by the voting members of the IBC. A two-thirds (⅔) majority of the voting membership of the IBC is required to accept any revisions to this document. This vote may be submitted by a written proxy if necessary. The IBC Charter shall be reviewed at least annually for any necessary revisions.

H. Conflict of Interest

In accordance with the *NIH Guidelines* (Section IV-B-2-a-4), a member of the IBC who submits a BUA for review or has a direct beneficial interest in a BUA submission cannot be involved (except to provide information requested by the IBC) during the discussion and voting process for the registration. Additionally, an IBC member who is a collaborator or personal relative of a PI whose BUA is reviewed by the IBC will not be present during the discussion and voting process. A PI who is not an IBC member is permitted to attend the IBC meeting at which his or her BUA request will be discussed in order to provide information to the committee, but that PI will not be present during deliberation and voting.

I. Bloodborne Pathogens

All studies involving materials derived from humans or non-human primates, including unfixed tissues, primary cells, and established cell lines must be regarded as potentially biohazardous and are regulated under the California OSHA Bloodborne Pathogens (BBP) Standard (https://www.dir.ca.gov/title8/5193.html). These materials must be manipulated under BSL-2 containment conditions and are regarded as "potentially infectious materials" under the BBP Standard. The BSO serves as the Bloodborne Pathogens Exposure Control Program Administrator for laboratory research and instructional use of human and primate-derived materials. Laboratories using these materials need to register with the IBC and document their use of human and primate-derived materials with the ORC. The current BBP Exposure Control Plan is available at https://ehs.fullerton.edu/programs/safety.php.

J. Transgenic Plants

Transgenic plants created and maintained in the laboratory and greenhouse environment are subject to provisions of NIH Guidelines and are part of the IBC purview. Transfer of transgenic plants or receiving of transgenic plants from other approved institutions is exempt from NIH guidelines. Field releases, however, are not covered by NIH Guidelines because the release of those organisms is subject to notification and permit requirements under the USDA. To effectively manage releases in accordance with the provisions of USDA notification or permit, all CSUF personnel and units associated with the work must be informed of these provisions and restrictions, even if the CSUF PI is not the responsible person on the notification or permit. Failure to do so may result in accidental environmental release, which can lead to sanctions for CSUF and the holder of the notification or permit.

K. Transgenic Animals

The purchase or transfer of transgenic rodents for experiments that require only BSL-1 containment are exempt from NIH Guidelines. The **creation** of transgenic rodents and other animals, however, is not exempt and must be registered with and approved by the IBC. The creation of transgenic animals includes direct gene delivery (i.e. transformation) and/or the crossing of two different transgenic strains (or a transgenic strain crossed with a non-progenitor wild-type strain).

L. Select Agents and Toxins

Infectious agents and toxins that are considered by the Department of Health & Human Services (DHHS) or USDA to have the potential to pose substantial harm or a severe threat to human, animal or plant health, or plant products are regulated as 'select agents'. The current select agent list (https://www.selectagents.gov/SelectAgentsandToxinsList.html) and this process includes a significant security clearance component, conducted by the Federal Bureau of Investigation, for the facility and all who will have access to the select agent or toxin. **CSUF does not support the use of select agents or toxins at this time**.

M. Dual Use

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, 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. Additional information is available at: https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/. **CSUF does not support research that involves DURC at this time**.

V. Application Review Procedures

The use of Cayuse online system for application submittals makes it easier for IBC members to review projects/activities and provide recommendations as to proper safety procedures. Investigators can access this system from the IBC website (https://www.fullerton.edu/doresearch/compliance/ibc.php). Registration of biological materials, as specified in Section III A of this Charter needing IBC approval are completed through a "Biological Use Authorization" (BUA) application accessed via Cayuse online system. Approved BUAs are valid for three (3) years, or as determined by the IBC.

A. BUA Application Review Procedures

After a BUA application is submitted, the ORC will cross-reference that the PI has completed the necessary IBC training prerequisites, determine the completeness of the BUA application and if more information is needed, will collaborate with the PI until the BUA is complete (pink sub-process #1 in Appendix A).

Once the BUA application is complete, the ORC forwards the BUA application to the BSO to perform a technical review (blue sub-process #2 in Appendix A). The BSO screens the BUA for biosafety considerations, safety risks, and facility suitability. Moreover, at this time, if applicable, the BSO will administratively review and approve BUAs involving only human/primate sourced material; all other BUAs that are determined to be technically acceptable will be forwarded to the ORC for inclusion on the IBC meeting agenda. The following procedures are followed:

1. *Committee Deliberation*. BUA applications are provided to all IBC and Ex-officio members, subject matter experts, and consultants at least ten (10) days prior to the scheduled meeting. The IBC Chair will assign one (1) Primary Reviewer to each application. Primary Reviewer leads the discussion of their assigned BUA applications. However, each member is expected to review all applications prior to the meeting, regardless if they were designated a Primary Reviewer, so that the application can be evaluated by the full committee. The IBC will vote on all BUA applications. When quorum is established, a simple majority of the voting members present is required when voting (green sub-process #3 in Appendix A).

    a *Potential Outcomes for Voting on BUAs*

        i *Approval:* the BUA application is approved as presented.

        ii *Approval with Conditions:* Work can commence on a BUA but there is additional biosafety training needed, typographical or other relatively easily corrected statements (e.g., disinfectants to be used) on the proposal that need to be addressed. Conditions will be relayed, in writing, to the PI. The PI will respond to the IBC as to how the conditions were addressed, in writing.

        iii *Table:* There are significant issues with the application, as written, that must be addressed before it can be approved. These would be questions relative to the facility to be used, training, work practices, occupational health, etc. Suggested changes or requests for additional information/clarification will be sent to the PI in writing. Proposals that are tabled must be revised/expanded as requested and re-reviewed at the next meeting if the PI wishes to pursue approval.

        iv *Rejected:* The proposal has significant facility, safety and/or other issues that cannot be adequately addressed by revisions. An example would be an animal experiment that involved ABSL-2 facilities or use

of an RG3 infectious agent. The reasons for rejection of the application will be detailed in writing and sent to the PI.

b *Remote voting;* Although face to face IBC meetings are preferred and encouraged by the NIH, occasionally a BUA application will require a timelier response from the IBC than the next scheduled meeting. In this case, an additional meeting or an e-mail vote could be taken, provided there are opportunities to comment and ask questions. If there are significant issues with the proposal, voting should be delayed until the IBC can meet in person.

2. *Investigator Presentations*. When the IBC Chair/BSO deems it advisable, investigators may be invited to IBC meetings to clarify their BUA application and respond to members' questions.

3. *Communicating with IBC*. Investigators communicate with the IBC through the ORC. PIs should follow specific instructions given by the IBC, ORC, BSO, or guidance posted on the ORC and/or EHS websites.

4. *Protocol Suspension/Termination*. Approval may be suspended/canceled if the PI is found to be flagrantly and/or routinely in violation of IBC policies and regulations. Recombinant DNA and infectious agent research/instruction not complying with NIH guidelines may cause NIH action affecting individual and institutional funding.

B. Updates and Amendments to Approved Registrations

The ORC will send annual surveys to collect information on approved BUAs. At this time, the PI will be asked to provide any changes to the approved BUA. If there are any changes to the BUA before the distribution of the annual survey, the PI must communicate these changes to the ORC in writing. The ORC will collaborate with the BSO/IBC Chair to monitor if changes in approved BUAs, whether by the annual survey or otherwise, require approval by the IBC.

There are three (3) types of changes:

1. *Updates* are changes without safety consequences. For instance, staff changes, use of additional equipment, changes in disinfectant or addition of new strains of previously approved or closely related cell type are updates. Updates should be sent to the ORC. These changes are added to the PI's file for the approved BUA.

2. *Amendments* are necessary when the change may have safety consequences, but the basic thrust of the study stays the same. In general, the change will not involve a change in containment. For example, use of different facilities, addition of animals or of a new pathogen or vector to a study will usually require an amendment. Addition of a toxic gene will also require an amendment. In general, amendments require the approval of the entire IBC and as such will be included on the agenda of the next applicable IBC meeting.

3. *New BUA applications* are required when there is a significant change in the basic thrust of an existing project/instruction; i.e., a new goal. BUAs must be renewed using the Cayuse online system.

C. Failure to Comply

PIs are expected to understand and comply with the IBC standards outlined in this Charter. Noncompliance includes, but is not necessarily limited to:

1. Failure to register biological materials, including non-exempt recombinant/synthetic DNA molecules;

2. Failure to provide annual updates and/or other required documentation within 90 days of the specified due date;

3. Poor biological safety/biological containment practices as documented through routine lab inspections; or

4. Failure to correct a documented (confirmed) biological safety complaint or concern. Noncompliance will be reported to the IBC which may result in retraining, suspension or termination of all approved registrations. The ORC, PI's Department Head, Dean, and/or other applicable administrators will be notified of the noncompliance, while granting agencies or regulatory authorities may be notified as required by their respective reporting standards.

VI. References

1. Cal OSHA Bloodborne Pathogens, California Code of Regulations, Title 8, Section 5193: https://www.dir.ca.gov/title8/5193.html
2. Biosafety in Microbiological and Biomedical Laboratories (BMBL), CDC-NIH, Sixth edition: https://www.cdc.gov/labs/BMBL.html
3. CDC-USDA Federal Select Agent Program: https://www.selectagents.gov/
4. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), April 2019: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
5. Canadian Pathogen Safety Data Sheets: https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html
6. Dual Use Research of Concern website: https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/
7. Cal OSHA Aerosol Transmissible Diseases Standard, California Code of Regulations, Title 8, Section 5199: https://www.dir.ca.gov/title8/5199.html
8. ABSA International Risk Group Database: https://my.absa.org/Riskgroups
9. NIH Guidelines Frequently Asked Questions: https://osp.od.nih.gov/biotechnology/nih-guidelines-faqs/

Appendix A: IBC Biological Use Authorization Submission Process