

PI Checklist for Work with Biohazards and Recombinant DNA
Office of Biosafety
(Updated August, 2019)

1. Per the University's Rule ([Use of Biohazards](#)), Texas A&M Institutional Biosafety Committee (IBC) approval is required for all research, teaching or testing activities conducted by a member of the faculty or staff of Texas A&M University or a Texas A&M System component with a signed Memorandum of Understanding with Texas A&M IBC ***prior to initiating*** work with:
 - a. Biological agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites and prions) that may cause disease in humans, animals, or plants
 - b. Recombinant or Synthetic Nucleic Acid Molecules as defined in the National Institutes of Health (NIH) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, including the creation or use of genetically modified plants and animals
 - c. Human and non-human blood, tissue, and cell lines; and
 - d. Toxins of biological origin as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) document
2. Registration with the TAMU IBC:
 - a. The initial step for approval to work with biohazards is to submit a complete IBC permit application to the IBC.
 - i. Only faculty (or faculty equivalent titles) may apply for an IBC permit.
 - b. All applicable forms are available on-line (<https://iris.tamu.edu>)
 - c. Instructions and assistance are available. (979.845.4969 or IBC@tamu.edu)
3. IBC Training Requirements: (Initial training requirements may be completed while the IBC permit is under review.)
 - a. ALL Principal Investigators (PI) submitting an IBC application must complete ***NIH Guidelines + University Rule*** training. This training is available online in TrainTraq. ***NIH Guidelines + University Rule*** training is required once, unless the training is significantly revised and/or updated.
 - b. All personnel (including the PI) who will be working in a biosafety level two (BSL-2) laboratory must be identified in the IBC application. All personnel must complete BSL-2 training, provided by Office of Biosafety staff, before being authorized to work in the BSL-2 lab. BSL-2 trainings sessions are offered weekly and upon special request for special circumstances. BSL-2 Training is valid for five years. Thereafter, refresher training is available online via TrainTraq.
 - c. All personnel who will be working in a biosafety level three (BSL-3) laboratory must be identified in the IBC application. All personnel must complete BSL-3 training, provided by Office of Biosafety staff, before being authorized to work in the BSL-3 lab. Instructor led BSL-3 training is available upon request, as needed. Please contact the Office of Biosafety at 979.862.4549 or biosafety@tamu.edu for assistance. BSL-3 training must be renewed annually.
 - d. All personnel listed on either BSL-2 or BSL-3 IBC permits must also be provided lab and agent specific training by the PI (or PI's designee). Documentation of this training must be provided to the IBC. The Office of Biosafety can provide PIs with a template form to fulfill this requirement;

alternatively, attestation that this training is included as part of the IBC application. A description of the content of training is required by the IBC as well.

- e. Bloodborne Pathogen (BBP) Training must be completed by all personnel at risk of exposure to human and/or non-human primate blood, tissues, body fluids, and/or other potentially infectious materials (e.g., human cell lines, human feces, etc.) in the course of IBC permitted research, teaching or testing activities. BBP refresher training is required annually. Both initial and annual refresher training may be completed online via TrainTraQ.
 - f. For personnel working in BSL-2 and BSL-3 labs, a one-time, online training (available in TrainTraQ) on the safe use of a biosafety cabinet will also be assigned.
 - g. Other trainings and risk mitigations may be assigned, as required by the IBC permit.
4. Laboratory Inspection and Certification:
- a. During the IBC review and approval process, laboratories will be assessed for biosafety standards by Office of Biosafety staff, using checklists developed per CDC BMBL and *NIH Guidelines* standards. Inspections will be scheduled with PIs or their designees.
 - b. The IBC permit cannot be approved until all lab space has been assessed and certified for the appropriate biosafety level.
 - i. Example inspection checklists are available:
(<https://rcb.tamu.edu/more/resourcehub/inspections>)
 - c. Laboratories are re-assessed annually, as part of the annual review process, or as needed.
5. IBC Approval:
- a. IBC applications describing rDNA studies that are not exempt of the *NIH Guidelines* must be reviewed by the full committee during a regularly convened meeting. NOTE: An application must be submitted at least 10 business days before the meeting date in order to be considered for review during the upcoming meeting.
 - b. The IBC typically meets the fourth Wednesday of each month, with the exception of November and December, when meetings may be rescheduled to accommodate holidays. IBC meetings are open to the public. To view a full schedule of Committee Meetings:
(<https://rcb.tamu.edu/biohazards/approvals/committeereview>).
 - c. IBC applications describing non-recombinant work with biohazards, or recombinant work that is exempt of the *NIH Guidelines*, must still be registered with the IBC but do not require review during a regularly convened meeting and can be approved by the IBC Chair on behalf of the IBC.
 - d. IBC approvals are valid for a period of three (3) years. Annual permit review is required as described below (Section 7).
6. Commencement of Work:
- a. Once the IBC approval memo, signed by the IBC Chair, is received by the PI, approved experiments may commence. A copy of the IBC approval letter will be provided to the PI's Department Head.

- b. The IBC approval letter will include a list of all biologically hazardous agents approved by the IBC, all approved locations of work (Building and room numbers) and assigned biosafety level(s).

7. Annual Requirements:
 - a. A one-page, annual review questionnaire should be submitted by the PI 30-60 days prior to the first and second anniversary of the IBC permit approval.
 - i. The annual review form is accessible online in the iRIS program.
 - ii. A laboratory visit will be scheduled as part of the annual review.
 - iii. Personnel training requirements will be reviewed at least annually to ensure that all personnel working at BSL-2/BSL-3 are current with respect to all IBC required trainings.

8. Amendments are required prior to implementing any changes to the existing IBC approval, including changes in:
 - a. Personnel: Addition (or removal) of laboratory personnel to BSL-2 and BSL-3 IBC permits must be submitted online in iRIS. (<https://iris.tamu.edu>).
 - b. Agents: New agents, procedures, recombinant activities, etc., not previously approved must be submitted for review by the IBC.
 - c. Locations: Any changes in location of work must be submitted to the IBC (<https://iris.tamu.edu>).
 - i. Lab locations being vacated must be decontaminated, and chemical and biological agents properly disposed of (and/or secured for transport), as appropriate. Vacated labs will be inspected and decommissioned by Environmental Health and Safety and the Office of Biosafety in accordance with the University Standard Administrative Procedure Laboratory Decommissioning ([24.01.01.M4.04](#)).
 - ii. As appropriate, all new lab spaces must be inspected and certified before work with biohazardous materials may commence in the new space.

9. Termination of IBC Permit:
 - a. Investigators leaving the institution or ceasing their activities with biohazardous materials should submit a termination request to the IBC. The termination form is found online here: <https://iris.tamu.edu>.
 - b. Requests for termination will initiate the laboratory decommission process described in 8.c.i.

10. Biosafety Occupational Health Program (BOHP) Enrollment:
 - a. Enrollment in the Biosafety Occupational Health Program is required of all personnel participating in IBC permitted activities taking place in BSL-2 or BSL-3 labs. BOHP enrollment is completed on-line: [Biosafety Occupational Health Portal](#)
 - b. Annual updates are requested and should be completed here: [Biosafety Occupational Health Portal](#)

11. Additional PI responsibilities:

- a. Biosafety cabinets (BSCs) must be inspected and certified at least annually and anytime they are significantly repaired or moved. Scheduling this service is the responsibility of the PI. (On the Bryan/College Station campus, the University has arranged for a contracted provider (Precision Air Technology) to perform this service.)
 - i. If the BSC will be moved to another building or sent to surplus, it is the PI's responsibility to schedule a gas decontamination of the HEPA filters prior to relocation of the BSC.
- b. Autoclave cycles used to sterilize solid or liquid biohazardous wastes must be initially validated using biological indicators to ensure proper cycle parameters have been established. Thereafter, autoclave cycles must be regularly verified, using biological indicators, to confirm proper functioning of the autoclave. All biohazardous waste must be treated and disposed of in accordance with 25 TAC 1.136.

Other Research Activities:

All research involving animals must be registered separately with the Institutional Animal Care and Use Committee (IACUC). IBC approval does not convey IACUC approval. Please see: <http://rcb.tamu.edu/animals>.

All research involving human subjects must be reviewed by and may require approval from the Institutional Review Board (IRB). IBC approval does not convey IRB approval. Please see: <http://rcb.tamu.edu/humansubjects>.

Any research that may be subject to Export Control regulations must be in compliance with Federal guidelines. Please see: <https://vpr.tamu.edu/resources/export-controls>.

Research activities involving the use hazards other than biohazards are not the scope or oversight responsibility of the Institutional Biosafety Committee or the Office of Biosafety. For questions regarding general lab safety, laser safety and/or work with chemicals, radiation, etc., please contact Environmental Health and Safety for assistance: <https://ehs.tamu.edu>.