

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

SOP Title: **IBC Protocol Submission, Review, and Approval**

SOP Number: **IBC-SOP-002**

Revision Number: 2

Effective Date: 6/15/2020

1. PURPOSE

- 1.1 The purpose of this document is to describe the process for application submission, review, and approval processes of IBC protocols.

2. KEY WORD DEFINITIONS:

- 2.1 **IBC:** Institutional Biosafety Committee
- 2.2 **PI:** Principal Investigator
- 2.3 **RCC:** Research Compliance Coordinator
- 2.4 **Quorum:** More than half of the voting members, needed to conduct official business at a convened meeting of the TU IBC
- 2.5 **NIH Guidelines:** *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules* (last revised April 2019)
- 2.6 **Approved:** The new/renewal protocol submission satisfactorily addresses all issues and the submission is fully approved. No modification is necessary on the part of the principal investigator (PI).
- 2.7 **Conditionally Approved:** Minor issues remain that must be addressed by the principal investigator prior to approval. The revised protocol submission is reviewed by a designated reviewer and may be approved outside of the full TU IBC if changes are deemed satisfactory.
- 2.8 **Tabled/Deferred:** In instances where significant issues have not been addressed or not enough detail is provided in the protocol for the TU IBC to make a proper risk assessment determination, the protocol will be tabled or deferred. The revised protocol will be reconsidered and will require full TU IBC review at the next convened meeting following the submission of the requested revision(s).
- 2.9 **Rejected/Not Approved:** The protocol submission is not approved and has not been recommended for further consideration as written, by the TU IBC.
- 2.10 **Official Business:** IBC business during a convened meeting of the TU IBC that requires a vote by a quorum of attending members (e.g. vote on approving a newly submitted protocol, vote on approving a revision to a IBC SOP, etc.).
- 2.11 **CITI:** Collaborative Institutional Training Initiative – is a web-based training program with research education content in various research areas including human subjects research, animal research and biosafety.
- 2.12 **Exempt:** Protocol submissions that are *not* subject to TU IBC review and oversight. Section III-F of the *NIH Guidelines* provides an Exempt Experiments List of recombinant or synthetic nucleic acid molecules that are exempt from the *NIH Guidelines* and where registration with a local IBC is not required. **However, the TU IBC has opted to review certain types of research even if it may fall in the List of Exempt Experiments. Gene*

editing technologies, such as CRISPR/Cas9, fall into this category of extra Enhanced review and must be submitted and approved by the TU IBC before research can commence. Factors that can lead to increased review may include new procedures, equipment or technologies not yet addressed in the NIH guidelines, etc.

- 2.13 **Enhanced:** Protocol submissions that are not subject to IBC review and oversight. currently under Section III-F of the *NIH Guidelines* but where the TU IBC at its discretion has opted to review certain types of research even if it may fall in the current List of Exempt Experiments. Gene editing technologies, such as CRISPR/Cas9, fall into this category of **Enhanced** review and must be submitted and approved by the TU IBC before research can commence. Factors that can lead to increased, **Enhanced** review may include new procedures, equipment or technologies not yet addressed in the *NIH Guidelines*, etc.
- 2.14 **Non-Exempt:** Protocol submissions that require TU IBC review and oversight. Any research containing recombinant and synthetic nucleic acid molecules that is **not** on the Exempt Experiments List from Section III-F of the *NIH Guidelines*.

3. RESPONSIBILITIES AND AUTHORITIES

Research Compliance Coordinator (RCC):

- 3.1 Processes new and 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 new and 3rd year renewal application submissions to the TU IBC Chair for initial review and to make determination (Exempt or Non-Exempt);
- 3.4 Forwards Annual Progress Reports and Modification Requests to the IBC Chair or chair designate for review/approval or to call for a convened meeting if changes are major or for any other concerns;
- 3.5 Assigns the next consecutive TU IBC protocol number to new submissions (i.e. IBC-002), if the Chair determines a new protocol submission as ‘Non-Exempt’ or ‘Enhanced’;
- 3.6 Drafts and sends out letters related to the application to the PI (i.e. tabled/deferred, requesting additional information letter, conditional approval letter, approval letters);
- 3.7 Maintains applications and any associated paperwork including hard and electronic copies (i.e. IBC protocols, 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 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 new and 3rd year renewal IBC applications to make initial determination of Exempt, Enhanced or Non-Exempt;
- 3.12 Conducts initial annual administrative reviews (reviews Annual Progress Reports) and determines if the annual review must go in front of the full Committee;
- 3.13 Conducts initial review of modification requests for major changes, increased biosafety level status or any other reasons to call for a convened meeting;
- 3.14 May designate TU IBC initial review to an IBC member, IBC sub-committee or ad hoc consultant(s) with appropriate subject matter expertise;
- 3.15 Manages and directs the convened TU IBC meetings; and
- 3.16 Gives final, signed approval to all new or continuing TU IBC protocols or modification requests to existing protocols, when all conditions are met.

TU IBC Member:

- 3.17 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)
- 3.18 Serves as a designated reviewer, on a sub-committee, and other duties as assigned by the Chair

4. INITIAL IBC PROTOCOL SUBMISSION REQUIREMENTS AND PROCEDURES

- 4.1 The Principal Investigator (PI) submission shall include:
 - 4.1.1 The IBC Protocol Application form. The PI shall use the latest form version of the TU IBC Protocol Form from the TU IBC webpage. The application must:
 - Be typed or text inserted into the form;
 - Be complete and address all sections of the form when applicable or state “non-applicable”;
 - Include detailed information on the research and safety procedures sufficient for the TU IBC to make a risk assessment determination;
 - Include the submission of the 3rd year Annual Progress Report if the PI is submitting a 3rd year Renewal Protocol; and
 - Be signed and dated by PI and the PI’s department chair. *(A submission with the original signatures is not required. The PI may scan and email the signature page or use an ‘electronic signature’ that is inserted into the document.)*
 - 4.1.2 The required CITI IBC training courses' completion certificates for every PI, Co-PI, staff, student and any other researcher listed on the IBC protocol.
- 4.2 Email submissions of Word documents are preferred. Email IBC submissions to the Research Compliance Coordinator (RCC).
- 4.3 If after the initial review by the IBC Chair the protocol is determined to be Enhanced or Non-Exempt, the PI shall be contacted and required to submit a laboratory safety manual for the safe lab practices related to their protocol.

- 4.4 If the application is incomplete, the RCC, IBC Chair, or chair designate will contact the PI and return the submission for revision.

5. IBC INITIAL REVIEW PROCESS FOR NEW IBC PROTOCOL SUBMISSIONS

- 5.1 The Research Compliance Coordinator (RCC) shall complete the preliminary review of each new IBC submission for completeness and 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 and determination (Exempt, Enhanced or Non-Exempt).

- 5.1.1 If the proposed research involves the use of recombinant or synthetic nucleic acid molecules **only**, the Chair will determine if the research is Exempt in accordance with Section III-F of the NIH Guidelines. The Chair shall seek guidance from NIH OBA if necessary).

- The TU IBC, through the IBC Chair or chair designate, can bring a protocol before the TU IBC for review before the research is determined to be Exempt, Enhanced or Non-Exempt. Factors that can lead to such review may include new procedures, equipment or technologies not yet addressed in the NIH guidelines, etc.
- If the TU IBC opts to review a protocol that would meet the Exempt category per the *NIH Guidelines*, at the increased review level of 'Enhanced', the TU IBC, at its discretion can choose the type of Enhanced review procedures it deems appropriate (review by the IBC Chair or Chair designate, by a member or sub-committee with subject matter expertise, or at a convened meeting with a quorum of members present).

- 5.1.2 If the research is determined to be **Exempt** and the TU IBC does not opt for increased Enhanced review, the Exempt determination will be indicated on the original application and the PI will be notified in writing that the research does not require IBC oversight.

- No TU IBC protocol number will be assigned.

- 5.1.3 If the research is determined to be **Enhanced** by the TU IBC (even if it may fall in the current List of Exempt Experiments. and the TU IBC opts for increased Enhanced review), the TU IBC, through the IBC Chair or chair designate, will determine what level of increased review.

- Enhanced review can take the form of:
 1. Review by the TU IBC Chair, Chair designate or TU IBC Member with subject matter expertise;
 2. Review by a sub-committee of TU IBC Member with subject matter expertise; **or**
 3. Review at a convened meeting of the TU IBC with a quorum of members present (similar to Non-Exempt review procedures).
 4. Forms of review 1 & 2 above, may approve a protocol, conditionally approve a protocol, ask for additional information/clarification ('table'), or request that the protocol be reviewed at a convened

meeting of the TU IBC with a quorum of members present, but cannot disapprove/reject a protocol.

5. If the form of review is review at a convened meeting with a quorum of members present, the TU IBC may approve a protocol, conditionally approve a protocol, ask for additional information/clarification ('table') or not approve/reject a protocol.

- Once approved, TU IBC protocols using gene-editing are subject to Annual Administrative Reviews and submitting a Laboratory Safety Manual, similar to Non-Exempt protocol requirements.

5.1.4 If the research is determined to be *Non-Exempt*, either per the *NIH guidelines*, the TU IBC Chair will contact the RCC to prepare for and schedule an IBC meeting.

- The PI will be contacted to submit a lab safety manual for their protocol;
- The RCC will assign the protocol the next consecutive number (e.g., IBC-002)

***Note:** "The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant or synthetic nucleic acid molecules cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to the specifics." The TU IBC (through the IBC Chair or chair designate) shall decide, at its discretion, what items to bring in front of a convened meeting of the TU IBC.

6 **IBC REVIEW PROCESS FOR NEW NON-EXEMPT IBC PROTOCOL SUBMISSIONS**

6.1 **Meeting timeline:** Due to the infrequency of Non-Exempt IBC protocol submissions, the TU IBC meetings will not be scheduled in advance. Once a new protocol has been determined to be Non-Exempt, the RCC will schedule an IBC meeting. The timeline to get a new Non-Exempt protocol submission on the agenda of a convened meeting of the TU IBC is generally about 1-month.

6.1.1 The submission deadline is the first working day of each month to get the protocol reviewed at an IBC meeting that same month (as long as the submission is complete and has had a satisfactory initial review)

6.1.2 Certain circumstances that may extend the review timeline longer than 1-month include:

- Planned or unplanned university closed days
- Exceptionally busy times during the academic year (start or end of academic year, finals, accreditation visits, etc.)
- During semester breaks and summer break, when it is difficult to secure a quorum
- Incomplete submissions by the PI

- 6.1.3 There are many unforeseen circumstances that may delay the 1-month review timeline. To increase the chances of a speedy approval, whenever possible, PIs should:
- Complete all IBC trainings for themselves and have their research staff listed on the IBC protocol complete all required training prior to the submission of the IBC protocol;
 - Submit a complete and detailed protocol submission;
 - Contact the IBC Chair or RCC and make them aware that a new submission is forthcoming;
 - Submit the IBC protocol two months in advance of their proposed start date whenever possible; and
 - Plan for unexpected delays.

7 **NON-EXEMPT REVIEW AT A CONVENED MEETING OF THE TU IBC**

- 7.1 The TU IBC has the authority to approve, require modification, or disapprove all research activities that fall within its jurisdiction.
- 7.2 The RCC will distribute meeting packets (containing agenda, previous meeting's minutes, protocol submissions, and other related documents) about 1-week before the scheduled meeting.
- All members will receive electronic copies of all meeting materials.
- 7.2.1 Non-affiliated members may request a hard copy to be mailed to them at their request or a hard copy will be ready for them at the meeting.
- 7.2.2 IBC members working at a TU campus site will receive a hard copy of the meeting packet in campus mail, which they will bring to the meeting.
- 7.3 Each IBC member may submit his/her analysis to the Chair either prior to or at the meeting.
- 7.3.1 If a member cannot attend (either in-person or via conference call), they have an opportunity to forward their comments to the IBC Chair prior to the meeting, to have their comments heard and recorded in the minutes, but cannot be part of vote or count toward the quorum.
- 7.4 Before the meeting date, IBC members are encouraged to contact the IBC Chair or the PI directly with any questions or concerns they have during their review. This will give the PI time to make revisions/clarifications to the protocol before the meeting date, for a better chance of getting their protocol approved on the day of the meeting.
- 7.4.1 The TU IBC, at its discretion, may contact the PI to request additional information, additional documents, to clarify the protocol before the discussion and vote at the convened meeting.
- 7.4.2 The TU IBC, at its discretion, may call in a PI via conference call during a convened meeting of the TU IBC to request additional information about their

protocol when additional information is needed to make a risk determination on a study. This procedure will only be used when deemed necessary (i.e. to avoid the tabling of a protocol until the next scheduled convened meeting because additional information is needed).

- The RCC will contact the PI before the meeting date to inquire if the PI will be available by phone at the scheduled date/time and if so, request a phone number that they prefer to be called on, if needed.
- If called into a meeting via conference call, the PI will be requested to give additional information and/or answer questions about their protocol before the discussion/vote. Once the information is obtained, the TU IBC will end the call with the PI in order to continue with the discussion and vote without the PI.

7.5 Review at a convened meeting of the TU IBC with a quorum of members present may approve a protocol, conditionally approve a protocol, ask for additional information/clarification ('table') or not approve/reject a protocol.

7.6 All decisions of the TU IBC will be communicated in writing to the PI by the RCC, IBC Chair, or chair designate

7.7 IBC members with a conflict of interest (e.g., the PI or faculty advisor for an IBC protocol being reviewed, financial conflict of interest, personal conflict of interest, etc.) shall recuse themselves from the review, discussion, and vote of that IBC protocol.

7.7.1. A conflicted IBC member may not be appointed as a designated reviewer or as part of a sub-committee responsible for the review of that protocol.

7.7.2. A conflicted IBC member may attend a convened meeting and give additional information and/or answer questions about the conflicted study, but will be required to leave the room during the discussion and vote on the protocol. The conflicted IBC member may return to the meeting after the discussion and vote.

- The conflicted IBC member will not count toward a quorum for the discussion and vote of the conflicted protocol. Therefore, quorum must be met even when the conflicted IBC members leaves the meeting or official business (i.e. a vote) cannot be conducted.

7.8 If the IBC does not have the appropriate expertise to evaluate a particular application, the use of subject matter experts or consultants may be used.

7.8.1 Consultants will give the Committee their analysis and answer questions but they cannot vote at the convened meetings or count toward the quorum.

8 IBC CONVENED MEETING DECISIONS

- 8.1 A **quorum** (more than half of the voting members) must be present (in-person or via conference call or other technology where attending members can hear each other in real time) to vote on an application submission or other official business.
- 8.2 **Approval:** The IBC submission satisfactorily addresses all issues and the submission is fully approved. No modification is necessary on the part of the principal investigator (PI).
- **IACUC, IBC, or Radiation Safety oversight:** If the approved IBC study involves research also subject to oversight by one or more other research compliance committee(s) (e.g., Institutional Animal Care and Use Committee–IACUC, Institutional Review Board–IRB, or Radiation Safety), the IBC approval letter will include a contingent statement that the TU IBC’s approval is contingent upon the PI also obtaining approval from the other research compliance committee(s). All approvals are required and all research compliance areas will require a copy of the other’s approval letter before the PI can commence with their research.
 - Once the IBC protocol is approved, it is approved only “as written”. The PI cannot deviate from the written protocol without first contacting the IBC and requesting a modification to their currently approved protocol, which may require the submission of a modification request.
 - The PI will be notified in writing that the application has been approved and registered with the IBC and requires no further revision by the PI.
- 8.3 **Conditional Approval:** Minor issues remain that must be addressed by the principal investigator prior to approval. The revised protocol submission is reviewed by a designated reviewer and may be approved outside of the full TU IBC if changes are deemed satisfactory. The PI will be notified in writing, listing minor requested revisions by the Committee, required as the conditions for approval.
- 9.3.1. The PI will be given ample time to submit the revised application in writing. However, if the conditions for approval are not met within 6 months of the initial IBC review date, submission of a new application will be required.
- 9.3.2. Multiple revisions are allowed and may be necessary in some cases.
- 9.4. **Tabled/Deferred:** In instances where significant issues have not been addressed or not enough detail is provided in the protocol for the TU IBC to make a proper risk assessment determination, the protocol will be tabled or deferred. The PI will be requested to submit revisions/additional information, that will require full IBC review upon the PI’s response to the requested revisions. The revised protocol will be reconsidered at the next convened meeting following the submission of the requested revision(s).
- 9.4.1. The PI is responsible for correcting deficiencies and resubmitting a revised application.

9.4.2. The PI will be notified in writing as to the reason(s) for the protocol being tabled or deferred to the next convened meeting of the TU IBC for reconsideration and given a list of revisions requested.

9.4.3. The PI will be given ample time to submit the revised application in writing. However, if the conditions for approval are not met within 6 months of the initial IBC review date, submission of a new application will be required.

9.5. **Rejected or Not Approved:** The protocol submission is not approved and has not been recommended for further consideration as written, by the TU IBC. The PI will be notified in writing as to the reason(s) for rejection of an IBC protocol.

10. APPEALS

10.1 PIs have a right to appeal IBC decisions concerning their research projects.

10.2 Request for appeal of an IBC decision must be made in writing to the IBC Chair.

10.3 Once a request for appeal has been received, the IBC Chair will place the appeal on the agenda for the next IBC meeting.

10.3.1. If a time constraint exists for the PI in terms of funding, the IBC Chair if practical, may choose to schedule a separate meeting for the appeal.

10.4 The IBC Chair will notify the PI of the IBC's decision in writing.

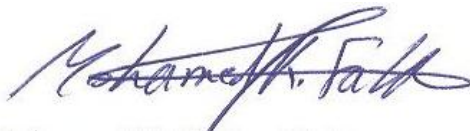
10.5 If the PI is still not satisfied with the IBC's decision, he or she may appeal to the Institutional Official (IO). The IO has authority to request that the IBC revisit or reconsider the protocol with further explanation/information.

10.5.1. Note: the IO cannot approve research that has not been approved by the TU IBC.

11. REVISION HISTORY

11.1 Version 6.15.2020 approved x/x/6/15/2020

12. STANDARD OPERATION PROCEDURES APPROVAL



Approved by: _____

TU IBC Chair

_____ Date Approved: 6/15/2020 _____

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