

The University of Tulsa Institutional Biosafety Committee –Standard Operation Procedures (SOPs)

SOP Title: **IBC Protocol Expiration Dates, Annual Reviews and Modification Requests**

SOP Number: **IBC-SOP-003**

Revision Number: 1

Effective Date: 9/20/2019

1. PURPOSE

- 1.1 The purpose of this document is to describe the process for application expiration dates, annual reviews and protocol closures.

2. KEY WORD DEFINITIONS:

- 2.1 IBC: Institutional Biosafety Committee
- 2.2 PI: Principal Investigator
- 2.3 RCC: Research Compliance Coordinator
- 2.4 Minor change: to a currently approved protocol include administrative changes such as change in personnel (not including the PI) or other procedural changes that would not increase risk group or biosafety level
- 2.5 Major change: to a currently approved protocol include changes to PI, quantity of material, organism or cell lines used, genome editing tools or other procedural changes that may increase the risk group or biosafety level.

3. RESPONSIBILITIES AND AUTHORITIES

Research Compliance Coordinator (RCC):

- 3.1 Processes 3rd year renewal applications, annual progress reports and modification requests by checking for completeness (including – appropriate signatures, all form sections are addressed, latest version of the forms used, etc.);
- 3.2 Verifies successful completion of required TU IBC training courses for all research personnel listed on TU IBC protocol submissions;
- 3.3 Forwards any IBC document submissions to the TU IBC Chair or chair designate for initial review and to make any determinations needed, such as Exempt or Non-Exempt or minor/major changes;
- 3.4 Forwards Annual Progress Reports and Modification Requests for review/approval or for major changes or any other reasons to call for a convened meeting;
- 3.5 Assigns the TU IBC protocol number to renewing submissions (e.g. IBC-002), to ‘Non-Exempt’ protocols;
- 3.6 Drafts and sends out letters related to the renewal application, to the PI (i.e. tabled/deferred, requesting additional information letter, conditional approval letter, approval letters);
- 3.7 Maintains IBC protocol files and any associated paperwork including hard and electronic copies (i.e. IBC protocols, modification request submissions, lab safety manuals, meeting minutes, etc.);
- 3.8 Coordinates and schedules convened TU IBC meetings and confirms a quorum is met;
- 3.9 Creates IBC meeting packets which include agenda, previous meeting minutes, new or continuing IBC protocols, modification requests and other relevant information; and

- 3.10 Records meeting minutes with the help of IBC Chair or member designate.

TU IBC Chair:

- 3.11 Conducts initial reviews of 3rd year renewal protocols to make initial determinations such as Exempt or Non-Exempt and minor/major changes;
- 3.12 Conducts initial annual administrative reviews (reviews Annual Progress Reports) and modification requests looking for major changes, increased biosafety level status or any other reasons to hold a convened meeting;
- 3.13 May designate TU IBC initial reviews to an IBC member, IBC sub-committee or ad hoc consultant(s) with appropriate subject matter expertise;
- 3.14 Manages and directs the convened TU IBC meetings; and
- 3.15 Gives final, signed approval to all 3rd year renewal or continuing TU IBC protocols or modification requests to existing protocols, when all conditions are met.

TU IBC Member:

- 3.16 Reviews TU IBC meeting packets and attends convened IBC meetings (in-person or via conference call or other technology where attending members can hear each other in real time)
- 3.17 Serves as a designated reviewer, on a sub-committee, and other duties as assigned by the Chair

4. NON-EXEMPT IBC PROTOCOL EXPIRATION DATES

- 4.1 IBC protocols tend to become 'out of date', regarding research goals, personnel and location after a period of several years despite annual progress report and modification request submissions. To solve this issue, initial non-exempt IBC protocol submissions will expire no later than 3-years after its initial approval date.
- 4.1.1 30-90 days before the 3-year anniversary of the initial approval, the PI shall submit a new (3rd year renewal) IBC Protocol Application submission if they wish to continue with protocol.
- 4.1.2 Although the RCC aims to send out reminders before the 3-year re-submissions are due, the PI is ultimately responsible for:
- tracking/calendaring when their 3-year renewal submissions are due and
 - submitting a TU IBC New/3rd year Renewal Protocol Form and the 3rd year TU IBC Annual Progress Report Form, before the current protocol expires.
- 4.1.3. A 'renewal' protocol application follows the same review procedures as a new protocol. Because of this, a PI may make modifications to their existing protocol without requiring a separate TU IBC Modification Request Form.

- To help expedite the review process, the PI should indicate on the TU IBC Application Form that their renewal protocol application has modifications from the currently approved protocol, explaining what modifications have been made and identifying where in the protocol these changes appear.
 - As with any modification requests, no proposed changes may be implemented until the PI has received written approval from the TU IBC that the renewal protocol with those changes has been approved (*unless to remove an immediate hazard*).
- 4.1.4 A 3-year protocol re-submission will retain the original TU IBC number as the original submission but will have the letter “R” with a number to reflect how many times the protocol has gone through a 3-year renewal
- (i.e. if a current TU IBC protocol (TU-002) has just resubmitted its first 3-year renewal application and has been approved, the renewal protocol number is (TU-002-R1)
 - Each approved renewal protocol will be filed in a separate protocol folder, but the separate protocol files of the same research study will be filed together (i.e. protocol files for TU-002 & TU-002R1 will be filed together) *both hard and digital copies.
- 4.1.5. Although in general TU IBC protocols will be approved for up to 3 years, the TU IBC shall decide at its discretion if a protocol shall be approved for a shorter period than 3 years. The criteria for approval periods will be based on a variety of factors (e.g. level of risk, use of new equipment, technologies, methods, etc.)

5. NON-EXEMPT IBC PROTOCOL ANNUAL ADMINISTRATIVE REVIEW

- 5.1 Although TU IBC protocols are generally approved for up to 3 years, approved non-exempt IBC protocols will have annual administrative reviews. Review procedures and timelines are consistent with initial submissions.
- 5.2 PIs shall submit an Annual Progress Report Form at least 30 days before the anniversary of their approval date. This gives the IBC Chair or chair designate time to conduct an initial administrative review of the Annual Progress Report.
- 5.2.1. The Annual Progress Report shall be:
- Typed or text inserted into the form,
 - Complete and address all sections of the form when applicable or state 'non-applicable', and
 - Signed and dated by the PI.
- 5.2.2. The IBC Chair, at their discretion, may designate a TU IBC member or IBC sub-committee to conduct the initial administrative review or solicit the guidance of a consultant with subject-matter expertise when conducting the initial administrative review if needed (e.g. conflict or subject matter expertise).

5.2.3 If after an initial administrative review, the TU IBC Chair or designate confirms no major changes have been made or proposed, and does not see any other reason to bring an annual administrative review in front of the TU IBC at a convened meeting, and is satisfied with the submitted Annual Progress Report, they will approve the annual administrative review.

- The Annual Progress Report Form will be signed/dated by the TU Chair or chair designate and forward to the RCC.
- The RCC will send out the annual administrative review continuing approval letter.

5.2.4 If after an initial administrative review, the TU IBC Chair or designate confirms that major changes to the currently approved protocol have been made, are being proposed, or for any other reason the IBC Chair or designate has questions/concerns that cannot be directly addressed by the PI, the Chair or designate may, at their discretion, call for a convened meeting to conduct the annual administrative review.

- The RCC will be contacted to schedule and prepare for a convened IBC meeting.
- The TU IBC may contact the PI to provide additional information, request additional documents or request that the PI be available in-person or via conference call to answer questions before the discussion and vote on the annual administrative review

5.3 Although the RCC aims to send out reminders 30-90 days before the annual administrative review is due, the PI is ultimately responsible for tracking/calendaring when their annual administrative review is due and submitting an Annual Progress Report before the current protocol's approval anniversary date.

6. REVIEW OF NON-EXEMPT IBC MODIFICATION REQUESTS

6.1 The PI shall submit a modification request submission (TU IBC MOD REQ Form) when proposing a change to a currently approved non-exempt IBC protocol. Review procedures and timelines are consistent with initial submissions.

6.1.1 The PI shall:

- Submit the modification request form 30-60 days before their proposed implementation date; and
- Not implement any proposed changes until they have received a written approval from the TU IBC of those changes (*unless to remove an immediate hazard*).

6.1.2 The TU IBC Modification Request Form shall be:

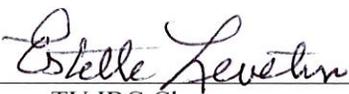
- Typed or text inserted into the form.
- Complete and address all sections of the form when applicable or state 'non-applicable', and
- Signed and dated by the PI.

- 6.1.3 The Research Compliance Coordinator (RCC) shall complete the preliminary review of each new IBC submission for completeness and to confirm required IBC training completion. If the application submission is complete, the RCC will date stamp the submission as received and forward it to the IBC Chair for initial review.
- 6.1.4 The TU IBC Chair or chair designate will conduct the initial review of the modification request.
- 6.1.5 The IBC Chair, at their discretion, may designate a TU IBC member or IBC sub-committee to conduct the review of the modification request submission or solicit the guidance of a consultant with subject-matter expertise when conducting the review if needed (e.g. conflict or subject matter expertise).
- 6.1.6 If after review, the TU IBC Chair or designate confirms that the proposed changes to the current protocol are ‘**minor**’ changes, is satisfied with the submitted TU IBC Modification Request Form, and does not see any other reason to bring a modification request in front of the TU IBC at a convened meeting, the TU IBC Chair/chair designate will approve and sign the form.
- Minor changes include administrative changes such as change in personnel (not including the PI) or other procedural changes that would not increase risk group or biosafety level
 - The PI will be notified of the approval in writing.
 - Once the PI has received the revision approval letter, they may implement the approved changes
- 6.1.7 If after review of the modification request, the TU IBC Chair or designate confirms that the proposed change to the current protocol is a ‘**major**’ change or a reason exists that may increase the risk group or biosafety level, the Chair or chair designate, at their discretion, may recommend the modification request go in front of the full TU IBC at a convened meeting. Review procedures and timelines are consistent with initial protocol submissions.
- If after the initial review, it is determined that there are *major changes*, the IBC Chair will notify the Research Compliance Coordinator to schedule and prepare for a meeting.
 - Major changes include changes to quantity of material, organism or cell lines used or other procedural changes that may increase the risk group or biosafety level.
 - The IBC Chair/chair designate will approve and sign the TU IBC Modification Request Form when the TU IBC approves the modification request.
 - The RCC will send out the revision approval letter
 - The approval date of the modification request submission does not alter the original IBC protocol expiration date of no more than 3 years from the original submission approval date.

7. **STANDARD OPERATION PROCEDURES APPROVAL**

7.1 Version 9.20.2019 approved 10/1/2019

8. **STANDARD OPERATION PROCEDURES APPROVAL**

Approved by:  Date Approved: 10-1-19
TU IBC Chair

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf