



# 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)**

## ***Introduction***

This VA Medical Center (VAMC) 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***

### **A. Institutional Authority of the IBC**

The Medical Center Director is responsible for all research activities conducted under the auspices of this VAMC. The R&D Committee, which reports to the Director, oversees the IBC. The VAPHS operates one IBC for all divisions.

### **B. Roles and Responsibilities of the IBC**

The IBC, established as a subcommittee of the R&D Committee, is responsible for the oversight and implementation of various aspects of research safety. Specifically the IBC is responsible for:

1. Reviewing and overseeing the biosafety of 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 thorough review of all research activities (either funded or non-funded) which involve those conducted at VAPHS or by VAPHS personnel with VA funding located off-site.

- a. This review 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. 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, is also included as part of the review process.
  - b. This review must occur during a convened meeting at which quorum (a majority of voting members) is present.
2. Providing written notification of the results of the IBC review to the R&D Committee, the Research Office, and the Principal Investigator.
  3. Conducting an annual review of all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review is based upon the date of initial 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.
  4. 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 Research Office and the VAPHS Safety Office for review and approval prior to the submission of a protocol for local review.
  5. 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, and
    - b. Reporting follow-up results to the R&D Committee.
  6. Reporting operational problems or violations of directives to the Research Safety Coordinator and the Research Office within 30 days of occurrence or detection, unless the IBC determines that a report has been previously filed by the PI.
  7. 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.

8. Maintaining adequate documentation of all IBC activities.
9. Forwarding minutes of the convened meeting to the Research Office.
10. Ensuring that all laboratory personnel receive annual research specific safety training.
11. Holding IBC meetings at least quarterly.
12. Ensuring coordination with other regulatory programs, personnel, or committees, such as the Radiation Safety Officer and/or Radiation Safety Committee.
13. 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.
14. Evaluating on an annual basis the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions.
15. Ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.
16. Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate.
17. 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.
18. Ensuring the development of a policy for the preservation of employee medical and Occupational Safety and Health Administration (OSHA) exposure records.
19. Cooperating with appropriate medical center personnel to review the quantity and type of hazardous waste generated by each PI annually.
20. Providing technical assistance in the reduction of the quantity of waste and/or recycling programs, where appropriate.

### ***3. Membership of the IBC***

The IBC must have at least five members, exclusive of ex-officio members; this must include 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 involved with recombinant DNA and provides expertise to the Committee in this area. In addition, the VAPHS IBC will also make attempts to satisfy VHA recommendations 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. This member should also have first-hand knowledge of the space and facilities assigned to each Principal Investigator (PI) to ensure that research operations can be conducted safely. Given that this is only a recommendation and not a requirement, an inability to identify one member who meets all criteria will not result in an improperly constituted IBC.

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

The Chairperson of the IBC shall be 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 shall be appointed to by the Medical Center Director in writing, based on the recommendations of the R&D Committee for a term of one year and may be re-appointed without any lapse in time. Both individuals shall have the right to resign from the position of Chairperson or Vice Chairperson upon notifying both the ACOS/R&D and the IBC with three months advance notice whenever possible to allow for an orderly transition.

The IBC Chairperson will also serve as a member of the VAPHS Animal Welfare Research Safety and Security (AWRSS) Executive Committee as well as an ad hoc member of the Research Compliance Committee. The IBC Chairperson is also 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 IBC Vice-Chairperson will have earned the M.D., Ph.D., or equivalent degree and will be 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 will represent, 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.

## **B. Appointment of IBC Members, Length of Service and Duties**

**Appointment:** IBC members are nominated by the R&D Committee and their names are forwarded to the VAPHS Director. The Medical Center Director shall officially notify members in writing of their appointment to the IBC for a period not to exceed three years. Members may be reappointed without any lapse in time.

**Qualifications of Members/ Composition of Boards:** In the appointment of IBC members, equal consideration shall be given to qualified persons of both genders. No appointment to the IBC shall be made solely on the basis of gender. Every effort will be 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 will be included as members in order to represent the population of subjects cared for by the VAPHS. The IBC members will not consist entirely of members of one profession. The IBC members shall be 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 monthly 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 the course of 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 Director of the VAPHS.

## **C. Alternate Members**

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

## **D. Ex Officio Members**

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. The Associate Chief of Staff for Research and Development (ACOS/R&D) also serves as an ex-officio, non-voting member.

**Role of the Research Compliance Officer(s) (RCO):** The VAPHS Research Compliance Officer(s) serves as a consultant to the IBC on regulatory issues. The RCO is expected to attend each IBC meeting.

**E. Conflict of Interest**

No IBC member may participate in the IBC’s review of any project in which the member has a conflicting interest, except to provide information requested by the IBC. Any 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 shall have this documented in the IBC minutes.

***4. IBC Record Keeping and Required Documentation***

**A. Record Retention**

All active records are maintained by the IBC Coordinator and are located in the Research Office. All non-active records are maintained by the Records Control Officer and are secured in the Research Office or in the Research Records Archives. All records will be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA’s Records Control Scheduled (RSC 10-1).

**B. Access to IBC Records**

Access to IBC records is limited to the ACOS/R&D, Deputy ACOS/R&D, AO, IBC Chairperson, IBC members, IBC Coordinator, authorized VA representatives, and officials of Federal and State regulatory agencies, including but not limited to ORO, 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.

**C. Training Records**

Proof of completion of training is required prior to the protocol being reviewed by the IBC. Records are maintained by the Research Office.

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 Bloodborne Pathogens (Universal Precautions) training. 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”.

#### **D. Research Tracking System**

The IBC uses a computerized tracking system, 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 (under review, approved, suspended, closed)

#### **E. Written Standard Operating Procedures**

The IBC SOPs are available to investigators on the Research Office Website. The Animal Welfare Research Safety and Security (AWRSS) Executive Committee is responsible for the review and approval of research safety policies, procedures, and guidance documents. The AWRSS reviews the SOPs no less frequently than every 3 years.

#### **F. Documentation of Convened IBC Meetings**

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 scientific voting committee member. 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, 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 to be 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 quorum is present is also documented. 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, the first and last name of the principal investigator, and the complete name of the project is also listed. For each new project, the motion passed by the committee (approved, contingently approved, tabled, 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.

A majority of the IBC 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 IBC Coordinator 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.

Minutes are reviewed and approved by the fully convened committee at the next meeting. Approved minutes must be signed by the Chairperson of the IBC. After approval, the minutes will be forwarded to the ACOS/R&D, Chief of Staff, and Director for signature and approval. IBC Staff will forward a copy of the IBC meeting minutes 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:**

All research projects involving biological, chemical, physical, and radiation hazards must be approved by IBC, the R&D, and a letter indicating that all appropriate approvals have been obtained must be issued by the ACOS/R&D prior to commencement. Therefore, investigators who are planning to conduct research involving biological hazards, animal or human blood, body fluids, organs, tissues, cell lines or cell clones, recombinant DNA, 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 this 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 Safety/Biosafety Subcommittee Protocol Survey”, along with all other required documentation to the Research Office. Submissions involving Human Subjects are forwarded to the IBC Coordinator and the IRB Coordinator to initiate parallel subcommittee reviews. Projects which involve non-human work are forwarded directly to the IBC Coordinator.

#### **B. Review Processes:**

Once a new submission is received by the IBC Coordinator, he/she will review the submission for completeness, any deficiencies are noted and then comments are issued to the investigator. Once the submission has been deemed complete, the IBC Coordinator will ask the Chair to assign reviewers.

- For Human and Science/Safety-only studies, 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 Biosafety Officer is also asked to review the submission. The designated reviewer is asked to review the protocol 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, biological hazards. The IBC Coordinator requests the written comments from the reviewer and Biosafety Officer the day before the committee meeting. The comments are distributed to the members at the meeting for reference during committee review and discussion of the submission. Approval of all protocols 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.
- For Animal studies, When a Principal Investigator (PI) submits an animal protocol to the Research Office it is electronically forwarded to the Chair. The Chair assigns one member from the IBC as the primary reviewer of the submission. The IBC Coordinator electronically mails the submission to the designated reviewer to pre-review the protocol for completeness of the application and compliance with information requirements, i.e. laboratory research and chemicals. If the project involves biological hazards, the Biosafety Officer is also asked to review the submission. The comments from the reviewer and Biosafety Officer are electronically mailed to the IBC Coordinator. The Investigator is

notified by the IBC Coordinator if the reviewers have requested modifications to the protocol. The Investigator makes the recommended changes and submits the revised protocol and a written response to the review comments. The reviewer and Biosafety Officer review the Investigators response and revisions and either request additional changes or recommend committee review. Prior to the full committee review, each IBC member is provided with written descriptions of activities (protocols) in the care and use of animals that involve laboratory research, chemicals, biological hazards. Approval of these protocols 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.

### **C. Determinations:**

The study review and discussion from the meeting will be recorded by the IBC Coordinator. Once a decision to approve, or withhold approval of the submission or of modifications required to secure IBC approval has been made, the IBC Chair or his or her delegate (e.g., Research Office personnel) notifies the investigator in writing. A letter from the IBC describing the committee's action is completed and forwarded to the investigator. This letter includes the result of the IBC review, which may include one of the following: approval, require modifications (to secure approval) or withhold approval. If the decision of the IBC is to require modifications, the investigator is given instructions to secure approval and must respond within 6 weeks.

When the IBC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:

1. If approved unanimously by all members at the meeting at which the required modifications are identified and if the entire current Committee has previously approved and documented, the Chair or designee will review the required modifications. 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 IBC administrative/support personnel.

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.

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

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

#### **A. Research Related Safety Incidents:**

The VAPHS IBC must be notified of the following types of research safety related incidents within 5 business days of any VAPHS Research Staff member becoming aware:

- Work-Related or Research-Related Injuries that require more than minor medical intervention (i.e., basic first aid), require extended surveillance of the affected individual(s), or lead to serious complications or death.
- Work-Related Exposures or Injuries of VA research personnel (or apparent research-related exposure of any other person) to hazardous, toxic, or infectious materials at greater than routine levels (i.e., Permissible Exposure Limits or Infection Threshold) or any exposure or injury that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death.
- Reportable Incidents Under Applicable Federal Standards, including but not limited to VHA Handbooks on research safety, NIH Office of Biotechnology Activities (OBA) guidelines, OSHA requirements, CDC requirements, Department of Transportation requirements, and Nuclear Regulatory Commission (NRC) requirements. Examples include, but are not limited to:
  - Any finding of noncompliance with research safety requirements by any VA office (other than ORO) or any other Federal or state entity. Subsequent reports to ORO based on findings made by

entities external to the facility must include a copy of the official findings.

- Initiation of VA research requiring safety review without written notification from the ACOS for Research that the project may begin.
- Conduct of research requiring safety review without required approval by the IBC or other relevant research review committees.
- Continuation of research beyond the expiration date established by the IBC without appropriate renewal of the protocol, even if the research is a continuation of work that was previously approved by all relevant research review committees.
- Failure to implement changes required by the IBC as a condition of approval.
- Unauthorized deviation from an IBC-approved protocol. *NOTE: The IBC must be consulted in advance of implementing changes to determine if a protocol modification requires prior IBC approval.*
- Failure to comply with continuing review requirements of the IBC or other relevant research review committees.
- Conduct of official IBC business by an improperly constituted committee or with less than a quorum of voting members present.
- Failure to correct identified programmatic or facility deficiencies within the periods specified in section 5.0,C.2
- Conduct of research by unauthorized personnel or personnel who lack appropriate training.
- Any noncompliance or other deficiency that substantively compromises the effectiveness of a facility's research safety programs.

#### 1. Submission Procedures

Investigators and/or research staff or any other individual aware of the incident should make a written report to the VAPHS IBC Coordinator, which includes the date of the event and a summary of the event.

#### 2. Review Procedures:

Within 3 business days of receipt of the report, the IBC Coordinator will forward the report to the IBC Chair. The IBC Chair will evaluate the report and place 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. *If the significance of a reported event is not clear, the IBC Chair, or designee, must consult the ORO Regional Office (RO) and the ORO Associate Director for Research Safety and Animal Welfare.*

At the next meeting of the fully convened IBC, the IBC will review the report, along with any other documentation deemed necessary for review and make a determination as to whether or not the incident described is indeed a reportable

incident or event. This determination will be documented in the meeting minutes. If the incident is deemed reportable, the IBC Chair must report the determination directly (without intermediaries) to the facility Director within 5 business days after the IBC's determination. This report must be made in writing, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research review committee. An initial report of an IBC determination is required regardless of whether the determination is preliminary and still under review or final disposition of the matter has been resolved at the time of the report. *NOTE: The IBC must reach a determination that a reportable event did (or did not) occur within 30-45 days after receiving a relevant report. Remedial actions involving a specific study or research team must be completed within 90-120 days of the IBC's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the IBC's determination, unless remediation requires substantial renovation, fiscal expenditure, legal negotiation, etc.*

**B. Suspensions or Terminations.**

Any suspension or termination of research made by the IBC, or other research review committee, ACOS/R&D or other facility official related to concerns about research safety must be reported directly (without intermediaries) to the facility Director within 5 business days after the suspension or termination occurs. The report must be made in writing with simultaneous copies, as applicable, to the ACOS for Research, R&D Committee, the IBC, and any other relevant research review committee.

**C. Laboratory Decommissions.**

The PI or Laboratory Director must obtain authorization (i.e., permission) from the IBC and the ACOS for Research prior to reassigning, vacating, converting to non-laboratory use, or otherwise decommissioning existing laboratory space that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses. The request for authorization to decommission laboratory space must be made in writing at least 1 month prior to implementation. Upon receiving such a request, the ACOS for Research must notify the VISN Safety Office to coordinate inventory and removal of hazardous materials, infectious agents, or equipment.

**D. 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.