IBC Protocol Review Process
Updated: May 2, 2017

General Planning:

- At present, plan for at least 5 to 6 months to get your protocol through the IBC and to get your lab certified for work.
- Answer the IBC's questions promptly.
- Don't wait several weeks to answer the IBC's questions then expect the committee to turn the protocol around in a few days.
- There will be at least three revision cycles for the protocol (pre-reviews and committee reviews) and at least one revision cycle for the lab inspection.
- In some circumstances, there could be more than four revision cycles.
- If your project requires IACUC and IBC approval, get IBC approval first.

Step #1: Submit your IBC Protocol

- The IBC Protocol Form has 4 parts. You may not need all of them.
    1. Part I – Must be filled out for every study
    2. Part II – Agent Information Table – Must be filled out for every Study
    3. Part III – Viral Vector Information – Only needed for viral vectors
    4. Part IV – Personnel Table and Signature Page – Personnel Table needed for all protocols but the Signature Page is only needed for BL2 protocols
- Write a quality protocol.
- Really read the questions and answer them thoroughly
- If you need help determining where your agents fall in the *NIH Guidelines*, please contact the Office of Research Compliance for help.
- A lab Standard Operating Procedures (SOP) manual must accompany the protocol.
- Read the *BMBL, 5th Edition* before writing your Lab SOPs.
- ORC has a BL2 Lab SOP Template for you to use.
- List all procedures to be conducted. If it is not written in the protocol, you can't do it. There is no such thing as an unapproved pilot study.
- IBC Forms can be found on the IBC Webpage at: http://www.pvamu.edu/research/office-of-research-compliance/institutional-biosafety-committee/ibc-forms/

Step #2: The Office of Research Compliance (ORC) will conduct a Protocol Pre-Review

- ORC will send the protocol back if all the relevant protocol questions are not answered.
- This is a good time to complete the CITI *Basic Biosafety* IBC training course required for everyone listed on the protocol.
- If you are the Principal Investigator, you must complete the *NIH Guidelines for PIs* training course either in person with Dr. Bruce Whitney or on Train Traq (Course #211485).
- If you have submitted a BL2 protocol, everyone listed on the protocol must take *BL2 Lab Training*. The first class must be done in person either with Dr. Bruce Whitney or through the TAMU Biosafety Office. Subsequent refresher classes can be taken on Train Traq.

Step #3: IBC Review

- All protocols go through full committee review.
- ORC schedules an IBC meeting when the protocol is ready not when it is turned in.
- There will be at least two committee revision cycles.

Step #4: Protocol Approval

- Protocol approval DOES NOT mean you can start work.
- Personnel must receive clearance from Occupational Health and the protocol lab must be certified as BL1 or BL2 before work can begin.

Step #5 – Part 1: Occupational Health (OH) Clearance

- Every person listed on the protocol must be cleared by OH before they can work on the protocol.
- Clearance involves two steps.
    1. OH Training – ORC will send training handouts for personnel to read. Personnel must read them and respond saying that they have read them.
    2. Enrollment – Risk Management & Safety will contact personnel and ask them to fill out an OH enrollment form. Personnel may need to consult with the OH Physician, get vaccinations or get extra personnel protective equipment before starting work.
- ORC will email each person with a copy to the Principal Investigator (PI) when they are cleared to work.

Step #5 – Part 2: Lab Certification

- Labs can be certified as BL1 or BL2
- BL1 Lab Certification
    1. The lab must meet BL1 standards according to the *BMBL*.
    2. ORC has a checklist for the PI to use to prepare their lab for inspection.
    3. An IBC Member can conduct the BL1 lab inspection.
- BL2 Lab Certification
    1. The lab must meet BL2 standards according to the *BMBL*.

2. ORC has a checklist for the PI to use to prepare their lab for inspection.
3. Dr. Bruce Whitney from Systems conducts all BL2 lab inspections.

- Answer ALL the required corrections/items.
- Take pictures of the corrected items to send to ORC.
- The lab corrections/items can go back and forth in more than one revision cycle.

Step #6: Protocol Approval, Lab Certification, and Occupational Health Clearance for Personnel

- All cleared personnel may begin work on the approved protocol in the certified lab spaces.

IBC Review Cycles:

Protocol Review:

- A complete re-review of the protocol is required every 3 years.
- An annual renewal form will be required annually. This is handled outside of an IBC meeting.

Occupational Health:

- An annual update is required for each person working on the protocol.
- OH approval is independent of protocol approval. It is dependent on the individual.

CITI *Basic Biosafety* IBC training course:

- Training must be retaken every 3 years
- All personnel listed on the protocol must complete this course.
- Training approval runs independently of protocol approval. It is dependent on the individual.

***NIH Guidelines for PIs* IBC training course:**

- Training must be retaken every year
- The protocol PI must complete this course. No one else should take it.
- The course can be completed in person with Dr. Bruce Whitney or on Train Traq (Course #211485).
- Training approval runs independently of protocol approval. It is dependent on the individual.

***BL2 Lab* IBC training course:**

- Training must be retaken every year
- All personnel listed on the BL2 protocol must complete this course.
- In fact, anyone working in a BL2 lab regardless of the reason for being there, must complete this course.
- The first course can be taken in person with Dr. Whitney or through the TAMU Biosafety Office.
- Subsequent classes may be taken on Train Traq.

- Training approval runs independently of protocol approval. It is dependent on the individual

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