

IBC GUIDELINE:	Institutional Biosafety Committee (IBC) Permit Application Review Process		
SOP #	100	IBC Approval:	January 8, 2019

Purpose:

All research at Texas A&M University Commerce in which rDNA and/or infectious biohazards are involved (including on humans, animals or plants) must be reviewed and approved by the Institutional Biosafety Committee (IBC).

Scope:

This Standard Operating Procedure (SOP) complies with regulations of the National Institutes of Health (NIH) for the use of rDNA and/or infectious biohazards in research.

Responsibilities:

All applicants must complete an IBC Permit Application (application) and receive approval of the submitted Biohazard Use Protocol (BUP) from the Institutional Biosafety Committee prior to the start of any research. These responsibilities include coordination and sharing of information between the IBC, IACUC and the IRB, as well as the grants and contracts office.

Procedures:

New Permit Application Review

1. Permit Application is received in Office of Research Compliance (ORC)
2. ORC reviews the application to ensure completion of compliance training for PI and other personnel listed in the application.
3. If the application is deemed incomplete or training requirements have not been met, an email is sent to the PI, and the application is held until all training requirements are met. Applications passing the compliance review will be assigned a number and sent to the IBC Chair, or a member of his/her choosing for preliminary review. The outcome of the preliminary review will be communicated to the PI. Any necessary changes/clarifications must be completed before the Chair can finalize the application.
4. The finalized application will be sent to committee members for review, and added to the IBC agenda.
5. ORC will notify the PI of the meeting date and time and offer an invitation to attend the meeting.
6. After committee review, if the application and associated biohazard protocol(s) need no revisions, the Chair will send an approval letter to the PI. If revisions are needed, the Chair will notify the PI by email indicating the requested changes.
7. Once revisions are made, the PI submits the revised documentation to ORC which then forwards it to the IBC Chair. Minor revisions will be verified by the Chair or a designated member of the committee. Major revisions will be reviewed by the full IBC committee at the next meeting.
8. Upon final approval, the PI will receive by email, an approval letter, approved IBC permit, including a copy of the approved BUP. Copies of all finalized documents are kept in ORC.

Amendments to the Permit Application:

Any changes or modification to the research must be reviewed and approved before the initiation of work.

1. An amendment to the application is sent to ORC.
2. ORC reviews the amendment to ensure that all compliance training is completed and up to date.
3. ORC sends the amendment to the Chair for review.
4. Amendments requesting personnel changes are reviewed by ORC for compliance training completion. After verification of training, an approval letter will be sent to the PI.

5. Amendments requesting changes in agents will follow the review process of a new application as outlined in new permit application.

Annual Permit Renewal:

The PI is required to submit an Annual Permit Renewal sixty (60) days prior to the first and second anniversary of the approval date. The process for the renewal is the same as the amendment process.

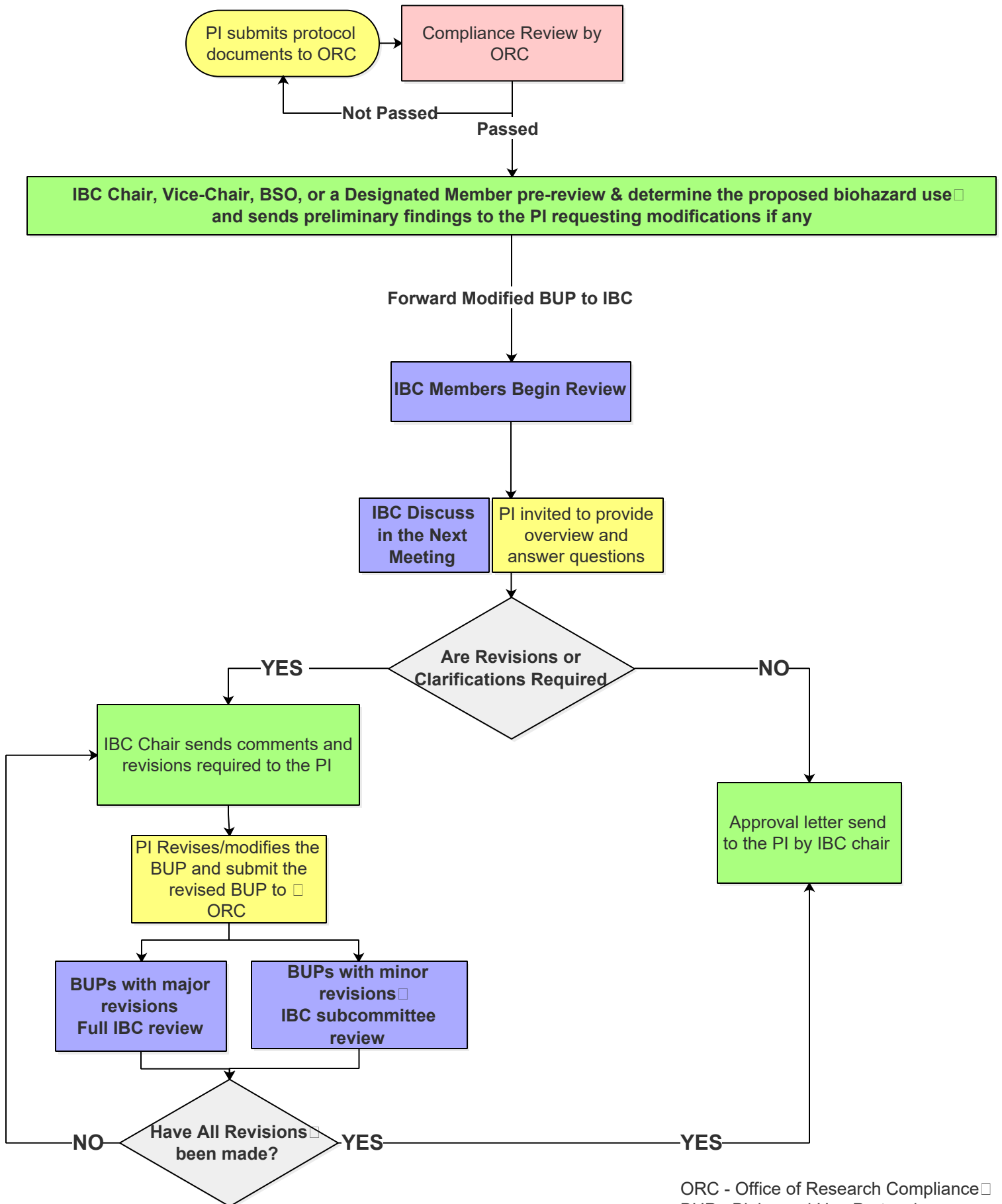
Expiration of Permit Applications:

All permits will expire three years after the original submission date. The PI must submit a new IBC Permit Application sixty (60) days prior to the expiration of the original approval. If a new application is not received and approved, the PI must **stop** all research until a new approval is received.

History:

Version 01 - Initial approval date – January 8, 2019

IBC PERMIT REVIEW WORKFLOW



ORC - Office of Research Compliance
BUP - Biohazard Use Protocol
IBC - Institutional Biosafety Committee