Navigating the IBC at OU-Norman

David W. McCauley, Ph.D.

Chair, Institutional Biosafety Committee

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IBC@ou.edu

What is the IBC?

Institutional Biosafety Committee

- **Established under the *NIH Guidelines* specifically for the review of research involving recombinant or synthetic nucleic acid molecules**

https://osp.od.nih.gov/biotechnology/nih-guidelines/

Institutional Biosafety Committee

Additional responsibilities

- **IBCs are typically assigned additional review responsibilities**
  - **Select agents and toxins**
  - **Blood borne pathogens**
  - **Xenotransplantation**
  - **Stem cell research**
  - **“Dual Use” research**
  - **Nanotechnology**

- **Broader purview is a matter of institutional discretion**

Makeup of the Committee

- Membership
  - At least five individuals
  - Appropriate recombinant and synthetic nucleic acid expertise collectively
  - Plant and animal experts, biosafety officer as appropriate
  - At least two members not affiliated with the institution

Makeup of the Committee

- **Biological Safety Officer (BSO)**
  - **A BSO must be appointed and be a member of the IBC if the institution conducts recombinant or synthetic nucleic acid research at:**
    - **Large scale (>10 L)**
    - **High containment (BL-3 or BL-4**

Trent Brown: University Environmental Health and Safety Officer (tbrown@ou.edu) Ph. 405-325-5147

- **The BSO's duties include:**
  - **Periodic inspection of labs**
  - **Reporting to the IBC and institution of any problems, violations, research-related accidents or illnesses**
  - **Developing emergency plans for handling accidental spills and personnel contamination**
  - **Advice on lab security**
  - **Technical advice to PIs and the IBC on research safety procedures**

Trent Brown: University Environmental Health and Safety Officer
(tbrown@ou.edu) Ph. 405-325-5147

David A. Clark, Laboratory Safety Officer
(david-clark@ou.edu) **Ph. 405-325-0820**

IBC Responsibilities

- **In a nutshell, what must IBCs review?**
  - **Research involving recombinant or synthetic nucleic acid molecules for conformity with the *NIH Guidelines***
  - **Potential risk to environment and public health**
    - **Containment levels per *NIH Guidelines***
    - **Adequacy of facilities, SOPs, PI and lab personnel training**
    - **Institutional and investigator compliance; e.g., adverse event reports**

Submitting a protocol for approval by the IBC

- Do I need approval, and at what level?
  - Consult NIH Guidelines
    - Recombinant DNA technology
  - Risk Groups
    - Pathogenic vs non-pathogenic strains
  - Determine required Biosafety Level (BSL)
    - Do I need a Biosafety cabinet (BSC) Containment?
  - Determine NIH Classification
    - III A-F (most of the research at OU is III D, E, F (exempt))

Submitting a protocol for approval by the IBC

Where to find the forms

OU-Vice President for Research http://www.ou.edu/research-norman

-> Grants

-> Compliance

->IBC

2 forms for download

New protocol

Revised protocol (small changes to your protocol that may not require full committee review)

What materials do I need to submit?

Completed form with all questions addressed (continual updates)

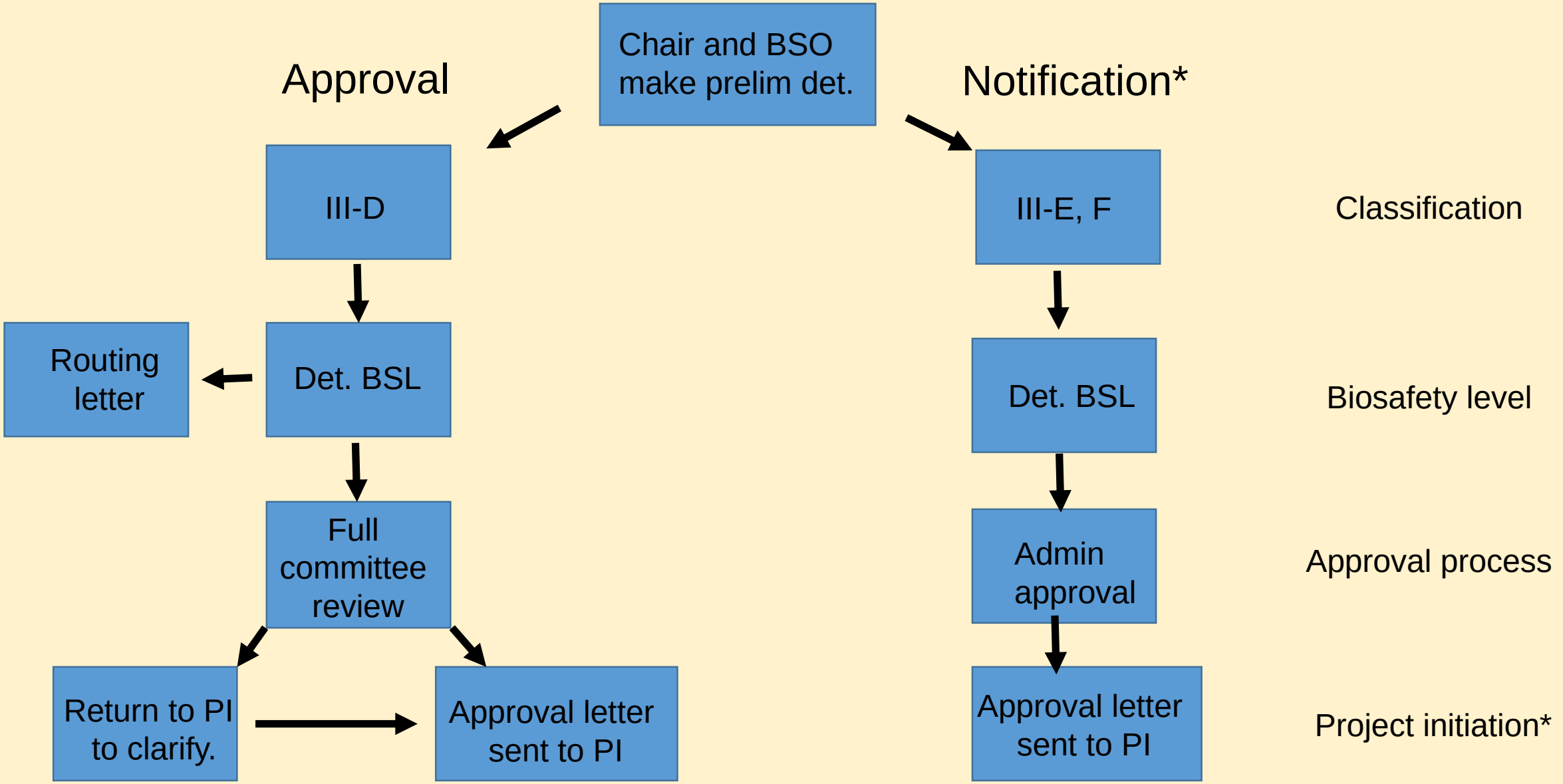
Abstract of the proposed project (or description if not a grant proposal)

Laboratory SOPs

Posted safety guidelines

Workflow/approval process after submission

Send to IBC@ou.edu (minimal 2 weeks before proposal is due)



The University of Oklahoma

INSTITUTIONAL BIOSAFETY COMMITTEE

PI Name
Chemistry & Biochemistry

Approval # (1155V)

RE: IBC Approval
IBC Number: 1155V
Title: *Microbial Biogeography of Triatomines in the context of T. cruzi infection and potential microbiome-based countermeasures to Chagas disease*

Dear Dr. PI

This letter is to grant current approval from the Institutional Biosafety Committee (IBC) for the above-referenced protocol under the following conditions:

- This approval is for 3 years from the original protocol approval date and only includes the work outlined in the protocol. Changes to the project, such as gene, vector, organism, virus or toxin use; Biosafety level; NIH classification; or Standard Operating Procedures (SOP), a new IBC Protocol Form must be completed and submitted for review.
- A new protocol must be completed and submitted prior to the expiration of the 3 year protocol approval period if work outlined in the protocol is to continue.
- Minor modifications to approved protocols, such as changes in funding source, project title, or project location, may be submitted on the *Protocol Resubmission Form* and include the reason for the modification. SOP changes must also be submitted.
- The deliberate transfer of any drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture, is not permitted. A new *IBC Protocol Form* must be completed and submitted, and the IBC and NIH must approve this transfer prior to initiation.
- Any employee added to this protocol should be trained on the standard operating procedures. Such training should be documented on the form found at: Training Documentation Form and the documentation forwarded to the IBC office at IBC@ou.edu before the employee performs work associated with this protocol.
- All protocol associates, including the Principal Investigator must remain current for all required annual training. (e.g- General Biosafety, Bloodborne Pathogens)

If you have questions or need additional information, please contact me at either 405-325-9038 or dwmccauley@ou.edu.

Sincerely,

David McCauley, Ph.D.
Chair, Institutional Biosafety Committee

Classification and expiration

Approval Date: 2/28/2019
Approved at: BSL 2
NIH Classification: III-D
Expiration Date: 10/19/2020

The University of Oklahoma

INSTITUTIONAL BIOSAFETY COMMITTEE

PI Name
Chemistry and Biochemistry

Approval # (1232)

RE: IBC Approval
IBC Number: 1232
Title: *Unlocking the potential of bacterial ParE toxins: developing a blueprint for co-opting molecular time bombs that impact bacterial cell survival*

Dear Dr. PI:

For routing only

This letter is to grant current approval from the Institutional Biosafety Committee (IBC) for the above-referenced protocol under the following conditions:

- This approval is for routing your protocol through the Office of Research Services only and requires IBC committee approval prior to the initiation of research activity related to this protocol. Upon review by the IBC, subsequent questions may arise that will require clarification on your part prior to approval of the protocol for the duration of the grant.
- Any employee working on this protocol should be trained on the standard operating procedures. Such training should be documented on the form found at: Training Documentation Form and the documentation forwarded to the IBC office at IBC@ou.edu before the employee performs work associated with this protocol.
- All protocol associates, including the Principal Investigator must remain current for all required annual training. (e.g- General Biosafety, Bloodborne Pathogens)

If you have questions or need additional information, please contact me at either 405-325-9038 or dwmccauley@ou.edu.

Sincerely,

David McCauley, Ph.D.
Chair, Institutional Biosafety Committee Approval Date: 4/10/2019

Approved at: BSL 2 NIH Classification: III-D

Stephenson Research and Technology Center 101 David L. Boren Blvd Room 2069 • Norman, Oklahoma 73109

Approvals and Revisions

New protocols- valid for 3 years from date of approval

Submit on most up-to-date form

Expired protocols need a new protocol submission

Revised protocols-

Small changes to your protocol that may not require full committee review (e.g., new/different microorganism)

Grant resubmissions

Same protocol, new title (proposal sent to diff. agency)

Going forward

Online submission

Currently working toward online submission

Umbrella approvals

Work performed using an already approved protocol would get unique number in a series (e.g., different grant proposal)

Questions?