Research and Development

Reporting of Research Events

Standard Operating Procedures

VA Long Beach Healthcare System

Standard Operating Procedures for the Reporting of Research Events to Institutional Officials and External Oversight Offices

1. PURPOSE. This Standard Operating Procedures Manual sets forth the policies and procedures for the reporting or certain research events to external regulatory and oversight agencies. This SOP addresses the reporting requirements of the VALBHS Research HCG, the R&D Committee and its subcommittees. This SOP does not address the reporting requirements of Principal Investigators to Sponsors or Regulatory agencies. These responsibilities are outlined in the IRB SOP.

2. BACKGROUND

Procedures for the reporting of Research Events to external agencies was previously incorporated into individual Committee and Subcommittee SOP's. This SOP integrates these procedures into a single document. This SOP incorporates procedures for reporting of Research Events to:

- VISN 22
- The Office of Research Oversight (Western Region)
- The Office of Research Oversight (Central Office)
- The FDA
- OLAW
- USDA
- ORD

3. SCOPE

This SOP:

- Identifies the research events that must be reported to Institutional Officials and to external agencies and offices.
- Identifies who is responsible for making the reports.
- Identifies what must be included in the reports.
- Identifies who these reports must be sent to and the timelines for submitting the reports.

4. DEFINITIONS

The following definitions are intended for use only within this SOP.

Administrative Hold. An administrative hold is a voluntary interruption of research

enrollments and/or ongoing research activities by an appropriate facility official, research investigator, or sponsor (including the VHA Office of Research and Development (ORD) when ORD is the sponsor). For the purposes of this Handbook:

- The term “administrative hold” does not apply to interruptions of research related to concerns regarding:
  - The safety, rights, or welfare of human research subjects, research investigators, research staff, or others; or
  - The safety or welfare of laboratory animals.
- The terms “suspension” and “termination” apply to research interruptions related to concerns about safety, rights, or welfare as defined below.
- An Administrative Hold must not be used to avoid reporting deficiencies or circumstances otherwise covered by VHA Handbooks or other federal requirements governing research.

Adverse Event (AE). An AE is any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research, or any risk associated with the research or the research intervention, or assessment. A local AE is one occurring at a site for which the VA investigator's Institutional Review Board (IRB) of Record is responsible. NOTE: AEs are further discussed in the IRB SOP.

Animal (Laboratory Animal). An laboratory animal is a live (non-human) vertebrate used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose. NOTE: The term “animal” is further defined in the SAS SOP.

Assurance (Assurance of Compliance). An Assurance of Compliance is a written commitment to a Federal department or agency to ensure compliance with applicable requirements. For example, the participation of human subjects in VA research requires a Federalwide Assurance (FWA) for the Protection of Human Subjects, and the participation of laboratory animals in VA research requires a Public Health Service (PHS) Animal Welfare Assurance.

Continuing Noncompliance. Continuing noncompliance is persistent or repeated failure, either in the past or extending into the present, to satisfy VA or other Federal research requirements. Thresholds for the determination of Continuing Noncompliance are described in individual subcommittee SOP’s.

Human Research. Human research is any research involving any of the following:

- One or more human subject(s).
- Data containing identifiable private information about one or more living individuals.
- One or more human biological specimen(s).

Human Subject. A human subject is a living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual; and/or
- Identifiable private information. NOTE: The term "human subject" and related terms are further defined in VA regulations and policy at Title 38 Code of Federal Regulations (CFR) Part 16 and VHA Handbook 1200.5 and locally in the IRB SOP.

Institutional Animal Care and Use Committee (IACUC). An IACUC is a committee formally designated by an institution to ensure compliance with animal research regulations and guidelines and maintenance of an Animal Care and Use Program (ACUP). At the VALBHS, the IACUC is synonymous with the Subcomittee for Animal Studies (SAS). NOTE: The term "Institutional Animal Care and Use Committee" and related terms are further defined in VHA Handbook 1200.7.

Institutional Official (IO). The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The Facility Director, or equivalent, serves as IO for VA research facilities that conduct research.

Institutional Review Board (IRB). An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research. NOTE: The term "Institutional Review Board" is further defined in VA regulations and policy at 38 CFR 16 and VHA Handbook 1200.5.

Investigator. An investigator is any individual who conducts research, including, but not limited to: the Principal Investigator, co-investigator, local site investigator, etc. A VA investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, and to the applicable VA facility's policies and procedures.

Memorandum of Understanding (MOU). An MOU is a written agreement entered into by and between two or more parties to set forth the terms, conditions, and understandings of the parties with respect to a specific activity. For example, an MOU may be developed to delineate each party's responsibilities, as allowable by law, in collaborations between two or more Federal agencies or between a Federal agency and a private entity.

Principal Investigator (PI). A PI is a qualified person designated by an applicant institution to direct a research project or program. The PI oversees scientific, technical, and the day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team.

- Appointment in VA. Any VA PI must hold a VA appointment.
- Site Investigator or Site PI. A Site Investigator or Site PI is an investigator at a site participating in a multi-site project who serves as the PI at that site.

Research. Research is a systematic investigation designed to develop or contribute to generalizable knowledge. NOTE: The term “research” is further defined in VA regulations at 38 CFR 16 and VHA Handbook 1200.5.

Research and Development (R&D) Committee. The R&D Committee is a committee responsible, through the Chief of Staff (COS) to the VA Facility Director, for oversight of the facility’s research program and for maintenance of high standards throughout that program. NOTE: The term “Research and Development Committee” is further defined in VHA Handbook 1200.1.

Research Compliance Officer (RCO). The RCO is an individual whose primary responsibility is oversight of research projects. VA RCOs must conduct periodic audits of research activities in accordance with VA requirements. A VA research facility’s lead RCO must report directly to the Facility Director.

Research Impropriety. For purposes of this SOP, the term "research impropriety" refers to noncompliance with the laws, regulations, or policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other matters as the Under Secretary for Health may assign. Research impropriety does not encompass improper procedures or conduct in areas outside of the jurisdiction of ORO, such as: waste, fraud, abuse, or fiscal mismanagement.

Research Misconduct. Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. NOTE: The terms “fabrication,” “falsification,” and “plagiarism” are further defined in VHA Handbook 1058.2.

Research Oversight Committee. For purposes of this Handbook, a Research Oversight Committee is any committee or subcommittee designated by a VA research facility to ensure compliance with Federal, VA, or facility requirements for the conduct of research (e.g., the IRB, SAS, R&D Committee).

Serious Noncompliance. Serious noncompliance is the failure to adhere to the laws, regulations, or policies governing VA research that:

- Results in substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of human subjects, research staff, or others; or

- Results in substantive harm or damage (or risk of substantive harm or damage) to the safety or welfare of laboratory animals; or
- Substantively compromises the integrity or effectiveness of research protections, either systemically or relative to a particular protocol or project.

Serious AE (SAE) or Serious Problem. For the purposes of this SOP:

- An SAE in research is an AE that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect.

- A serious problem in research is one that results in:
  - Substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of research subjects, research staff, or others; or
  - Substantive harm or damage (or risk of substantive harm or damage) to the safety or welfare of laboratory animals.
- An AE or problem in research is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent an SAE or other Serious problem.

Suspension or Termination of Research. For purposes of this SOP:

- Suspension refers to a temporary interruption in the enrollment of new subjects or other ongoing research activities.
- Termination refers to a permanent halt in the enrollment of new subjects or other research activities.
- The terms “suspension” and “termination” apply to interruptions related to concerns regarding:
  - The safety, rights, or welfare of human research subjects, research investigators, research staff, or others; or
  - The safety or welfare of laboratory animals.
- Suspension and termination do not include:
  - Interruptions in human research resulting solely from the expiration of the IRB approval period.
  - “Administrative holds” or other actions initiated voluntarily by an appropriate facility official, research investigator, or sponsor for reasons other than those described above under Suspension or Termination of Research.

Unanticipated or Unexpected Problem or AE. An unanticipated or unexpected problem or AE is one that is unforeseen in terms of nature, severity, or frequency of occurrence, as documented in the protocol or other materials approved by the R&D Committee, IRB, SAS, or other relevant oversight committee. For human research, such materials may include the informed consent document, clinical investigators’ brochure, product labeling, etc.

VA Facility. A VA facility is any entity that is operated by VA, including but not limited to: VA hospitals, medical centers, and healthcare systems; space owned, leased, or rented by VA; and space that is “shared” with a non-VA entity (unless the VA space is leased to a non-VA entity and specifically designated in writing not to be used by VA or VA employees for research). A VA facility may include multiple campuses and satellite components. The terms “facility,” “VA facility,” and “VA institution” are considered synonymous for purposes of this SOP.

VA Facility Director. A VA Facility Director is the Director of a VA Medical Center or a VA Healthcare System. For the purposes of this Handbook, the terms “Facility Director” and “Medical Center Director” are considered synonymous. The Facility Director serves as the IO for VA research facilities and programs.

VA Investigator. A VA investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (see 5 CFR Part 334). A VA investigator must comply with all applicable VA and VHA regulations and policies (see Investigator and Principal Investigator above.

VA Research. VA research is research conducted by a VA investigator on VA time or using VA resources (regardless of location), or by a VA investigator in a VA facility as defined above. The research may be funded by VA, by other sources, or be unfunded. NOTE: The term "VA Research" is further discussed in VHA Handbook 1200.1.

5. ABBREVIATIONS

AAALAC Association for Assessment and Accreditation of Laboratory Animal Care
AAHRPP Association for the Accreditation of Human Subject Protection Programs
ACOS Associate Chief of Staff for Research and Development
or ACOS/R&D
ACUP Animal Care and Use Program
AE Adverse Event
AO Administrative Officer for Research and Development
or AO/R&D
APHIS Animal and Plant Health Inspection Service
AWA Animal Welfare Act
BSL Biosafety Level
COS Chief of Staff
CVMO Chief Veterinary Medical Officer
DMC Data Monitoring Committee
FDA Food & Drug Administration
FWA Federalwide Assurance
HCG Healthcare Group
IACUC Institutional Animal Care and Use Committee (SAS at VALBHS)
IBC Institutional Biosafety Committee
IO Institutional Official
IPA Intergovernmental Personnel Act
IRB Institutional Review Board
ISO Information Security Officer
MOU Memorandum of Understanding
MPA Multiple Project Assurance
NIH/OBA National Institutes of Health / Office of Biotechnology Activities
OLAW Office of Laboratory Animal Welfare
ORD Office of Research and Development
ORDA Office of Recombinant DNA Activities
ORO Office of Research Oversight
ORO CO ORO Central Office
ORO RO ORO Regional Office
PBM Pharmacy Benefits Management

PHS	Public Health Service
PI	Principal Investigator
PO	Privacy Officer
R&D	Research and Development
RCO	Research Compliance Officer
SAE	Serious Adverse Event
SAS	Subcommittee for Animal Studies (local equivalent to IACUC)
SIA	System Interconnection Agreement
SOP	Standard Operating Procedure
SRS	Subcommittee on Research Safety
USDA	United States Department of Agriculture
WOC	Without Compensation
VA	Veterans Administration
VALBHS	VA Long Beach Healthcare System
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VMU	Veterinary Medical Unit

6. REPORTING CHANGES IN AFFILIATION, ACCREDITATION, AND COMMITTEE's.

A. Required Reporting. The following must be reported:

- **Assurance Changes.**
  - Any change in the facility's FWA, or other ORO-approved Assurance.
  - Any change in the facility's Animal Welfare Assurance status as filed with the PHS Office of Laboratory Animal Welfare (OLAW).

- **MOU Changes.**
  - Any change in an MOU with an affiliate institution or other entity related to the designation of IRB(s) or other human research protection arrangements.
  - Any change in an MOU with an affiliate institution or other entity regarding animal welfare or animal care and use arrangements.
  - Any change in an MOU with an affiliate institution or other entity regarding research laboratory safety arrangements
  - Any change in an MOU with an affiliate institution or other entity regarding research laboratory security arrangements
  - Any substantive change in an MOU or System Interconnection Agreement (SIA) with an affiliate institution or other entity related to information security or research privacy arrangements.

- **Accreditation Problems.**
  - Failure of the VA facility to achieve the accreditation status required by ORD for AAHRPP accreditation of the Human Research Protection Program, or any change in the facility's accreditation status.

- Failure of the VA facility to achieve the accreditation status required by ORD for AAALAC accreditation of the Animal Care and Use Program , or any change in the facility's accreditation status.

- **Committee Changes.**
  - Changes in IRB membership or MPA signatory officials. Any change in the facility's designated IRB(s) will be reported as is described in the IRB SOP section QA 902.
  - SAS Changes. Any change in the facility's designated SAS membership will be reported as described in the SAS SOP.
  - Changes in the IBC Roster. The IBC must submit to NIH/OBA at least annually:
    - A roster of all IBC members clearly indicating the Chair, contact person, biological safety Officer, Animal gene transfer expert, human gene transfer expert, and non-affiliated members.
    - Biographical sketches of all IBC members

5) Research Compliance Officer Change.

a) The Medical Center Director will report any appointment, resignation, or change in the status of the facility Research Compliance Officer to ORO VHA Central Office, with a copy to the relevant ORO research officer, within 10 business days after the appointment, resignation, or change takes effect.

B. Reporting Responsibility & Timeline. Reports are prepared by the ACOS/ R&D or designee, and are forwarded to the Facility Director for approval through the Chief of Staff. The Facility Director must submit the report to ORO CO, with a copy to the appropriate ORO RO and the VISN Director, as soon as possible, but no later than 5 business days after being informed of them. Problems with accreditation must also be reported to AAHRPP and/or AAALAC if human or animal research is involved as described in the respective reporting sections below.

7. ANNUAL REPORTS.

- **Facility Directors Certification of Research Oversight.** ORO requires the Medical Center Director to submit an annual certification before July 15th. The certification form may be obtained from the VA ORO webpage under the heading "ORO Checklists". Checklists are to be submitted to the ORO Western Regional Office (see section 22)

- **Human Research**

  - **AAHRPP Reports.** AAHRPP requires accredited organizations to submit annual reports between triennial site visits.

- **Report Format.** Organizations must submit a standard form that includes the following:
  - A summary or table of major problems or deficiencies identified in the 12 months, and how they were resolved.
  - A brief description of all programmatic changes that positively or negatively influenced the Human Research Protection Program.
  - The results of any federal or accrediting review of its Human Research Protection Program.

- **Animal Research**

1) AAALAC Reports. Every third year a comprehensive AAALAC Program Description must be completed prior to the scheduled triennial AAALAC site visit , and annually, an abbreviated report also must be submitted to AAALAC .

a) **Distribution & Timeline.**

- Annual and Triennial Reports must be submitted to AAALAC (see section 18).
- A copy of each annual report and all correspondence to and from AAALAC must be submitted to the following CVMO no later than 30 days after submission to AAALAC, or receipt from AAALAC:
  - CVMO
    - Atlanta VA Medical Center, Research Service – 508/151V, Room 4A106, 1670 Clairmont Rd., Decatur, GA 30033 (404) 728-7644
  - ORO RO
    - 14560 2nd St., Bldg. 2641, Suite B, Riverside, CA 92518 (909) 801-5167
- The triennial Program Description should not be submitted to ORD or the CVMO, unless a copy is requested.

2) PHS Assurances and Annual Assurance Updates

a) A PHS Assurance to conduct animal studies is required.

b) New PHS Assurances and annual updates must be forwarded to the CVMO's office within 30 days of submission to PHS.

3) The following reports and correspondence must be forwarded to the CVMO office or ORD, as indicated:

a) USDA Annual Report of Research Facility. This report (required by the USDA Animal Welfare Act Regulations and Standards) must be completed and submitted to ORD by November 15 each year as a component of Part II of the Research and Development Information System (RDIS). The forms are collected by ORD and sent to the appropriate USDA sector office. A copy of each form is also sent to the CVMO's office by ORD. Species not covered by the definition of an "animal" by USDA AWA should not be included on this form. Instead, such animals should be reported on the VMU Annual Report .

b) VA VMU Report. An annual VA VMU Report for the previous fiscal year must be completed using the website designed for that purpose by January 15. In contrast to the USDA Annual Report of Research Facility described in the preceding subparagraph, all animal species used must be included in the Annual VMU Report. Instructions for properly completing this report can be obtained from the CVMO.

4) Animal Welfare. The Director must notify ORO CO Research Safety & Animal Welfare Group, with a copy to the VISN Director, within 5 working days of being informed of the following:

a) Unanticipated loss of animal life.

b) Animal theft or potentially dangerous escape.

c) Work-related or research related injury to any person requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.

d) Incidents reportable under applicable standards, including noncompliance or deficiency that substantively compromises the effectiveness of facility's animal research protection/oversight programs.

e) Suspensions or terminations of research activities related to animal safety, health, or welfare; safety, rights, or welfare of research staff or others; or operations problems causing research interruptions.

f) Any change in facility's Public Health Service (PHS) Animal Welfare Assurance.

g) Any change PHS Animal Welfare Assurance of an affiliate or other entity on which the facility relies.

h). Any new MOU or substantive change in an MOU related to laboratory animal welfare or animal care and use arrangements.

i) Facility failure to gain full accreditation or change in facility accreditation or in affiliate accreditation affecting facility research

8. SEMI-ANNUAL REPORTS

A. IACUC Semi-Annual Self-Assessment Reviews. Semi-annual Self-assessment Reviews must be prepared by the SAS as described in the SAS SOP.

1) Report Format.

The following must appear in the report:

- The name, address, and facility number, with the date(s) that the self-assessment was performed.
- If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.
- The report must distinguish significant deficiencies from minor deficiencies.

A significant deficiency is one which, in the judgment of the SAS, is or may be a threat to the health or safety of the animals.
Examples of such deficiencies are:

- Animal research facility heating and cooling equipment that cannot maintain consistent temperatures in the ranges specified in the most current Guide.
- An inadequate program for the surgical care of animals.
- An inadequate program for the medical care of animals.
- Conduct of research not approved by the SAS.
- Inadequate caretaker staffing.
- Inadequate SAS administrative support such that the SAS cannot fulfill its regulatory mandates.

A minor deficiency is one that does not fit the preceding definition of a significant deficiency. Examples of minor deficiencies are difficult to provide because local circumstances strongly influence whether a deficiency is considered significant or minor.

d) The report must state any minority views.
e) A list of SAS members present during the semi-annual self-assessment review with the name, the degree(s) held, and the SAS role (veterinarian, scientist with animal research experience, lay member, non-affiliated member) of each member. At least three SAS members (including the veterinarian) need to conduct the program and facilities review, unless exceptional circumstances prevent such attendance. All members of the SAS are strongly encouraged to participate in the semi-annual self-assessment review; however, the review team must include at least two voting members of the SAS. ***NOTE:*** *Attendance by the lay and non-affiliated members is especially encouraged.*

2) Approvals.
A majority (of all voting SAS members) must vote to approve the report; each member must indicate approval by signatures next to the typed name and committee role. Then the report must be discussed with the medical center Director by the SAS Chairperson, veterinarian, and one or more research administrators (other SAS members may also attend as dictated by local SAS policy). The medical center Director then must sign the report indicating that the report has been reviewed.

3) Distribution and Timeline.
Once the medical center Director has signed the report, it must be sent to the CVMO through the medical center Director within 60 days of the self-review date.
NOTE: *A copy needs to be sent to the local R&D Committee for review, but R&D Committee approval is not needed before the document is sent to the CVMO.*

- Under no circumstances may an SAS semi-annual report be altered by any local official once a majority of voting SAS members has voted to approve the report.
- Under no circumstances may local officials pressure SAS members to change the wording of such reports to language more favorable to the institution. Local officials may comment or indicate their non-concurrence with information in the report in a cover letter.
- The report must be retained on file for at least 3 years by the research office.

4) Failure to Resolve Significant Deficiencies with 15 days.
Failure to correct a significant deficiency (identified during a semi-annual IACUC program or facility self-assessment review) according to the schedule approved by the SAS requires additional reporting.

- **Report Format.**
  The report needs to include all of the following:
  - The date when the SAS identified the deficiency.
  - The timetable and plan approved for correction.
  - Why the correction(s) could not be completed according to the timetable.
  - The revised timetable.
  - The plan to finish the correction(s).

- **Distribution.**

The USDA AWAR (see 9 C.F.R. §2.31[c][3]) states that the failure to correct a significant deficiency must be reported in writing within 15-business days of the self-imposed deadline by the SAS, through the Institutional Official, to USDA and any Federal agency funding that activity. This required 15-business day reporting period is extended to cover all categories of reportable deficiencies.
NOTE: *Consistent with NIH Notice NOT-OD-05-034 dated 2/24/05, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," facilities should notify appropriate agencies by phone immediately that a full, written account of a reportable deficiency is forthcoming.*

9. REPORTING OF EVENTS (GENERAL REQUIREMENTS).

The following problems are evaluated by the R&D committee and/or appropriate subcommittee(s) of the R&D committee. The specific procedures that are employed in

the evaluation are described in the committee SOP(s). The reporting procedures that are described here are triggered if the committee(s) makes the following determinations:

A. Unanticipated or Unexpected Problem or AE.

1.) Unanticipated problems are reported to the AO/Research.

2.) The AO/ Research will distribute the report to the appropriate committee for review.

3.) The appropriate committee will determine if:

- The problem is unanticipated.
- The problem is related to the experimental procedures.
- The problem represents an increased risk of harm to human or animal subjects or others.
- ***If the problem is all of the above, then it must be reported***

4) The committee will also determine if:

- The problem is Serious
- The problem is Continuing.

5) The specific procedures that describe how these decisions are made are described in the following:

- Human Subjects and Privacy Issues (IRB SOP).
- Animal Research (SAS SOP)
- Research Safety (SRS SOP)
- Recombinant DNA (IBC SOP)

B. Serious Problems. If the problem is serious (see above) then the problem must be reported.

C. Continuing Problems. If the problem is continuing then it must be reported.

D. Work-Related and Other Injuries. Any work-related injury to personnel involved in
research, or any research-related injury to any other person, that requires more than minor medical intervention or leads to serious complications or death, must be reported.

E. External Noncompliance Findings. Any findings of noncompliance related to any of the following:

- Human Research Protection
- Animal use and care
- Research safety
- Laboratory security
- Information security or privacy

by any VA office, any other federal department or agency , or any other entity must be reported. The Facility Director's report to ORO must include a copy of the entity's official findings.

F. Terminations or Suspensions of Approval. Terminations or suspensions of approval of research that are related to concerns about the safety, rights, or welfare of

human or animal research subjects, research staff, or others must be reported. The procedures for the termination or suspension of Approval are described in:

- The R&D SOP
- The IRB SOP
- The SAS SOP

10. EVENT REPORTING (GENERAL)

A. Review and Approval of the Report.

- All Reports will be reviewed and approved by the Chair of the originating committee or subcommittee e.g., IRB, SAS, R&D etc.
- All Reports will be reviewed and approved by the Director, or designee.

B. Distribution of the Report within the Facility.

The AO/ R&D, or designee, will distribute reports to the following VALBHS officials and committees:

- The Investigator
- The VALBHS Privacy Officer (PO) (if the report involves unauthorized use, loss, or disclosure of individually identifiable patient information).
- The VALBHS Information Security Officer (ISO) (if the report involves
- violations of information security requirements of that organization).
- The RCO
- The IRB
- The R&D committee
- The ACOS R&D
- The Director VALBHS, or designee

C. External Distribution.

The Director, or designee, will send the report to the following external officials and agencies, as appropriate:

- ORO Western Region and Other VA Offices as described in section 22.

Additional external reporting is required if the problem involves the use of :

- Human Subjects as described in section 11.
- Animals Subjects as described in section 12.
- Safety as described in section 13.
- Laboratory Security as described in section 15.
- Information Security as described in section 16.
- Recombinant DNA as described in section 14.
- The FDA (if the study is subject to FDA regulations) as described in section 20.
- The appropriate designee of the funding department or agency (if the study is funded by such an agency).
- The appropriate designee of the sponsoring company or organization (if the study is supported by such an agency).

11. REPORTING EVENTS RELATED TO HUMAN RESEARCH

A. Reports Within the Facility.

(1) Problems Involving Risks to Subjects or Others. Investigators, RCOs, and other members of the VA research community must report all problems involving, or suggesting, risks to subjects or others in VA research to the Associate Chief of Staff for Research (ACOS/R&D) and the IRB as soon as possible but no later than 5 business days after becoming aware of the problem. Such problems include, but are not limited to:

(a) Interruptions of subject enrollments or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.

(b) Any work-related injury to personnel involved in human research, or any research-related injury to any other person, requiring more than minor medical intervention or that leads to serious complications or death.

(c) Any VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to one or more of the facility's research projects.

(d) Any Data Monitoring Committee (DMC) report describing a safety problem.

(e) Any sponsor analysis describing a safety problem. NOTE: Sponsor "AE Reports"
lacking meaningful analysis are not considered problems.

(2) SAEs. VA investigators must report all local SAEs in VA research to the ACOS for R and the IRB as soon as possible, but no later than 5 business days after the event has become known to the investigator. The procedures for the reporting and review of SAE's are described in the IRB SOP.

B. External Reporting.

- To VISN and ORO as described in sections 22 & 23.
- To FDA (see section 20) if the research involves the use of Drug Products, Biologic Products, or Medical Devices.
- To AAHRPP (see section 19) if any of the following apply:
    - Inquiry from a government oversight office such as the Office of Human Research Protection or the FDA when the inquiry could result in a for – cause investigation.
    - Any findings or change concerning the Human Research Protection Program that might affect the ability to continue to meet AAHRPP standards.
    - Any sanctions taken be a government oversight office.

C. RCO Findings of Apparent Serious or Continuing Non-Compliance.

The Research Compliance Officer must report any findings of apparent Serious or Continuing Non-compliance that are discovered in the course of the regulatory audits. Reports must be submitted through the Director's Office to the ORO Regional Office within 5 working days of detection. Copies must be sent to the VA

Office of Research & Development, the VISN Director, and the local responsible committee of the R&D Committee.

12. REPORTING EVENTS RELATED TO ANIMAL RESEARCH

A. Mandated Reporting. As a condition of extending the privilege of conducting animal research to individual medical centers, VA Central Office expects that the IACUC and institutional administrators will avoid any appearance of hiding or suppressing deficiencies. NOTE: This goal is best achieved by prompt reporting of deficiencies before others outside of the program do so. Consistent with NIH Notice NOT-OD-05-034 dated 2/24/05, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," facilities should notify appropriate agencies by phone immediately that a full, written account of a reportable deficiency is forthcoming.

PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1) any serious or continuing noncompliance with this Policy;
2) any serious deviation from the provisions of the *Guide* [*for the Care and Use of Laboratory Animals*] ; or
3) any suspension of an activity by the IACUC."

The specific procedures and criteria for these determinations are described in the SAS SOP.

Although an ORD veterinary hold is not considered an SAS suspension, it must be reported to other Federal agencies if the SAS and IO find that information in the ACORP represents a reportable deficiency.

B. Reports Within the Facility.
(1) RCOs, and other members of the VA research community must report all problems involving the care and utilization of animals in VA research to the ACOS/R&D and the SAS as soon as possible but no later than 5 business days after becoming aware of the problem.

C. Reports to ORO Central Office.
Reports of the following should be directed to the appropriate ORO CO groups as follows:

1) Research Safety and Welfare Group. Matters that involve Animal Welfare, Research Safety, or Laboratory Safety.

2) Research Information Protection Group. Matters that involve Research Information.

D. External Reporting.

1) Report Format. Reports should address all of the following:

- When and how the SAS became aware of the problem.
- When the investigation was performed to determine facts and detail the circumstances that led to the non-compliance.
- The results of that investigation
- What corrective actions the SAS approved to stop the noncompliant activity and prevent future recurrences.
- When the SAS convened a quorum to make the determination.

2) Timeline and Distribution. OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

Deficiencies meeting any of the criteria in subparagraph 7(a) must be reported in writing within 15 business days through the ACOS for R&D and the medical center Director to the following agencies and offices:

(a) ORD (by contacting the CVMO's office).
(b) OLAW, as required by PHS Policy.
(c) The Animal Care Section at USDA APHIS, as required by AWAR, if the deficiency involves a species meeting the definition of an animal in the AWAR, or if the deficiency impacts the care or use of such a species.
(d) AAALAC, as required by AAALAC rules of accreditation.
(e) The affiliate's SAS, if a joint SAS is not present and the project involves animals purchased with funds awarded to the affiliate, or if an agreement between the VA and affiliate requires such notification.

3) Correspondence. A copy of all correspondence between OLAW, USDA, AAALAC and VA facilities must be forwarded to the CVMO and ORO within 15 business days of receipt.

13. REPORTING EVENTS RELATED TO RESEARCH SAFETY

A. Mandated Reporting. Safety Officers, RCOs and other members of the VA research community must report all problems involving information security to the ACOS/R&D and the Chair of the SRS as soon as possible but no later than 5 business days after becoming aware of the problem.
The following must be reported:

(1) Work-Related and Other Injuries. Any work-related injury to personnel in VA research, or any research-related injury to any other person, that requires more than minor medical intervention or leads to serious complications or death.

(2) Work-Related Exposures. Any work-related exposure of VA research personnel to hazardous materials at greater than routine levels or that requires more than minor medical intervention or leads to serious complications or death.

(3) Reportable incidents under applicable standards, including any deficiency that substantively compromises the effectiveness of the facility research safety programs.

(4) Suspensions or terminations of research activities related to the safety, rights or welfare of research staff or others.

(5) Unauthorized Laboratory Decommissions. Laboratory space that is being reassigned, vacated, or converted to non-laboratory use and requires identification and disposal of hazardous materials and/or equipment between uses.

(6) Any substantive change in an MOU related to research safety arrangements.

B. Distribution of the Report within the Facility.
The AO/ R&D, or designee, will distribute reports to the following VALBHS officials and committees:

- The Investigator
- The SRS Committee
- The RCO
- The IRB (if the project involves human subjects)
- The SAS (if the project involves the use of animals)
- The R&D committee
- The ACOS R&D
- The Director VALBHS, or designee

C. External Reporting.
1) Timeline and Distribution.

The Facility Director must submit reports to the following offices as soon as possible, but no later than 5 business days after being informed of them:

- ORO RO (see section 22)
- Laboratory decommissions must also be reported to the VISN Safety Office.

14. REPORTING EVENTS THAT INVOLVE RECOMBINANT DNA.

Events that involve the use of recombinant DNA are reviewed by the IBC according to procedures that are described in the IBC SOP. The following reporting sequence is initiated if the IBC determines that reporting is required.

A. Reports Within the Facility.

- IRB Reporting. The IBC Chair will inform the IRB Chair immediately if serious problems involve the treatment of human subjects. IRB reporting will follow the procedures defined in the IRB SOP.
- SAS Reporting. The IBC Chair will inform the SAS Chair immediately if serious problems involve research that utilizes animal subjects. SAS reporting will follow the procedures defined in the SAS SOP.

- R&D Reporting. The IBC will report any significant action, and determinations of serious or continuing non-compliance, to the R&D Committee within 2 working days that such a determination has been made.

B. External Reporting

- General Reporting. The decision tree for reporting is described in section 7 "GENERAL REQUIREMENTS FOR THE REPORTING OF EVENTS".
- NIH Reporting. Any significant problems, violations of the NIH Guidelines, or any significant research related accidents and illnesses must be reported to NIH/ORDA within 30 days, unless it can be verified that a report has already been filed by the Principal Investigator. Reports shall be sent to:

The Office of Recombinant DNA Activities
National Institutes of Health/MSC 7010
6000 Executive Boulevard, Suite 302
Bethesda, MD. 20892-7010
(301) 496-9838

15. REPORTING EVENTS RELATED TO RESEARCH LABORATORY SECURITY

A. Mandated Reporting. RCOs and other members of the VA research community must report all problems involving laboratory security to the ACOS/R&D and the Research Security Officer as soon as possible but no later than 5 business days after becoming aware of the problem. The following must be reported:

1) Injuries. Any injury or harm to a human individual or laboratory animal related to a break-in, security breach, or other security problem involving a VA research facility.

2) Biosafety Level 3 (BSL-3) Breaches. Any break-in or security breach involving a VA BSL-3 research laboratory.

3) Other Breaches. Any break-in or security breach involving a VA research facility that results in any of following:
a) Loss of any quantity of a select agent or toxin.
b) Loss of any quantity of a highly hazardous agent (see VHA Handbook 1200.06).
c) Substantial damage to the facility.
d) Substantial loss of equipment or resources.

4) Findings of noncompliance by entities external to the facility.

5) Any noncompliance or other deficiency that substantively comprises the effectiveness of the facility's research laboratory security system.

6) Suspensions of terminations of research related to laboratory security concerns.

7) Any substantive change in an MOU related to research laboratory security arrangements.

B. Distribution of the Report within the Facility.
The Research Security Officer, or designee, will distribute reports to the following VALBHS officials and committees:
- The VA Police
- The Security subcommittee
- The RCO
- The IRB (if the project involves human subjects)
- The SAS (if the project involves the use of animals)
- The R&D committee
- The ACOS R&D
- The Director VALBHS, or designee

C. Timeline and Distribution.
The Facility Director must submit reports as soon as possible, but no later than 5 business days after being informed of them to:
- ORO Western Regional Office and VISN 22 (see section 22)

16. REPORTING EVENTS RELATED TO RESEARCH INFORMATION PROTECTION

A. Mandatory Reporting. RCOs, ISO's, PO's and other members of the VA research community must report all problems involving information security to the ACOS/R&D, the PO, and the ISO within 1 of becoming aware of the problem. The following must be reported:
1) Unauthorized Activities. Any unauthorized, research-related access, use, disclosure, transmission, removal, theft, or loss of VA sensitive information, including, but not limited to:
- Protected health information
- Individually-identifiable private information (as defined in 38 CFR 16.102(f)(2))
- Confidential information
- Privacy Act-protected information.

2) The following must be reported to the ACOS/R&D, the PO, and the ISO within 5 business days of becoming aware of the problem:
- Findings of noncompliance related to research information security or privacy by entities external to the facility.
- Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.
- Suspensions or terminations of research related to information protection concerns.

3) Other Incidents. Any research-related incidents reportable to the Office of Information and Technology (OI&T) Network and Security Operations Center (NSOC).

Note: Uses and disclosures of PHI under invalid or nonexistent HIPAA authorization or waiver or deficient ISO or PO review must be reported to the ORO Regional Office. All other research information protection incidents must be reported to CO Research Information Protection Group.

B. Distribution of the Report within the Facility.
The AO/ R&D, or designee, will distribute reports to the following VALBHS officials and committees:

- The Investigator
- The Information Security Officer (ISO)
- The Privacy Officer (PO)
- The Security subcommittee
- The RCO
- The IRB (if the project involves human subjects)
- The SAS (if the project involves the use of animals)
- The R&D committee
- The ACOS R&D
- The Director VALBHS, or designee

C. External Reporting.
1) Timeline and Distribution
The Facility Director must submit reports as soon as possible, but no later than 5 business days after being informed of them to:

- ORO Western Regional Office and VISN 22 (see section 22).

17. REPORTING RESEARCH MISCONDUCT.

A. Procedures. The full procedures for handling research misconduct allegations are found the VALBHS SOP for “Ethical Standards and Misconduct in Research”.

B. Notification Requirements. ORO Central Office must be notified as soon as possible (preferably by telephone or email) of any allegation of research misconduct. Subsequent written notification must be provided as specified by ORO Central Office.

18. REPORTING TO AAALAC.

Reports to AAALAC should be addressed to:

American Association for Accreditation of Laboratory Animal Care
11300 Rockville Pike, Suite 1211
Rockville, MD 20852-3035
Phone (301) 231-5353 e-mail accredit@aaalac.org

19. REPORTING TO AAHRPP.

A. Required Reporting & Timeline.

- The Medical Center Director must report any sanctions taken by a government oversight office to AAHRPP within 24 hrs.
- The Medical Center Director must report any of the following to AAHRPP as soon as possible, and preferably within 72 hours:
    - Inquiries from a government oversight office e.g. ORO, OHRP, FDA, when the inquiry could result in a for-cause investigation.
    - Any findings or change that might affect the ability to continue to meet AAHRPP standards.

B. Distribution of Reports.

- ORO and other VA Offices (see section 22)

AAHRPP
2301 M Street NW, Suite 500
Washington, DC 20037
Phone (202) 783-1112; email: accredit@aahrpp.org

20. REPORTING TO FDA

Under 21 CFR 56.113, an IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB`s action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

21 CFR 56.108(b) requires that the IRB follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of:

- Any unanticipated problems involving risks to human subjects or others;
- any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or
- any suspension or termination of IRB approval.

When reporting suspensions or terminations of IRB approval, please include the IND or IDE number, the full name of the research protocol, the name(s) of the clinical investigators, and the reason(s) for the suspension or termination. These reports may be submitted via e-mail or in hard copy by FAX or mail. Submit information to the following locations/contacts:

For Drug Products:

Please report suspension or termination of IRB approval; unanticipated problems involving risks to human subjects; or serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB to:

Ms. Dana Walters
Dana.Walters@fda.hhs.gov
Division of Scientific Investigations (HFD-45)
Office of Compliance
Center for Drug Evaluation and Research
White Oak Campus
10903 New Hampshire Ave.
BLDG 51, Rm. 5341
Silver Spring, MD 20993
Phone: (301) 796-3150
Fax: (301) 847-8748

For Biologic Products:

Please report suspension or termination of IRB approval; unanticipated problems involving risks to human subjects; or serious or continuing noncompliance with the regulations or the requirements or determination of the IRB to:

Ms. Patricia Holobaugh
Patricia.Holobaugh@fda.hhs.gov
Bioresearch Monitoring Branch (HFM-664)
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research/FDA
1401 Rockville Pike, Room 400S
Rockville, MD 20852-1448
Phone: (301) 827-6347
Fax: (301) 827-6748

For Medical Devices:

Please report suspension or termination of IRB approval; unanticipated problems involving risks to human subjects; or serious or continuing noncompliance with the regulations or the requirements or determination of the IRB to:

Ms. Sheila Brown
Sheila.Brown@fda.hhs.gov
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire
WO66 RM 1651
Silver Spring, MD 20993
Phone (301) 796-6563
Fax: (301) 847-8120

21. REPORTING TO OLAW/USDA

A. Required Reporting& Timeline. Institutions should notify OLAW promptly, i.e., without delay. The AO/R&D must provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW. The AO/R&D must provide the Director with a report of

any determinations by the SAS within 5 working days of when the determination(s) was made. The Medical Director must report research events to the ORO RO as soon as possible, but no later than 5 business days after being informed of them:

B. Distribution of Reports.

The Facility Director must simultaneously submit reports to the following:

- OLAW
- USDA AWAR
- ORO Western Regional Office
- The Director VISN 22

If the event involves serious or continuing noncompliance identified by an RCO, during an informed consent or regulatory audit, a report must also be sent to the VHA Chief Research and Development Officer (CRADO), or designee.

C. Report Format.

Include as many of the following items of information as possible in the initial contact with OLAW. A follow-up report may address anything not known at the time of the initial report and should summarize the institution's corrective action. If a long term plan is necessary, describe the plan and include a reasonable schedule. This information will allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation.

Information to be included:

- Animal Welfare Assurance number (http://grants.nih.gov/grants/olaw/assurance/300index.htm);
- relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;
- a full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by the institution to address the situation; and
- description of short- or long-term corrective plans and implementation schedule(s).

Preliminary and final reports should be made to:

OLAW:

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

For questions or further information, contact:

Director, Office of Laboratory Animal Welfare
Office of Extramural Research,
Office of the Director, National Institutes of Health
RKL 1, Suite 360
6705 Rockledge Dr .
Bethesda , MD 20892-7982
(For express or hand-delivered mail use zip code 20817)
Telephone (301) 496-7163
olaw@od.nih.gov

USDA:

United States Department of Agriculture. Animal and Plant Inspections Service,
Western Region
2150 Centre Ave
Bldg B, M/S 3W11
Ft. Collins, CO 80526
Phone (970) 494-7478; e-mail cmorris@aphis.usda.gov

22. REPORTING TO ORO WESTERN REGION AND OTHER VA OFFICES.

A. Required Reporting & Timeline. The Medical Center Director must report research events to the ORO RO as soon as possible, but no later than 5 business days after being informed of them:

B. Distribution of Reports.
The Facility Director must simultaneously submit reports to the following:

- ORO Western Regional Office
  - If by US Mail:
    - PO Box 8349, Moreno Valley, CA 92552-8349
  - If by Express Delivery:
    - 1450 2nd Street, Bldg. 2641, Suite B, Riverside, CA 92518
  - If by fax:
    - (909) 801-5176
  - If by email: paul.hammond@va.gov and Cynthia.kerenyi@va.gov.

- The Director VISN 22
  - By email to the VISN 22 Chief Medical Officer
  - By interoffice mail: Mail code: 10N/22

If the event involves serious or continuing noncompliance identified by an RCO, during an informed consent or regulatory audit, a report must also be sent to the VHA Chief Research and Development Officer (CRADO), or designee. ORD has established an e-mail for this purpose at:

Compliance.reports.ord@va.gov

If there are problems with this address then contact Peggy Hanson at (202) 461-1696.

Reporting to ORO in writing within five business days after being notified of a research problem or even (including serious and continuing non-compliance, unanticipated problems involving risks to subjects or others, and suspensions and terminations) for which such reporting is required under VA Handbook 1058.01.

A written report from the Facility Director is required whether or not disposition of the event has been resolved at the time of the initial report.

Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the appropriate ORO office at intervals and in a manner specified by that office.

C. Report Format.

Reports of research events must include:

(1) The name and any relevant Assurance number of the reporting VA facility.
(2) The title of the research project(s).
(3) The number(s) used by the facility's IRB, SAS, or Research Service to identify the project(s).
(4) The name of any external sponsor(s) of the project(s).
(5) The funding source(s) for the project(s).
(6) A detailed description of the event being reported.
(7) A detailed description of the actions taken (or to be taken) to address the reported event, including systemic actions where warranted.
(8) The name of any agencies or organizations external to VA that were notified, or are to be notified, of the event.

23. APPLICABLE REGULATIONS AND GUIDELINES

FDA Information Sheet #4
VALBHS MPA
VALBHS MPA, Appendix D
21 CFR 56.108(b)
21 CFR 312.64(b)
21 CFR 812.150
38 CFR 16
45 CFR 46

Biosafety in Microbiological and Biomedical Laboratories (5th Edition). Centers for

Disease Control and Prevention and National Institutes of Health.

Guide for the Care and Use of Laboratory Animals. National Research Counsel, 1996.

NIH NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

Public Health Service Policy on Humane Care and Use of Laboratory Animals. National Institutes of Health.

Title 5 CFR Part 334, Temporary Assignments Under the Intergovernmental Personnel Act.

Title 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins.

Title 9 CFR Parts 1, 2, 3, and 4. USDA Animal Welfare Act Regulations and Standards.

Title 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins.

Title 21 CFR Part 50, Protection of Human Subjects.

Title 21 CFR Part 56, Institutional Review Boards.

Title 21 CFR Part 312, Investigational New Drug Application.

Title 21 CFR Part 812, Investigational Device Exemptions.

Title 29 CFR Part 1910, Occupational Safety and Health Standards.

Title 29 CFR Part 1960, Federal Employee Occupational Safety and Health Standards.

Title 38 CFR Part 16, Protection of Human Subjects.

Title 42 CFR Part 73, Select Agents and Toxins.

Title 45 CFR Part 160, Administrative Data Standards and Related Requirements: General Administrative Requirements.

Title 45 CFR Part 164, Administrative Data Standards and Related Requirements:
Security and Privacy.

VA Directive 6502, VA Enterprise Privacy Program.

VA Handbook 6500, Information Security Program.

VHA Directive 1058, Responsibilities of the Office of Research Oversight.

VHA Handbook 1050.01, National Patient Safety Improvement Handbook.

VHA Handbook 1058.2, Research Misconduct.

VHA Handbook 1058.01Research Compliance Reporting Requirements.

VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.

VHA Handbook 1058.04, Debarments and Suspensions based on Research Impropriety in VA Research.

VHA Handbook 1200.1, Research and Development Committee Handbook.

VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.

VHA Handbook 1200.7, Use of Animals in Research.

VHA Handbook 1200.8, Safety of Personnel Engaged in Research.

VHA Handbook 1605.1, Privacy and Release of Information.

24. RESCISSIONS. November 05, 2009.

25. REVIEW AND RECERTIFICATION. This SOP is scheduled to be reviewed and reissued every 3 years.

26. APPROVAL.

Approved: _____ Date: _____
Chair, R&D Committee