

## Reportable Events Atlanta VAMC

### 1. OBJECTIVES:

- a) Outline local policies and procedures for the documentation, determination and reporting of Serious Adverse Events (SAEs) and Serious Problems (SPs) in VA research.
- b) Comply with federal guidelines regarding the documentation, determination and reporting of SAEs and SPs.

*\*NOTE: Incidents, events or problems that involve the unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information, or confidential information as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act or 38 U.S.C. must be reported within 1 hour as described in the AVAMC policy entitled: “Research Information Incidents.”*

### 2. DEFINITIONS:

**Adverse Event (AE)** – An untoward physical or psychological occurrence in a human subject participating in research.

**Local** – occurring at the reporting facility’s own research site(s).

**External Adverse Event or Unanticipated Problem Involving Risks to Subjects or Others** – An Adverse Event or an Unanticipated Problem Involving Risks to Subjects or Others experienced by subjects enrolled by investigators at sites other than AVAMC sites.

**Related** – The event or problem may reasonably be regarded as caused by, or as probably caused by, the research.

**Serious Adverse Event (SAE)** - An Adverse Event in human subjects participating in research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

**Serious Problem (SP)** – A serious problem is a problem in human research that may reasonably be regarded as:

- a. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; **OR**
- b. Substantively compromising the effectiveness of a facility’s human research protection or human research oversight programs.

**Unanticipated Adverse Event or Unanticipated Problem (UP)** – The adverse event or problem is either new or greater than previously known in terms of nature, severity, or frequency of occurrence. In order for the event to be **unanticipated**, it cannot be listed in the study

protocol, the Informed Consent, Investigator's Brochure, Sponsor's Information, or expected in the study population. These can be both external and internal (local).

Note: "Serious Problems" may include UPs.

**VA Research** – Research conducted by VA investigators serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments while on VA time, utilizing VA resources, or on VA property (including space leased to or used by VA and also includes space utilized at a non-VA facility but has an approved off-site waiver to perform part or all of the research off-site). The research may be funded by VA, by other sponsors, or be unfunded.

### **1. Principal Investigator's Responsibilities:**

- a) Ensure that deaths of research subjects that are unanticipated and related to the research conducted in local VA studies are reported immediately to the IRB orally and written reports must be submitted **within 5 business days** of discovery.
  - a. Please call one of the staff members listed below in order to complete the oral notification requirements:
    - i. Jane Guidot, CSC Manager: 404-321-6111 ext. 6933
    - ii. Jennifer Whelan, HRPP Quality Manager: 404-321-6111 ext. 3452
    - iii. Shara Karlebach, QA and Education Consultant at the Emory IRB: (404) 712-0727
    - iv. Maria Davila, Team Lead, QA and Education Consultant at the Emory IRB: (404) 712-0724
    - v. Rodney Thompson, VA Research Compliance Officer: 404-321-6111 ext. 6964

**\*\*Note:** If the PI does not know the relationship of the unanticipated death to the research, report the death **within 5 business days** of discovery and indicate that the relationship to the research study is **unknown**.

**\*\*Note:** Deaths that are anticipated AND related to the research or if the relationship to the anticipated death is **unknown**, report within **5 business days** of discovery.

**\*\*Note:** Deaths that are anticipated AND unrelated need to be reported at time of continuing review only.

- b) Ensure that Unanticipated Serious Adverse Events and Unanticipated Serious Problems involving risks to subjects or others in human subjects that are related to the research conducted at the Atlanta VAMC must be reported to the IRB **within 5 business days** of discovery.
- c) Ensure that required changes to study documents are submitted as amendments to the IRB in addition to submitting the Reportable Event.
- d) Ensure that a complete summary of all local Deaths, Serious Adverse Events, Unanticipated Problems, and Serious Problems are reported to the IRB at Continuing Review as required.

## **2. PI Procedures for Reporting SAEs and Serious Problems:**

**For studies that are approved by the VA Central IRB (CIRB) - The PI should report SAEs/SPs to the VA CIRB (per VA CIRB policies and procedures).**

**For studies that are approved by the Emory IRB – The following events/problems must be reported using eIRB as follows:**

- a) For locally occurring events, please refer to our step by step instructions for submitting locally occurring UPs at Emory-affiliated sites within 5 business days. (Remember deaths of research subjects that are unanticipated and related to the research conducted in local VA studies require immediate oral reporting to the IRB— one of the 5 contacts listed above).
- b) For externally occurring events, please refer to our step by step instructions for submitted external occurring UPs at non-Emory-affiliated sites.

**ONCE eIRB is FILLED OUT, SEND AN EMAIL**

**TO: [VAReportableEvents@atlaref.org](mailto:VAReportableEvents@atlaref.org)**

**WITH THE PI'S NAME AND STUDY eIRB NUMBER TO ALERT THE RESEARCH OFFICE THAT AN UP/RE HAS BEEN SUBMITTED TO THE IRB.**

## **3. PI Annual Continuing Review Reporting Requirements for local SAEs /UPs:**

The PI is responsible for submitting a summary of all local reportable events at Continuing Review to the Emory IRB using the “Atlanta VA Periodic Reportable Event Summary” posted on the Atlanta VA research website. The PI is also responsible for tracking any events that did not meet the 5 business day reporting threshold and documenting why this event did not need to be reported within that time frame.