# 1. PURPOSE

1.1. This procedure establishes the process to manage the following information related to VA Research:

1.1.1. Unanticipated and related research deaths
1.1.2. Local SAEs that are both unanticipated and related to the research
1.1.3. Serious problems that are unanticipated and related to the research
1.1.4. Information security incidents related to VA Research

1.2. This procedure begins when an IRB receives information related to VA Research that is not a request for a determination[i] (regardless of whether the information is reportable) or receives reportable new information as part of a submission.

1.3. This procedure ends when required reporting to the VA has been completed.

# 2. POLICY

2.1. VA Research is research that is conducted by investigators (serving on VA compensated, Without Compensation (WOC), or Intergovernmental Personnel Act (IPA) appointments) while on VA time or on VA property.

2.1.1. VA research may be funded by VA, by other sponsors, or be unfunded.
2.1.2. VA Research must have Research & Development (R&D) Committee approval before it is considered VA Research and before it can be initiated.
2.1.3. All research activities approved by the VA facility's R&D Committee are considered VA Research.

2.2. VA personnel are required to notify the Associate Chief of Staff for Research and Development (ACOS/R&D), Information Security System Officer (ISSO), Privacy Officer (PO), and relevant investigators immediately (i.e. within one hour) upon becoming aware of any information security system incidents related to VA research, including any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI.

2.2.1. The ACOS/R&D must immediately notify the IRB when relevant.

2.3. VA personnel are required to provide written notification to the ACOS/R&D must occur within 5 business days of becoming aware of any research information security incidents described above.

2.3.1. The ACOS/R&D must immediately notify the IRB when relevant.

# 3. RESPONSIBILITY

3.1. An IRB chair or <Designated Reviewer> follows this SOP.

# 4. PROCEDURE

4.1. Follow "SOP: New Information HRP-112".

4.2. If the IRB receives a notification under this SOP:

4.2.1. If the notification involves an unanticipated and related death:

4.2.1.1. Alert the VA Office of Research Oversight (ORO) by telephone or email within 2 business days of receipt of oral notification.

4.2.2. Review the report within 5 business days of receipt of the written notification and determine and document whether any immediate action is required to eliminate apparent immediate hazards to subjects.

4.2.3. If immediate action is required to eliminate apparent immediate hazards to subjects, notify the Local VA Facility Liaison within 5 days of the determination.

4.2.4. Have the convened IRB review the incident at its next convened meeting (within 30 days) using "CHECKLIST: New Information VA (HRP-390)"

4.2.5. If the convened IRB makes any determinations that are noted on "CHECKLIST: New Information VA (HRP-390)" to be reportable, notify the Local VA Facility Liaison within 5 days of the IRB's determination.

# 5. REFERENCES

5.1. VHA Directive 1200.05 (March 3, 2020)

5.2. VHA Directive 1058.01 (June 15, 2015)

[i] "Determination" means a request for approval, a request for an exemption, or a request for a not human subjects research definition.