**Reportable Events – Initial 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#):**

**Initial Primary Reviewer:**       **Date Event Reviewed:**

***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. Death & Apparent UPIRTSO** *(only complete if* ***A and/or B*** *above is selected)*

1. Are any actions warranted to eliminate apparent **immediate** hazards to subjects or others?

[ ]  Yes *-* describe what actions need to be initiated promptly:[ ]  No

2. Does this event call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting?

[ ]  Yes- explain why immediate attention is required:[ ]  No

**III. Apparent Serious and/or Continuing Noncompliance** *(if* ***C*** *above is selected)*

1. Does this event call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting?

[ ]  Yes- explain why immediate attention is required:[ ]  No

*If no, the event will be scheduled for the next convened IRB meeting.*

**IV. Research Information Security and Privacy Incident** *(only complete if* ***D*** *above is selected)*

1. Are any actions warranted to eliminate apparent ***immediate*** hazards to subjects?

[ ]  Yes- describe what actions need to be initiated promptly:[ ]  No

2. ISSO, PO or Records Management office, as applicable, consulted for determining whether and what remedial actions are warranted? [ ]  Yes [ ]  No [ ]  N/A

3. Were immediate notifications made by the discovering individual, as per VA requirements (see **Report Timelines** on submitted REF)? [ ]  Yes [ ]  No

4. Does this event also meet criteria for any other type of event listed above (e.g. a UPIRTSO or Apparent Serious and/or Continuing Noncompliance)? ***NOTE:*** *This assessment includes failure to meet immediate notification timelines.*

[ ]  Yes *If YES, check the applicable box in section I, then complete the related subsequent section(s).*

 [ ]  No *If NO (e.g. RISPI only), further review by a convened board not required.*

**V. Systemic Deficiency** *(if* ***E*** *above is selected)*

1. Does the apparent systemic deficiency indicate persistent failure by any research review committee including the IRB?

[ ]  Yes *If YES, event report must be forwarded to R&DC for review.*

 [ ]  No *If NO, the event will be reviewed by convened IRB.*

2. Does this event call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting?

[ ]  Yes- explain why immediate attention is required:[ ]  No

*If no, the event will be scheduled for the next convened IRB meeting.*

**Additional Comments:**

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.va.gov/portlandresearch/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)

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[ ]  **Local Death that is local, unexpected, and related or possibly related**

[ ]  ORO and the Medical Facility Director notified by the ACOS/R&D (or designee), within 1 business day after receiving initial oral notification of the death, on  *(date completed)*

[ ]  Scheduled for next convened IRB meeting on  *(Note: must not exceed 30* ***calendar*** *days of initial written notification)*

*OR;*

[ ]  Immediate attention required. IRB to convene an emergency session on

[ ]  **UPIRTSO**

[ ]  Scheduled for next convened IRB meeting on  *(Note: must not exceed 30* ***calendar*** *days of initial written notification)*

*OR;*

[ ]  Immediate attention required. IRB to convene an emergency session on

[ ]  **Apparent Serious or Continuing Non-Compliance**

[ ]  Scheduled for next convened IRB meeting on  *(Note: must not exceed 30* ***calendar*** *days of initial written notification)*

*OR;*

[ ]  Immediate attention required. IRB to convene an emergency session on

[ ]  **Research Information Security and Privacy Incident**

[ ]  Scheduled for next convened IRB meeting on  *(Note: must not exceed 30* ***calendar*** *days of initial written notification)*

*OR;*

[ ]  Immediate attention required. IRB to convene an emergency session on

*OR;*

[ ]  N/A – *RISPI only; does not also meet criteria for UPIRTSO or Apparent Serious or Continuing Non-Compliance as noted in Section IV above.*

[ ]  **Systemic Deficiency**

[ ]  Report forwarded to R&DC per 1058.01 (e.g. persistent failure by IRB to adhere to requirements governing VA research)

[ ]  Scheduled for next convened IRB meeting on  *(Note: must not exceed 30* ***calendar*** *days of initial written notification)*

*OR;*

[ ]  Immediate attention required. IRB to convene an emergency session on