Protocol Tracing for Institutional Biosafety Committee (IBC) Protocols

Comments:
It is the responsibility of the Principal Investigator or Lab Director to perform a written risk assessment of the proposed research experiment. Biosafety Professionals can provide assistance in this process by reviewing and making comments. The Biosafety Professional and others assisting the Principal Investigator cannot provide the technical expertise and experience required of those directing biohazardous research experiments.

Biohazard and Regulated Biological Materials Registration Form
Have you designed a registration form that obtains all of the relevant information that the IBC needs to conduct their review? A well designed form will also help the Principal Investigator provide all the required information to document their written risk assessment. The registration form should be reviewed periodically and updated where necessary, especially when you are not getting appropriate information, or when regulations change, or when new research techniques create novel risk situations.

Registration forms may also have trigger questions or notes that inform the Principal Investigator (PI) that additional information is required and direct them to additional forms or whom to contact for next steps. Modern online registration forms can be designed to auto-populate additional questions when certain yes/no questions have been answered in the affirmative. Examples of research experiments that are candidates for separate registration forms or processes include human gene transfer research experiments, Dual Use Research of Concern protocols, and research protocols involving Select Agents and Toxins.

Initial Review of the Registration Form:

- ☐ Is the registration form complete and accurate?
- ☐ Has it been signed?
- ☐ Have all of the questions been answered?
- ☐ Has the PI included a description of the experiment in lay terms for the community members?
- ☐ Are all sections or the form adequately completed?
- ☐ If there is jargon and acronyms, have these been adequately described or spelled out?
- ☐ Is there sufficient information for the IBC to conduct its review?
- ☐ Did the PI conduct an adequate written risk assessment?

☐ Has the PI provided detailed standard operating procedures that outline risk management elements of work practices, engineering controls, personal protective clothing and equipment, and information about the proposed facility?

☐ Are there any Red Flags or items that may be of concern for the IBC?

☐ Should this protocol be assigned to expert reviewers from the IBC before submission of all protocols to IBC members? Expert reviewers can be asked to provide a detailed review of the project to IBC members at the meeting scheduled to review the project.

☐ Does the experiment make sense? Is it scientifically valid? (This is important especially if animals are involved).

Get the registration form completed, updated and corrected before it gets submitted to the Committee.

☐ Have researcher experience forms been obtained from the PI and the lead researchers on the protocol to document that they have prior experience with the biohazard or other similar biohazards?

☐ Is an internship in another laboratory needed for the PI and lead researcher to gain hands on experience with the proposed biohazards?

☐ Is a review of the PI's laboratory and inspection of the proposed work practices required prior to the Committee meeting?

- Is the facility still in compliance with CDC/NIH and your institution's policies?
- Is lab airflow inward from surrounding areas into the proposed lab location?
- How much foot traffic is in the lab? (Especially around proposed research areas).
- Are biosafety cabinets present, available, certified and proposed for use?
- Are chemical fume hoods present if needed for volatile and toxic chemicals?
- Are the biosafety cabinets and chemical fume hoods clutter free?
- What personal protective equipment has been identified for use in the protocol?
- Have the biological waste collection points been identified?
- Has Biowaste collection and treatment been described?

- Will the project involve centrifugation? If yes, will safety buckets or sealed rotors be utilized? Are researchers trained to open these sealed containment devices inside the biosafety cabinet?
- Will sharps be utilized? Are they required for the experiment (if in vitro only)? If sharps are used for an in vitro experiment, can plastic alternatives be utilized instead?
- Are sharps containers located in the immediate vicinity of use? (Within arm's reach of the researcher).

☐ Does the PI and lab staff have a strong compliance record? With the IBC, Environmental Health & Safety (EHS), the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB)?

☐ Has the PI and researchers completed all required EHS, Biosafety and other applicable (IACUC) trainings?

☐ If the protocol has been assigned to IBC subject matter experts, have they provided a written review that can be distributed to the IBC prior to the meeting?

☐ Have all supporting references listed by the PI in the protocol been obtained and made available to IBC members if needed?

☐ Has the PI selected the correct NIH Classification for the proposed work (if it involves recombinant and synthetic nucleic acid molecules)?

☐ Is the Biosafety Level selected by the PI appropriate?

☐ Has the Biosafety Officer, IBC Chair or IBC Administrator/Other created a protocol summary spreadsheet for distribution to IBC members that includes the following:

- Principal Investigator and Protocol #
- General summary of the scientific protocol
- NIH classification and BSL
- Lab training and research experience
- Lab inspection of work practices and facility
- Any special notes, relevant information and concerns

☐ Confirm that any additional supporting documentation has been obtained for the protocol file and have ready to submit to IBC members (inspection report summaries, Pathogen Safety Data Sheets or Agent Summary Statements, Research Experience Forms, Vector/Plasmid maps, host cell lines, inserted recombinant or synthetic nucleic acids, and all animals and plants involved).

Distribution of IBC Packets and Scheduling of IBC Meeting

☐ All protocols, summary spreadsheet, past minutes, agendas and other pertinent material submitted to IBC members in advance of the meeting This should include any written summary reviews of the protocol by the primary expert reviewers of the IBC.

☐ IBC Meeting scheduled and communicated to IBC members.

☐ Notify primary reviewers if a formal presentation is required for the meeting.

☐ Invite the PI and lead researcher to the IBC meeting if warranted. This could include a novel or elevated risk project, a request to lower the normal containment level, or a complex or controversial protocol. NIH III-A, III-B and III-C projects would qualify has high risk or complex. Projects involving recombinant or synthetic nucleic acids molecules with Risk Group 4 or Risk Group 3 RNA or DNA would also be of special interest for the IBC.

Committee Meeting

☐ Record attendance, time the meeting started, discussion points, and major decisions made at the meeting. Record motions including those making a motion and those who confirm the motion along with voting results of those in favor, opposed or abstaining.

☐ Capture all salient commentary related to the protocol. Make sure the minutes reflect conformity with the NIH Guidelines requirements for minutes (there has to be sufficient information present in the minutes to show the rationale for any decisions made at the IBC meeting).

☐ Note any contingencies required by the IBC for the protocol (these items, if confirmed after the meeting, shall be verified and documented and presented to the IBC at the next meeting).

☐ Communicate results of the IBC review to the Principal Investigator. A letter informing the PI that the project was approved as is, approved with contingencies, or not approved shall be provided.

☐ A standard written approval document can provide a consistent mechanism for communication of IBC decisions to PIs. It can provide standard information and also specific information pertinent to this protocol.

☐ Determine the renewal periodicity and include this renewal date in the approval letter.

☐ Include any other authorizations that must be obtained, such as an IACUC or IRB approval.

Post-Approval Monitoring

☐ Protocol shall be renewed on regular interval as determined by the IBC. PIs should be notified to renew their protocols at least 60 days prior to the renewal date.

☐ Annual lab inspections should review the status of all approved protocols (active, inactive, what was done in the last 12 months, what research is being conducted at the current time, and what is proposed in the next year).

☐ The approval letter should also dictate clearly that prior approval is required prior to making any significant changes to the protocol. The PI should be reminded that an update is required for any significant changes, including, but not limited to:

- Location changes
- New research materials that will elevate the risk of the project
- Different research vectors
- Changes in existing vectors that will elevate the risk
- The addition of animal or plant research