

VA Pittsburgh Healthcare System

Institutional Biosafety Committee (IBC**)**

Standard Operating Procedures

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Standard Operating Procedures for the VA Pittsburgh Healthcare System (VAPHS) Institutional Biosafety Committee (IBC), also known as the Subcommittee on Research Safety (SRS)

# *Introduction*

This VAPHS 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 VAPHS Research and Development (R&D) Committee, is committed to providing a safe environment for all research personnel. This SOP details the policies and procedures related to the Committee’s functions and oversight.

# *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 and Security Program (RSSP) 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 guidelines from the National Institutes of Health (NIH) and/or Centers for Disease Control and Prevention (CDC) must also be followed.

The VAPHS IBC is registered as an IBC through the NIH Office of Science Policy (OSP) in order to receive funding from the NIH for research involving recombinant or synthetic nucleic acid molecules. As a registered IBC, the VAPHS is responsible for ensuring that all research involving recombinant or synthetic nucleic acid molecules conducted at or sponsored by the VAPHS is conducted in compliance with the NIH Guidelines. The IBC shares membership with the Subcommittee on Research Safety (SRS) and functions in accordance with VHA Directive 1200.08. The committee reviews protocols that involve recombinant or synthetic nucleic acid molecules, biohazards, chemical hazards, hazardous materials and physical hazards conducted by VA personnel with VA funding. The location where research is conducted can be at VA property or at off-site VA laboratories. This includes the safety of personnel with potential exposure to these hazards and the security of the facility in which the research is conducted and the agents used in the research. This applies to all VA research conducted in VA research laboratories, both on-site and off-site.

# *IBC Roles and Authorities*

1. **Institutional Authority of the IBC**

The Medical Center Director is responsible for all research activities conducted under the auspices of this VA Medical Center and serves as the Institutional Official (IO). The R&D Committee, which reports to the Medical Center Director, oversees the IBC.

1. **Roles and Responsibilities of the IBC**

The IBC, established as a subcommittee of the R&D Committee, is responsible for managing implementation of the RSSP. Specifically, the IBC is responsible for:

1. Reviewing and overseeing the safety of all research activities involving biological, chemical, physical, and radiological hazards for compliance with all applicable regulations, policies, and guidelines prior to initiating the research project. This includes a thorough review of all research activities (either funded or non-funded) conducted at VAPHS or by VAPHS personnel with VA funding located off-site.

* 1. This review includes a risk assessment of the biological, chemical, physical and radiological hazards involved in the work, facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted, as well as VA research involving non-exempt recombinant or synthetic nucleic acid molecules. Such a review is accomplished locally by use of the form entitled, Part II, Research Institutional Biosafety Committee Protocol Survey. When the protocol under review is being submitted for VA funding, VA Form 10-0398, Research Protocol Safety Survey (RPSS), is also included as part of the review process.
	2. Written notification of the results of the IBC review will be provided to the R&D Committee, the Research Office, and the Principal Investigator (PI)

2. Conducting an annual review of all active research protocols involving biological, chemical, physical, and radiological hazards, regardless of funding status or source. The date of continuing review is based upon the date of IBC approval. Research protocol changes not included in the original application must be documented as an amendment request and must be submitted to the IBC for review and approval prior to the implementation of the changes. Amendments may require review at a fully convened meeting, as described in section 5D.

3. Ensuring that a complete list of all products containing chemicals designated or identified by OSHA and/or the EPA as “hazardous” is reviewed by the IBC for approval and included in the facility-wide reviews to ensure that appropriate approvals for their handling and use are in place.

4. 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:

a. Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated. The deficiencies noted for all wet laboratory inspections (internal and external) will be reported to the IBC at a fully convened meeting once an official report has been received. The Biosafety Officer (BSO) will inform the IBC when the deficiencies cited have been addressed and/or corrected. These items will be documented in the IBC meeting minutes. The BSO will keep track of the deficiencies that are open items and continue to update the IBC as items are corrected. In the event that the remediation of the deficiencies is not within the requested timeframe, the IBC will be consulted for additional action.

b. Reporting the final remediated actions to the R&D Committee upon completion.

5. Reporting operational problems or violations of directives to the Research Office within 30 days of occurrence or detection, unless the IBC determines that a report has been previously filed by the PI.

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

7. Maintaining adequate documentation of all IBC activities.

8. Forwarding minutes of the convened meeting to the R&D Committee.

9. Ensuring that all laboratory personnel receive annual research-specific safety training.

10. Holding IBC meetings at least quarterly.

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

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

13. Evaluating the effectiveness of the laboratory’s Chemical Hygiene Plan on an annual basis and making necessary revisions.

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

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

16. Requesting, when appropriate, 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.

17. Ensuring the development of a policy for the preservation of employee medical and OSHA exposure records.

18. Conducting semi-annual security assessments of VAPHS laboratories and research secured areas. The IBC ensures that review of access records for VA laboratories occurs at least monthly.

19. Developing processes to activate and decommission laboratories as needed including transfers of assignment of laboratories from one PI to another.

20. Ensures that the PI or Laboratory Director complies with all regulatory and facility requirements that apply to safety or security in research, as described in Directive 1200.08.

# *Membership of the IBC*

The IBC has at least five members, exclusive of ex-officio members; this includes two members not affiliated with the Institution. The VAPHS complies with all requirements with respect to composition of an IBC as specified in the NIH Guidelines and is allowed to review recombinant DNA studies. One member of the Committee performs research involving recombinant DNA and provides expertise to the Committee in this area. In addition, the VAPHS IBC includes at least one IBC member with expertise specific to Occupational Safety and Health; Environmental Protection; and Department of Transportation International Air Transport Association. This member also has first-hand knowledge of the space and facilities assigned to each PI to ensure that research operations can be conducted safely.

1. **Appointment of the Chairperson and Vice Chairperson, Length of Service and Duties**

The Chairperson of the IBC is a voting member of the Committee who has a significant physical presence at the VAPHS and is involved with the research program.

**Appointment:** The IBC Chairperson and Vice Chairperson are appointed by the Medical Center Director in writing, based on the recommendations of the R&D Committee for a term of up to three years and may be re-appointed without any lapse in time. Both individuals have the right to resign from the position of Chairperson or Vice Chairperson upon notifying both the Associate Chief of Staff for Research and Development (ACOS/R&D) and the IBC with three months advance notice whenever possible to allow for an orderly transition.

The IBC Chairperson is automatically nominated as a voting member of the R&D Committee. The IBC Chairperson must not simultaneously serve as chair of the R&D Committee.

**Qualifications:** The IBC Chairperson and Vice-Chairperson have earned an M.D., Ph.D., or equivalent degree and are nominated to the R&D Committee by the ACOS/R&D for appointment.

**Authority:** The IBC Chairperson and Vice Chairperson have the authority to approve the agendas of the IBC meetings as presented by the Research Office. The IBC Chairs can recommend or appoint other members to represent the IBC to the institutional administration and the research staff. The IBC Chairperson or Vice Chairperson also has the authority to call an ad-hoc meeting of the IBC as necessary.

1. **Appointment of IBC Members, Length of Service and Duties**

**Appointment:**  Nominees for the IBC are recommended by the ACOS/R&D in consultation with the IBC, are approved by the R&D Committee and appointed by the Medical Center Director in writing for terms of up to 3 years. Reappointment to the IBC may be granted at the end of the term without a lapse in service.

**Qualifications of Members/Composition of Boards:** In the appointment of IBC members, equal consideration is given to qualified persons of both genders. No appointment to the IBC is made solely based on gender. Every effort is made to ensure that the IBC membership does not consist entirely of men or entirely of women. Whenever possible, members of cultural and ethnic minorities are included as members in order to represent the population of subjects cared for by the VAPHS. The IBC members do not consist entirely of members of one profession. The IBC members are sufficiently qualified to review the research through their experience, expertise and diversity, including consideration of race, gender, cultural backgrounds, and sensitivity to community issues and/or attitudes.

**Duties:** Each IBC member is expected to attend regularly scheduled meetings of the IBC. Members are also expected to provide a complete, detailed and written review of assigned protocols as primary or secondary reviewers when they are assigned a review.

The IBC Chairperson has the authority to declare the position of any IBC member vacant if the IBC member misses more than two consecutive IBC meetings or more than five meetings during a 12-month period or fails to consistently provide written reviews when requested. In this case, a nomination for a replacement will be requested from the R&D Committee for consideration by the Medical Center Director.

1. **Alternate Members**

Alternate members may substitute for regular members and are formally appointed as alternate members by the Medical Center Director. Alternate members may be nominated by the R&D Committee. These alternates replace regular IBC members who are, on occasion, unable to attend convened meetings of the IBC.

1. **Ex Officio Members**

Ex Officio members include the Medical Center Director (non-voting), Chief of Staff (non-voting), Associate Chief of Staff (ACOS) R&D (non-voting), Deputy ACOS/R&D (non-voting), Business Manager R&D (non-voting), Administrative Officer (AO)/R&D (non-voting), Chemical Hygiene Officer/BSO (appointed by the R&D Committee) (voting), Radiation Safety Officer (RSO) (voting), and Industrial Hygienist (IH)/Facility Safety Officer (voting). The ex-officio members must include a liaison member from the local R&D Committee (non-voting), and an employee union safety representative, or other union designee, whose voting status is determined by the applicable union contract.

Role of Research Compliance Officer(s) (RCO):

The RCO may not serve as a voting member of the IBC but may attend IBC meetings upon request by the IBC.

1. **Conflict of Interest**

No IBC member (voting or non-voting) may participate in the IBC’s review or in the approval of a research project in which the member is either personally involved and/or has a conflicting interest, except to provide information requested by the IBC. Voting members who have conflicts of interest are required to recuse themselves from deliberations and are not counted toward the quorum for that specific protocol. Members with a conflict of interest are documented in the IBC minutes.

# *IBC Record Keeping and Required Documentation*

1. **Record Retention**

All active records are maintained by the IBC Coordinator and are stored in the Research Office. All non-active records are maintained in long term storage. All records are retained in accordance with VHA’s Records Control Schedule (RSC 10-1).

1. **Access to IBC Records**

Access to IBC records is limited to the ACOS/R&D, Deputy ACOS/R&D, AO, Business Manager, IBC Chairperson, IBC members, IBC Coordinator, authorized VA representatives, and officials of Federal and State regulatory agencies, including but not limited to the Office of Research Oversight (ORO), the Office of Research and Development (ORD), and OSHA. Research investigators will be provided reasonable access to files related to their research. All other access to IBC records is limited to those who have a legitimate need for them, as determined by the Medical Center Director, the R&D Committee and/or VA Central Office.

If the IBC receives a request or comments and/or questions from the general public, the information must go through the VAPHS Freedom of Information Act (FOIA) Officer. A formal FOIA request must be submitted. Redaction of any information, including the monthly minutes is carried out before information is provided to the public. If public comments are made on IBC actions, the VAPHS IBC will forward both the public comments and the IBC’s response to the NIH OBA.

1. **Training Records**

Proof of completion of applicable training is required prior to review of the protocol by the IBC. Records are maintained by the Research Office. Researchers working in a lab at the VAPHS are required to take laboratory safety training as well as any other applicable trainings for the work performed (radiation safety, bloodborne pathogens, etc.).

1. **Research Tracking System**

The IBC uses a computerized tracking system, Manage Institutional Review Board database (MIRB™), to track protocols. Upon receipt, all proposals are entered into the database and assigned a unique identification number. MIRB includes the following information:

1. Title of the Research (Protocol)
2. Names of the PI and co-investigators where appropriate
3. Funding source (if any)
4. Date of initial approval
5. Date of most recent continuing approval
6. End of current approval period
7. Current status (pending, approved, suspended, closed)
8. **Written Standard Operating Procedures**

The IBC SOPs are available to investigators on the VAPHS SharePoint site or through a request made to the IBC Coordinator. The IBC in conjunction with the BSO are responsible for the review and approval of research safety policies, procedures, and guidance documents. The BSO reviews all SOPs annually and all guidelines every 3 years to ensure that the content is current. SOPs and guidelines are approved by the R&D Committee, per VHA Directive 1200.01. The IBC annually evaluates the effectiveness of the VAPHS Laboratory and Clinical Research Safety/Biosafety Manual and Chemical Hygiene Plan.

1. **Documentation of Convened IBC Meetings**

The IBC usually meets on the second Thursday of every month but is only required to hold meetings at least quarterly. Meetings are conducted in person or teleconference, whenever a member is unable to attend in person. The IBC Coordinator or Research Office designee assembles the agenda and all meeting documents for the IBC members on SharePoint at least 3 days before the meeting. SharePoint will contain copies of all business item documents, the previous month’s meeting minutes, initial review submissions, and modifications/amendments (if applicable). At the time the agenda is posted to SharePoint, the IBC Coordinator also sends a separate email to all committee members to notify them that the agenda is available on SharePoint. A follow-up email with the agenda documents as an attachment is also sent to those members who do not use SharePoint. Each new protocol is assigned to one scientific voting committee member. This member serves as the primary reviewer and is expected to lead a discussion of the protocol. Consistent parliamentary procedures are used to conduct business. The parliamentary system used allows 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 is not recorded. A motion must be seconded for a vote to occur. For a motion to pass, a majority of those present, which also must constitute a quorum, must vote affirmatively.

The IBC minutes are written and published within 3 weeks of the meeting. At the top of the first page, in a large typeface and on separate lines, are placed 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 numbered. All voting members present, excused or absent (non-voting members may be listed separately) are listed. For each member, his or her role on the committee and whether they are voting or non­voting is also noted. Whether or not the number of voting members present constitutes a quorum is also documented. The minutes are arranged into at least three sections: review of previous minutes, old business, and new business. Business items are 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 PI. The final disposition of each project is clearly stated in the minutes. For each project under consideration, the first and last name of the PI and the complete name of the project are listed. For each new project, the motion passed by the committee (approved, approved pending clarification, deferred or disapproved) is recorded with the exact vote, which includes the number voting for the motion, the number voting against, and the number abstaining.

A majority of the IBC members (or their designated alternates) constitutes a quorum and must be present to conduct a convened meeting. In order for research to be approved, it must receive the approval of the majority of those members present at the meeting. A quorum equals more than half of voting members. The IBC Coordinator documents the minutes and tracks 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 are reflected in the minutes to ensure that an outside observer can understand the issues discussed, and recognize the specific revisions and clarifications requested for each protocol under consideration. To prevent a conflict of interest, the minutes document which members recused themselves for which project(s). 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 are attached to the minutes.

The minutes are reviewed and approved by the fully convened committee at the next meeting. Approved minutes are signed by the Chairperson of the IBC. After approval, the minutes are forwarded to the ACOS/R&D, Chief of Staff, and Medical Center Director for signature and approval. IBC Staff forward a copy of the signed IBC meeting minutes to the R&D Committee for review and approval. The minutes must be reviewed by the R&D Committee within 60 days of finalization. Minutes are maintained by the R&D Office and are made available to VA Central Office upon request.

# *IBC Review Process and Approval Considerations*

1. **Submission Procedures**

All research projects involving biological, chemical, physical, and radiological hazards, as well as research involving non-exempt recombinant or synthetic nucleic acid molecules, must be approved by IBC and the R&D Committee. In addition, a letter indicating that all appropriate approvals have been obtained is issued by the ACOS/R&D prior to commencement of the project. Therefore, PIs who are planning to conduct research involving biological hazards, animal or human blood, body fluids, organs, tissues, cell lines or cell clones, recombinant or synthetic nucleic acid molecules, chemicals, controlled substances, and/or ionizing or non-ionizing radiation must abide by the following submission procedures:

1. Submit a complete chemical matrix specific to the project (i.e., products containing chemicals designated or identified by OSHA and/or EPA as “hazardous”) to the Research Office for IBC review of the protocol.
2. Submit VAPHS Form “Part II: Research Institutional Biosafety Committee Protocol Survey”, along with all other required documentation to the Research Office. When the protocol under review is being submitted for VA funding, RPSS (VA Form 10-0398), is also included as part of the review process.
3. **Review Processes**

Once a new submission is received by the IBC Coordinator, he/she reviews the submission for completeness, notes any deficiencies and then issues comments to the investigator. Once the submission has been deemed complete, the IBC Coordinator asks the Chair to assign reviewers.

* For Human and Science/Safety-only studies with safety related research activities, the IBC Coordinator informs the Chair of the title of the project. The Chair assigns one member from the IBC to act as the primary reviewer at the next full committee meeting. If the project involves biological hazards, the BSO is also asked to review the submission. The assigned reviewer is asked to review the Part II form for completeness of the application and compliance with information requirements, i.e., laboratory research and chemicals. Prior to the full committee review, each IBC member is provided with written descriptions of activities (protocols) that involve laboratory research, chemicals, and biological hazards. The IBC Coordinator requests the written comments from the reviewer and BSO, if necessary, the day before the committee meeting. The comments are distributed to the members at the meeting for reference during committee review. The primary reviewer leads the discussion of the submission and any IBC member is encouraged to provide additional comments or suggestions. Approval of all protocols is granted only after review at a convened meeting of a quorum of the IBC and with the approval vote of a majority of the quorum present.
* For Animal studies, the IBC Coordinator informs the Chair of the title of the project. The Chair assigns one member from the IBC as the primary reviewer of the submission. If the project involves biological hazards, the BSO or IH is also asked to review the study documents as the secondary reviewer. The IBC Coordinator electronically mails the study documents to the assigned reviewer(s) to pre-review the submission for completeness of the application and compliance with information requirements, i.e., laboratory research and chemicals. The comments from the primary reviewer and BSO/IH are electronically mailed to the IBC Coordinator. The IBC Coordinator forwards the reviewers’ comments to the PI. The PI is asked to respond back to the IBC Coordinator with a written response to the reviewers’ comments and submit the revised protocol and/or applicable forms with changes highlighted. The IBC Coordinator electronically mails the PI’s response and revised forms to the primary reviewer and BSO/IH for verification that their comments/recommendations have been adequately addressed. If additional changes or recommendations are requested, this information is forwarded to the PI. The reviewer and BSO/IH must be satisfied with the PI’s response and revised documents before the project is recommended for review at the next convened meeting. Once the reviewers are satisfied with the PI’s response to the comments, each IBC member is provided with a written description of activities (protocols) in the care and use of animals that involve laboratory research, chemicals, and biological hazards for discussion at the next convened meeting in which a quorum (a majority of voting members) of the IBC is present. The study documents, along with the comments and the response by the PI, are discussed by the assigned reviewers. IBC members are encouraged to provide additional comments or suggestions, if applicable. Approval of these study documents may be granted only after review at a convened meeting of a quorum of the IBC and with the approval vote of a majority of the quorum present.

**Exemption from the Requirement for IBC Review**:

Research that is exempt from IBC review and approval includes the following:

(1) Research that only involves the collection and analysis of biospecimens by VA clinical personnel within clinical areas, or the performance of standard clinical procedures in clinical areas or offices.

(2) Research that clearly does not involve collection of specimens or use of VA laboratories, such as health services research, chart reviews, and database research.

(3) Research conducted in VA research laboratories that does not involve any hazards. This type of research must be documented by completion of the RPSS or Part II: Research Institutional Biosafety Committee Protocol Survey, indicating that the answers to all questions are “No”

The IBC Coordinator will conduct an administrative review of the IRB application or completed RPSS or Part II: Research Institutional Biosafety Committee Protocol Survey to determine whether a protocol is exempt from IBC review. If the research study does not appear to involve any hazards, the PI may be asked to provide a written statement as confirmation. A checklist will be completed to confirm that the above IBC review and approval exemption criteria have been met. If the IBC coordinator requires clarification to determine the exemption status, the Chair will make the assessment. IBC members shall be advised of the research studies determined to be exempt from IBC review. This is accomplished by listing the studies on the agenda of the next convened meeting under the notifications section and documented in the meeting minutes.

**IBC Review Determinations:**

The discussion of a study’s initial review is documented in the meeting minutes by the IBC Coordinator. The committee’s decision to approve, approve pending clarification, defer or disapprove must be made by the majority of those voting members present at the meeting. A quorum must be maintained for each vote to occur. A letter from the Chair describing the committee’s action is forwarded to the PI.

If a majority of the committee decides to approve the study, the approval is finalized with the signatures of the IBC Chair and the Facility Safety Officer (also the IH). The complete study is sent to the next convened R&D Committee meeting for final approval and notification of approval by the ACOS/R&D. The PI receives the subcommittee approval letters, the combined R&D approval letter and ACOS notification that the project has been approved and research can begin on the project.

If the decision of the IBC is to approve pending clarification, the investigator is given instructions on what is required to secure approval and must respond within 6 weeks.

When the IBC requires clarifications for approval of a protocol, the responses are reviewed as follows:

1. If approved by a majority of the members at the meeting at which the required clarifications are identified and if the entire current Committee has previously approved and documented, the Chair or designee will review the response and required modifications for approval. However, if any member calls for full committee review of the modifications, such modifications can only be reviewed and approved by full committee review.

2. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by the IBC Coordinator.

The Chair or designee 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 are finalized with the signatures of the IBC Chair and the IH/Facility Safety Officer.

If the decision of the IBC is to disapprove the study, the investigator is given instructions for re-submission. This re-submission undergoes the same review process as when initially submitted.

1. **Annual Reviews**

Each PI’s VA laboratory program is reviewed by the IBC at a convened meeting on an annual basis. All active VA research protocols involving recombinant or synthetic nucleic acid molecules, biological, chemical, physical, and radiological hazards, regardless of funding status or source are reviewed. The investigator completes a continuing review submission form, which provides information regarding the hazards, biosafety levels, or changes since the last review of the currently approved protocol. The date of continuing review is based on the date of IBC initial approval. The continuing review form responses and confirmation that lab inspections and personnel trainings are up to date are reviewed and approved by the Chair, or designee. Any proposed research protocol changes not included in the original application must be documented in an amendment request form and must be submitted to and reviewed by the IBC prior to implementation of the proposed changes.

The outcome of the continuing review will be listed on the agenda of the next convened meeting and documented in the meeting minutes. The R&D Committee and PI are notified in writing of the outcome and committee determination.

As part of the laboratory program annual review, the BSO conducts annual inspections of all VA laboratories to evaluate risk assessments, issues related to employee safety and security, space allocations, and verifies the status of the project. These elements are documented in the inspection report, which also includes any identified deficiencies or concerns. The BSO also participates in annual inspections of laboratories for VA-funded PIs who conduct research off-site. All inspection reports and corrective action plans, if applicable, are reviewed by the IBC at a convened meeting. The IBC will approve, require modifications to secure approval or withhold approval/terminate the protocol. Termination of the protocol may be because of, but not limited to, such issues as hazards that cannot be appropriately managed, continuing noncompliance by the PI/Laboratory Director, or for other appropriate reasons as determined by the IBC.

1. **Amendment Reviews**

An amendment must be reviewed and approved prior to implementation of any changes that affect the safety components or BSL of the protocol. To amend a study, the investigator must complete an amendment request form. The amendment request form, along with the revised protocol forms (per the requested changes), must be submitted to the Research Office. All research project amendments involving a change in biological, chemical, physical, or radiation hazards to an IBC-approved protocol are reviewed at a fully convened IBC meeting.

Changes that may be handled administratively or in consultation with the IBC Chair include:

 1. Correction of typographical errors

 2. Correction of grammar

 3. Contact information updates

4. Change in personnel, other than the PI.

The IBC Coordinator will conduct an administrative review to ensure that all such personnel are appropriately identified, adequately trained. The Chair and/or the IBC Coordinator will review the investigator’s amendment request and revised documents for administrative approval. The amendment approval will be documented in the minutes of the next convened IBC meeting.

Requested changes to the protocol, such as an increase in the possibility for exposure or a change in the handling of one or more of the following requires review at a fully convened IBC meeting:

* + biological hazards,
	+ animal or human blood, body fluids, organs, tissues, cell lines or cell clones,
	+ recombinant or synthetic nucleic acid molecules,
	+ chemicals,
	+ controlled substances, and/or
	+ ionizing or non-ionizing radiation

PIs who want to amend their approved protocol must abide by the following submission procedures:

1. Submit the study amendment request form to request changes to safety related study procedures.

2. Submit the revised forms for the project to indicate the requested changes or additions (e.g., the chemical matrix (if adding or deleting chemicals specific to the project), VAPHS Form “Part II: Research Institutional Biosafety Committee Protocol Survey”, and any other required documents deemed necessary) to the Research Office. The amendment request is added to the next meeting agenda. The Chair acts as the primary reviewer or may assign a committee member to act as the primary reviewer. Amendments involving a change in the biosafety level are also reviewed by the BSO. Each IBC member receives a copy of the amendment submission in their agenda packet for discussion at the meeting in which a quorum of the IBC is present. After the committee review and discussion is complete, a vote is taken to approve, approve pending clarification, defer or disapprove the amendment. The committee’s decision must receive the approval of a majority of those voting members present at the meeting. A quorum must be maintained for each vote to occur. For each amendment, the motion passed by the committee (approved, approved pending clarification, deferred or disapproved) is recorded with the exact vote, which includes the number voting for the motion, the number voting against, and the number abstaining.

If a majority of the committee decides to approve the amendment, the PI receives the subcommittee approval letter.

If the decision of the IBC is to approve pending clarification, the investigator is given instructions to secure approval and must respond within 6 weeks.

When the IBC requires clarifications for approval of the amendment, responses are reviewed as follows:

1. If approved by a majority of the members at the meeting at which the required clarifications are identified and if the entire Committee has previously approved and documented, the Chair or designee will review the response and required modifications for approval. However, if any member calls for full committee review of the modifications, such modifications can only be reviewed and approved by full committee review.

2. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by the IBC Coordinator.

The Chair or designee will review the PI’s response/revisions and decide if the PI has adequately addressed the contingencies. If the revised versions of the applicable forms are approved, the PI will receive the subcommittee approval letter for the amendment.

If the decision of the IBC is to disapprove the amendment, the investigator is given instructions for re-submission. This re-submission undergoes the full amendment review process.

**E. Study Closures**

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

# *Review of Problems, Suspensions, and Terminations, and other Potentially Reportable Events*

1. **Research Related Safety Incidents**

The VAPHS IBC must be notified of the following types of research safety related incidents:

* Human Deaths: VA personnel, including WOC and IPA appointees must ensure oral notification to the IBC immediately upon becoming aware of any human death that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area). The IBC must alert ORO by email or telephone within 2 business days after receiving such notification. The Medical Center Director and the ACOS/R&D must receive concurrent notification. VA personnel, including WOC and IPA appointees, must ensure written notification of the IBC within 5 business days of becoming aware of the death.
* Human Accident, Injury, Illness or Exposure: VA personnel, including WOC and IPA appointees, must ensure written notification of the IBC within 5 business days after becoming aware of any serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area).
* Reportable Incidents Under Applicable Federal Standards: VA personnel, including WOC and IPA appointees, must ensure written notification of the IBC within 5 business days after becoming aware of any incident related to research safety that is reportable under relevant VHA Handbooks/Directives or applicable Federal requirements including OSHA requirements.
1. Submission Procedures:
2. In the case of a human death, a phone call must be made immediately to the IBC Coordinator at 412-360-2382 or the BSO at 412-360-2842. A written report (via email) must be submitted to the email address VHAPTHIBCReport@va.gov within 5 business days after becoming aware of the death (**\*NOTE**: Emails sent to this address can only be sent from the VA Network. If you are unable to send from a VA email address, please call the IBC Coordinator at 412-360-2382 or the BSO at 412-360-2842). Within 2 business days of receipt of the report, the IBC Coordinator or BSO will send written notification (via email) to ORO, with concurrent copies to the IBC Chair, ACOS/R&D and Medical Center Director.
3. In the case of the other reportable events listed in Section 6.A, investigators and/or research staff or any other individual aware of the incident should make a written report to the email address VHAPTHIBCReport@va.gov within 5 business days of becoming aware of the event (**\*NOTE**: Emails sent to this address can only be sent from the VA Network. If you are unable to send from a VA email address, please call the IBC Coordinator at 412-360-2382 or the BSO at 412-360-2842). The report should include the date of the event, affected protocol(s) by name and MIRB (study) number, and a detailed summary of the event(s).
4. Review Procedures:

Upon receipt, the IBC Chair evaluates the report and places the item on the agenda for review at its next scheduled convened meeting, unless in the opinion of the IBC Chair, the incident presents a significant risk to the safety of research personnel or the environment, in which case he/she may convene an emergency session of the IBC.

At the next fully convened meeting, the IBC reviews the report, along with any other documentation deemed necessary for review and determines whether the incident described is indeed a reportable incident or event. This determination is documented in the meeting minutes. The IBC Chair must notify the Medical Center Director and the ACOS/R&D within 5 business days after any determination that a reportable incident has occurred. If the IBC determines that an incident is reportable, the Medical Center Director must also report the incident or event to ORO within 5 business days. If the IBC determines that an incident is not reportable, the IBC must communicate that determination to the Medical Center Director and the ACOS within 5 business days of its determination. If the IBC is unable to decide within 60 calendar days after receiving notification of the relevant event, it must immediately notify the Medical Center Director, who, within 5 business days after receiving the IBC’s notification, must provide ORO with an acceptable justification for the delay and an acceptable completion timeline.

***NOTE:*** *If the significance of a reported event is not clear, the IBC Chair, or designee, may consult the ORO Regional Office (RO) and the ORO Associate Director for Research Safety and Animal Welfare.*

1. **Laboratory Decommissions**

The PI or Laboratory Director must obtain authorization (i.e., permission) from the ACOS/R&D prior to decommissioning or reassigning existing VA laboratory space (including modifying, vacating, or converting to non-laboratory use) that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses. The request for authorization to decommission or reassign laboratory space must be made in writing at least 1 month prior to implementation, if there are no extenuating circumstances concerning the PIs presence at VAPHS (e.g. death, legal issues). Upon receiving such a request, the BSO, in collaboration with the ACOS/R&D, will evaluate the space and determine if there are any specific hazards that require remediation. The BSO will complete a checklist to confirm that all elements for vacating a laboratory have been covered in accordance with the Guidelines for Principal Investigators Vacating Research Laboratories at VAPHS. The checklist must be signed by the PI, the BSO, the IH, the Radiation Safety Officer (if applicable), and the ACOS/R&D. The BSO will report the laboratory closure to the IBC at a convened meeting.

1. **Research Information Security**

VAPHS R&D Policy #014, VAPHS Research Information Protection Incident Reporting Policy, outlines the methods and timelines for reporting research information security incidents to facility officials and oversight agencies. VA personnel, including WOC and IPA appointees, must ensure notification of the ACOS/R&D, Information System Security Officer (ISSO), Privacy Officer (PO), and relevant investigators immediately (i.e., within one hour) upon becoming aware of any information security incidents related to VA research by submitting an email to VHAPTHRIPP@va.gov following the template outlined in Appendix A of VAPHS R&D Policy #014. (**\*NOTE**: Emails sent to this address can only be sent from the VA Network. If you are unable to send from a VA email address, please call the IBC Coordinator at 412-360-2382 or the BSO at 412-360-2842). The ACOS/R&D must immediately notify the IBC, where relevant.

Notifications of information security incidents must be reviewed by the IBC, when relevant, at its earliest practicable convened meeting, not to exceed 30 business days from the date of notification. The IBC must determine whether the incident constitutes a serious problem and in conjunction with the ISSO and/or the PO, whether and what remedial actions are warranted by the facility or the relevant investigator(s). If the IBC determines that the incident constitutes a serious problem, then the committee must notify the Medical Center Director and the ACOS/R&D within 5 business days. If the IBC makes additional determinations under its authority, any reporting requirements pertinent to such determinations must also be satisfied.

1. **Reporting to Oversight Agencies**

VAPHS R&D Policy #001, VAPHS Research and Development Reporting Policy, outlines the methods and timelines for reporting events to facility officials and oversight agencies, including the information that must be included in the reports and how such reports are to be prepared and sent.

***7.* *Managing Conflicts of Interest***

**Investigator Conflicts**

All PIs, co-PIs, and investigators are required to complete a Department of Veterans Affairs Research Financial Conflict of Interest (FCOI) Statement at the time of initial review, at continuing review, and any time they are being added to an IACUC protocol (as a PI, co-PI or investigator). A FCOI statement must also be submitted when there is a change to the current statement on file with the Research Office. The revised FCOI statement is necessary when an answer on Section I changes to “yes” or when there is a change in the reasoning for a “yes” answer. FCOI statements are submitted to the IBC Coordinator and are reviewed in accordance with VAPHS R&D Policy #010, Financial Conflict of Interest.

Non-financial conflicts of interest may also occur. Such conflicts are identified as outlined in VAPHS R&D Policy #008, Non-Financial Conflicts of Interest. Conflicts of interest related to VA administrative duties that involve research projects or contract management responsibilities will be reviewed by the IBC.