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IBC Standard Operating Procedures

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Standard Operating Procedures for the VA Pittsburgh Healthcare System Institutional Biosafety Committee (IBC)

Introduction

This VA Medical Center Institutional Biosafety Committee (IBC) Standard Operating Procedure (SOP) is a reference for members of the VAPHS Research Community, including committee members, staff, and investigators. The IBC, a local subcommittee of the VA Pittsburgh Healthcare System Research and Development Committee, is committed to providing a safe environment for research subjects (human and animal) and all research personnel. This SOP details the policies and procedures related to the Committee's functions and oversight.

1. Regulatory Mandates Governing the IBC

Ensuring personnel safety in Veterans Health Administration (VHA) research necessitates oversight at the national and local levels on policies involving the use of Biohazards, Chemical Hazards and Physical Hazards. A Research Safety Program must be maintained and consistent with VA policies, Federal statutes and regulations from Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Nuclear Regulatory Commission (NRC), etc., and any applicable state and local requirements. All applicable National Institutes of Health (NIH) and/or Centers for Disease Control and Prevention (CDC) guidelines must also be followed.

2. IBC Roles and Authorities

This facility's medical center Director is responsible for ensuring that the research safety program is staffed adequately and that resources are available to maintain full compliance with all applicable regulations and standards of safety.

The IBC must ensure that all research activity is in compliance with all applicable regulations, policies, and guidelines prior to submission for R&D approval and/or funding. The IBC is charged with the following responsibilities:

(a) Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site.

1. The review of the Research Protocol Safety Survey (RPSS) must include a risk assessment of the facilities, level of containment, laboratory procedures, practices,

training and expertise of personnel involved in the specific research conducted including recombinant DNA research.

2. All research projects involving biological, chemical, physical, and radiation hazards must be approved by IBC and then by the R&D Committee prior to commencement. The IBC must review proposed research at convened meetings at which a quorum (majority of voting members) is present.

(b) Providing written notification of the results of IBC review to the R&D Committee, the Research Office, and the PI.

(c) Annually reviewing all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review will be based on the date of IBC approval. Research protocol changes not included in the original application must be documented on an amended RPSS and must be submitted to the IBC for review prior to the implementation of the changes.

(d) Ensuring that a complete list of all products containing chemicals designated or identified by OSHA and/or EPA as “hazardous” has been submitted to the Safety Officer for review and approval prior to the submission of a protocol for local review.

(e) Coordinating all safety-related activities in research laboratories including mandatory and non-mandatory training, safety inspections, accident reporting, and liaison activities with all facility safety committees and officials; to include:

1. Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and
2. Reporting follow-up results to the R&D Committee.

(f) Reporting operational problems or violations of directives to the Research Safety Coordinator and the Research Office within 30 days of occurrence or detection, unless SRS determines that a report has been previously filed by the PI.

(g) Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising the R&D Committee and Employee Health Practitioner on the need for such surveillance.

(h) Maintaining adequate documentation of all SRS or equivalent subcommittee activities.

(i) Forwarding minutes to the Research Office

(j) Ensuring that all laboratory personnel receive annual research specific safety training.

(k) Holding SRS meetings at least quarterly.

(l) Ensuring coordination with other regulatory programs, personnel, or committees, such as the Radiation Safety Officer and/or Radiation Safety Committee.

(m) Ensuring the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.

(n) Annually evaluating the effectiveness of the laboratory’s Chemical Hygiene Plan and making necessary revisions.

(o) Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.

(p) Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate.

- (q) When appropriate, requesting the appointment of an ad hoc committee consisting of members with appropriate expertise, to investigate and report on occupational injuries, illnesses, and adverse environmental events.
- (r) Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records
- (s) Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.
- (t) Providing technical assistance in the reduction of the quantity of waste and/or recycling programs, where appropriate.

3. Membership of the IBC

Number and Qualifications of Members: It is recommended that the Institutional Biosafety Committee (IBC) include member(s) from the facility safety committee, such as the Safety Officer or the Facility Infection Control Committee; the Institutional Animal Care and Use Committee (IACUC); the Radiological Safety Officer; and a liaison from an affiliated university Institutional Biosafety Committee. Each IBC must have at least five members, exclusive of ex-officio members; this must include two members not affiliated with the Institution. If the facility conducts research with recombinant DNA, it must comply with all requirements with respect to composition of an Institutional Biosafety Committee as specified in the NIH Guidelines. It is recommended that at least one IBC member possesses specific occupational safety and health, environmental, and Department of Transportation expertise to ensure that all pertinent hazards in protocols are identified. It is also advisable this member have first hand knowledge of the space and facilities assigned to each Principal Investigator (PI) to ensure that research operations can be conducted safely. The ex-officio members must include; a liaison member from the local Research and Development (R&D) Committee (voting), the Chemical Hygiene Officer (appointed by the R&D Committee) (voting), the Administrative Officer (AO) for R&D or other non-voting representative from the R&D office and an Employee Union Safety Representative, or other union designee, whose voting status is determined by the applicable union contract.

Appointments: The medical center Director appoints the IBC chairperson for the term of 1 year. The IBC Chairperson may be re-appointed without any lapse in time; however the IBC chairperson may not simultaneously chair the R&D Committee or another research subcommittee. The medical center Director must officially appoint members to the IBC in writing; specifying the length of their appointment.

4. IBC Record Keeping and Required Documents

The IBC meets on the third Thursday of every month, but is only required to hold meetings at least quarterly. The research office provides agenda packets to the IBC members at least 3 business days before the meeting. This packet includes an agenda with all business items listed, including reviewer assignments for all new protocols and copies

of all protocol forms. Each new protocol must be assigned to one voting committee members. This member serves as the primary reviewer, and is expected to lead a discussion of the protocol. Consistent parliamentary procedures must be used to conduct business. The parliamentary system used needs to allow for discussion of each item, motions, seconds to motions, and official votes tallied by yeas, nays, and abstentions. To protect anonymity, the identity of the members making a motion, seconding a motion, and voting yea, nay, or abstain should not be recorded. A motion must be seconded for a vote to occur. For a motion to pass, a majority of a quorum present must vote affirmatively.

The IBC minutes must be written and published within 3 weeks of the meeting. At the top of the first page, on separate lines in a large typeface, place the bolded name of the facility and facility number, the official address, the official committee name, and the date of the meeting. Abbreviations are not acceptable. Subsequent pages are to be numbered. List all voting members present, excused or absent (non-voting members may be listed separately). For each member, note their role on the committee and whether they are voting or nonvoting. Indicate if a quorum is present. A quorum is defined as a majority (more than 50 percent) of voting members present. The minutes are arranged into at least three sections: review of previous minutes, old business, and new business. Business items need to be retained under old business in subsequent minutes until the final approval is given by the IBC, the project is disapproved by the IBC, or the project is withdrawn from consideration by the investigator. The final disposition of each project needs to be clearly stated in the minutes. For each project under consideration, list the first and last name of the principal investigator, and the complete name of the project. For each new project, the motion passed by the committee (approved, approved pending clarification, deferred, disapproved) must be recorded with the exact vote, which must include the number voting for the motion, the number voting against, and the number abstaining. In order for the project to be approved, it must receive the approval of a majority of those voting members present at the meeting. A majority of the Institutional Biosafety Committee members (or their designated alternates), must be present to conduct a convened meeting. In order for research to be approved, it must receive the approval of those members present at the meeting. A quorum equals more than half of voting members. The Research Office Staff member taking the minutes at the meeting will track the quorum throughout the meeting. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the protocol must be tabled and only non-protocol related issues may be discussed. Committee deliberations on each project must be reflected in the minutes so that an outside observer can understand the issues discussed, and recognize the specific revisions and clarifications requested for each protocol under consideration. The minutes must note which members recused themselves for which project(s) to prevent conflicts of interest. If they are important to understanding the conduct of business, copies of any internal or external reports or correspondence with outside agencies referenced in the minutes need to be attached to the minutes.

Approved minutes must be signed by the Chairperson of the IBC and forwarded to the Research and Development (R&D) Committee for review and approval. Minutes must be

maintained by the R&D Office and made available to VA Central Office upon request.

5. IBC Review Process and Approval Considerations

A. Submission Procedures:

The Research Office receives “Part I: Request for Review” and “Part II: Research Safety/Biosafety Subcommittee Protocol Survey” forms. These forms are submitted to the IBC for full committee review if the research involves one or more of the following: 1) biological hazards, 2) animal or human blood, body fluids, organs, tissues, cell lines or cell clones, 3) recombinant DNA, 4) chemicals, 5) controlled substances, and/or 6) ionizing or non-ionizing radiation. All research projects involving biological, chemical, physical, and radiation hazards must be approved by IBC and then by the R&D Committee prior to commencement. The review of the Research Protocol Safety Survey must include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research. The PI must submit a complete list of all products containing chemicals designated or identified by OSHA and/or EPA as “hazardous” to the Safety Officer for review and approval prior to the submission of a protocol for local review.

There are circumstances where expedited review of protocols is appropriate, and will not require review by the full IBC. Expedited initial review of a Research protocol can be approved by the subcommittee Chair when the following conditions are met: 1) all answers on the “Part II: Research Safety/Biosafety Subcommittee Protocol Survey” are negative/not applicable; 2) and the protocol is a clinical study that involves the collection of human body fluids or tissues collected exclusively by clinical/pathology personnel or by research personnel that have been properly trained. Notification of the approval will be communicated to the full Committee at the following meeting.

B. Review Processes:

When a Principal Investigator (PI) submits a new protocol to the Research Office the Program Clerk will determine whether the protocol qualifies for full committee review or expedited review, as outlined in the Expedited Review of Research Protocols by the Institutional Biosafety Committee (IBC) policy. If full committee review is required, the Program Clerk will ask the Chair to assign one member from the IBC to be the reviewer and electronically mail the submission to the reviewer for review of the applicable forms. The designated reviewer will evaluate the protocol to ensure completeness and compliance with all regulations, policies, and guidelines.

- For Human and Science/Safety-only studies, the reviewer’s written comments/recommendations should be electronically mailed to the Program Clerk prior to the next IBC meeting so a copy can be provided to all committee members to use as reference during the full committee review and discussion at the regularly scheduled meeting.
- For Animal studies, the IBC reviewer’s written comments should be electronically mailed to the Program Clerk who will then forward these to the PI

along with the comments from the IACUC reviewers. The PI will then be responsible for addressing these comments and submitting revised forms back to the Program Clerk in a timely fashion. The PI's response and revisions will be forwarded to the reviewer for verification that the recommended changes were made.

C. Determinations:

The study review and discussion from the meeting will be recorded and the Program Clerk will notify the PI of the committee's decision regarding the status of the study.

If the decision of the committee is to Contingently Approve the protocol, the PI must respond within 6 weeks and submit the revised forms to the Research Office.

The Chair will review the PI's response/revisions and decide if the PI adequately addressed the contingencies. If the revised versions of the applicable forms are approved, they will be finalized with the signatures of the IBC Chair and the Facility Safety Officer.

If the decision of the committee is to Table the protocol, the PI must respond within 6 weeks by submitting the revised forms to the Research Office and the study will be reviewed again by the full committee at the next regularly scheduled meeting.

D. Annual Reviews:

The IBC annually reviews active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review is based on the date of IBC approval. Research protocol changes not included in the original application must be documented on an amendment and must be submitted to and reviewed by IBC prior to the implementation of the changes. Expedited review of Amendments may be approved by the Chair as long as there is no significant change in exposure or handling of one or more of the following: 1) biological hazards, 2) animal or human blood, body fluids, organs, tissues, cell lines or cell clones, 3) recombinant DNA, 4) chemicals, 5) controlled substances, and/or 6) ionizing or non-ionizing radiation. A significant change would involve a change in the hazard level such that the safety of personnel would be affected in a manner greater than in the initial protocol and then a full committee review may be required.

E. Study Closures:

The closure of a Research protocol can be approved by the subcommittee Chair. In the case of study closure, the Research Office will notify the Chemical and Radiation Safety Officers of the study closure if the protocols involved use of chemicals and/or radiation. These safety officers will document and/or certify the proper storage or disposal of these research materials.

6. Required Training

Researchers working in a lab at the VAPHS are required to take the following web-based courses: "Basic Laboratory Safety Training" and "Introduction to VA Biosecurity Concepts". Researchers working with Ionizing Radiation at VAPHS are required to

complete the web-based course entitled “VAPHS Research Radiation Safety Training”. Researchers working with Biological Hazards at the VAPHS are required to complete training in Universal Precautions. Researchers who ship Biological Hazards and/or Infectious Substances at the VAPHS are required to complete the appropriate training for certification in “Shipping Hazardous Materials”.

Those researchers who are working in a lab at the University of Pittsburgh are required to submit a copy of their University of Pittsburgh’s Safety Training record to the Research Office. Training courses are required to be renewed on an annual basis.

7. Managing Conflicts of Interest

IBC members having a scientific or monetary conflict of interest for the protocol under consideration may provide information helpful to the IBC prior to deliberations, but must recuse themselves from the meeting once deliberations begin. The IBC meeting minutes must reflect those members who were excused from the vote.

Approved 12/2007