**Reportable Events – Meeting Reviewer Checklist**

*If more than one Research Event on the report is to be reviewed, use a separate checklist for each.*

**Principal Investigator:**       **Study Number (ID#):**      

**Meeting Primary Reviewer:**       **Date of Meeting for Report Review:**

***Reviewer attestation****: By entering my name above, I am confirming that I completed this review and did not have a conflict of interest with this study.*

**Event #:**       **Date (range) of Event:**       **Pt ID *(if applicable)*:**       **Related event #(s) *(if applicable)*:**      

**I. Event Classification: check ALL that apply,** *(for guidance, see* ***“Definitions”*** *and* ***“Guidance Documents”*** *below)***:**

1. **Death –** **local, unexpected, and related or possibly related**
2. **Apparent UPIRTSO**
3. **Apparent Serious and/or Continuing Noncompliance** *(including* ***protocol deviations*** *that meet criteria for reporting [e.g. Apparent Serious Noncompliance])*
4. **Research Information Security** **and Privacy Incident (RISPI)**
5. **Systemic Deficiency**

**II. Report Timeliness:** *(see* ***Report Timelines*** *on REF)*:

1. For reports of a local death (A) or a RISPI (E), were immediate notifications made by the discovering individual, as per VA requirements?  Yes  No  N/A – not local death or RISPI

2. If A is checked, was the event reported in writing to the IRB within 1 business day of a study team member’s awareness?  Yes  No  N/A – not local death

3. If B, C, D and/or E is checked, was the event reported in writing to the IRB within 5 business days of a study team member’s awareness?  Yes  No  N/A – event is local death

4. If **No** to any question above (1 thru 3), does the late reporting constitute apparent serious and/or continuing noncompliance?  Yes *(If YES, check event classification* ***C*** *above.)*  No

**III. Deaths and UPIRTSOs**

1. Do you feel that the event was Unexpected?  Yes  No  Insufficient information

2. Do you feel that the event is Related or Possibly Related to the research?

Yes  No  Insufficient information

3. For deaths, was it a Local research death? *(VA defines Local research as “research approved by the reporting VA medical facility regardless of whether it is conducted on-site or at another institution such as the VA medical facility’s academic affiliate.”)*

Yes  No   N/A – not a death

4. For deaths, do you feel that it meets criteria for a UPIRTSO?

Yes  No  N/A – not a death

5. For UPIRTSOs, do you feel that the event is indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized?

Yes  No  Insufficient information  N/A – not a UPIRTSO

6. Do you feel that any protocol, informed consent or other modifications are warranted? Yes  No

If Yes:

* 1. describe the modification(s) that are warranted:
  2. should the study team notify previously enrolled subjects? Yes  No
  3. should the study team solicit updated consent and/or authorization from previously enrolled subjects? Yes  No

If Yes to c, when should such notification or consent and/or authorization take place and how should it be documented?

**IV. Apparent Serious and/or Continuing Noncompliance**

1.Do you feel that the event constitutes actual Serious and/or Continuing Noncompliance? Yes  No

*(To help determine whether it is* ***continuing****, review all logs of reported events for this study.)*

2. Do you feel that any remedial actions are needed to ensure present and/or future compliance?

Yes  - describe remedial action(s) needed:  No

**V. Systemic Deficiency**

1.Do you feel that the event constitutes an actual Systemic Deficiency that could substantially compromise the VA medical facility’s research protection program or information security processes? Yes  No

2. Do you feel that any remedial actions are needed to ensure the effectiveness of research protection programs or information security processes? Yes  - describe remedial action(s) needed:  No

**Additional Comments (if applicable):**

Definitions

**Adverse event (AE):** any untoward physical or psychological occurrence in a human subject participating in research, whether or not considered related to the subject’s participation in research.

**Continuing Noncompliance**: repeated instances of noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

**Identifiable Private Information:** Identifiable private information is information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the private information.

**Local Research:** Local research is research approved by the reporting VA medical facility regardless of whether it is conducted on-site or at another institution such as the VA medical facility’s academic affiliate.

**Noncompliance:** Noncompliance is any failure to adhere to applicable requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.

**Protected Heath Information (PHI):** Protected health information (PHI), as defined by the Health Insurance Portability and Accountability Act (HIPAA), is individually identifiable ***health*** information transmitted or maintained in any form or medium by a covered entity, such as VHA. NOTE: For more information, see VHA Directive 1605.01, Privacy and Release of Information. ***NOTE:*** *HIPAA Identifiers + Heath Information = PHI.*

*List of HIPAA Identifiers located :* [*https://www.portland.va.gov/research/documents/hrpp/18-HIPAA-identifiers.doc*](https://www.va.gov/portlandresearch/documents/hrpp/18-HIPAA-identifiers.doc)

**Research Information Security and Privacy Incidents (RISPIs):** include: *1)* any inappropriate access, loss, theft, noncompliant storage, transmission, removal or destruction of PHI or other VA research information deemed to be sensitive; *2)* theft, loss or noncompliant destruction of equipment containing PHI or other VA research information deemed to be sensitive; or *3)* uses and disclosures of PHI for research without legal authority (e.g., without a valid authorization or waiver of authorization).

**Serious Adverse Event (SAE):** an untoward occurrence, whether or not considered related to a subject’s participation 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 Noncompliance**: any failure to adhere to requirements for conducting research that may reasonably be regarded as: *1)* Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects or others, including their rights to privacy and confidentiality of identifiable private information; *2)* Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research; *3)* Presenting a genuine risk of substantive harm to the health or welfare of animals used in research; *4)* Presenting a genuine risk of substantive reputational harm to VA; or *5)* Substantively compromising a VA medical facility’s Animal Care and Use Program (ACUP), Human Research Protection Program (HRPP), Research Safety and Security Program (RSSP), or research information security processes.

**Systemic Deficiency:** A systemic deficiency is a fundamental, underlying problem that jeopardizes the effectiveness of a VA medical facility’s research protection system(s).

**UPIRTSO - Unanticipated Problem in Human Subjects Research Involving Risks to Subjects or Others:** an incident, experience or outcome that is: *a)* unexpected; *b)* related or possibly related to participation in the research; and *c)* indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

1) “Unexpected” refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

2) “Related to participation in the research” means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome.

3) “Possibly related to participation in the research” implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.

4) An apparent unexpected SAE that is related or possibly related to participation in human subjects research also meets the definition of a UPIRTSO for VA purposes (as per VHA Directive 1058.01).

Guidance Documents

[IRB Policies and Procedures](http://www.va.gov/portlandresearch/documents/irb/irb-sop.pdf) (see “Reportable Events in Research” section)

[VHA Directive 1058.01 – Research Compliance Reporting Requirements](http://vaww.va.gov/vhapublications/publications.cfm?Pub=1)

[VA National Rules of Behavior and VA Handbook 6500, Risk Management Framework for VA Information Systems—Tier 3: VA Information Security Program](https://www.va.gov/vapubs/Search_action.cfm?FormNo=6500)

***For Office Use Only:***

***INSTRUCTIONS:*** *Committee analyst/coordinator checks applicable items A-F, and then routes to IRB Co-Chair or designee. IRB Co-Chair or designee will review checklist, complete any needed items below and inform the committee analyst/coordinator when the minutes for the event may be completed.*

Check all of the following that apply:

1. Death (regardless of determinations made at convened meeting)
2. UPIRTSO:

the convened committee determined that the event was unexpected, related or possibly related to the research, and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized

the convened committee was unable to make a determination on the event due to insufficient information or due to a lack of sufficient time to complete its review

1. Serious and/or continuing noncompliance determination by convened committee
2. Suspension or early termination of VA Research by the IRB due to:

the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements; or

concerns about the safety, rights, or welfare of human subjects or others.

1. Systemic Deficiency
2. None of the above

***For IRB Co-Chair/designee Use Only:***

If any of the preceding boxes A-E in this section are checked, the following must occur:

Committee reports to Director, RCO and ACOS/R&D within 5 business days after determination:  *(date completed)*

Director reports to ORO within 5 business days after their notification:  *(date completed)*

If any of A-E in this section is selected, the following must also occur:

Director reports “promptly” to OHRP:  *(date completed)*

If FDA-regulated:

Director reports “promptly” to FDA:  *(date completed)*

n/a – not FDA-regulated