VA Portland Health Care System (VAPORHCS) Institutional Review Board

**Reportable Events Form (REF)**

**Report timelines:**

* **For category 1 (i.e. local death),** must be reported **orally to the IRB and Associate Chief of Staff for Research (ACOS/R) immediately, within one (1) hour**, upon awareness by the discovering individual. The death must then be **reported on this form within one (1) business day of awareness.**
* **For category 4 (RISPI),** VA policy requires an individual's **immediate reporting, preferably within one (1) hour,** of any suspected or actual information security or privacy incidents to their **supervisor and local Information Security Officer (ISSO), Privacy Officer (PO) and/or Records Management official, as applicable**, upon discovery. (See Guidance Documents below: “VA National Rules of Behavior and VA Handbook 6500, Risk Management Framework for VA Information Systems—Tier 3: VA Information Security Program.”)
* **For categories 2, 3, 4 and 5**, **report the event on this form within five (5) business days of awareness.**

**Report categories: *NOTE:*** *See “****Guidance Documents****” for further reporting guidance and “****Definitions****” section for bolded terms located below.*

1. **Death** that is **local, unexpected,** and **related** or **possibly related** –*Include* ***redacted*** *copies of all medical records relevant to the event.* ***NOTE: See report timelines above.***

***NOTE:*** *If event is for death that is local, unexpected and related or possibly related, also indicate if it constitutes an apparent UPIRTSO.*

1. Apparent **UPIRTSO (Unanticipated Problem in Human Subjects Research Involving Risks to Subjects or Others)** –*For local AEs meeting this definition, include* ***redacted*** *copies of all medical records relevant to the event. If the event is an outside report of an offsite AE meeting this definition, submit documentation received from the sponsor, etc.*
2. Apparent **Serious** and/or **Continuing Noncompliance** – *This includes protocol deviations that meet criteria for reporting (e.g. Apparent Serious Noncompliance). Protocol deviations that do not meet criteria for reporting on this form must be summarized and submitted at continuing review/annual review/annual check-in.*
3. **Research Information Security and Privacy Incident (RISPI)** – ***NOTE:******See report timelines above.***
4. Apparent **Systemic Deficiency** *-* ***NOTE****: An event that meets this criterion for reporting does not necessarily need to be study-specific and may be submitted by any VA personnel who becomes aware of any apparent systemic deficiency (see definition below).*

**FOR VA IRB STUDIES: Submit this completed form and any attachments to** [**pvamc-irb@va.gov**](mailto:pvamc-irb@va.gov) **or via the IRB Secure Fax Line #503-273-5152. NOTE: If the REF does NOT include Social Security Number(s) it may be submitted via VAIRRS.**

**FOR OHSU/VA Joint IRB STUDIES:** **Submit this completed form in an eIRB Reportable New Information (RNI) submission.**

* ***NOTE: Do NOT include any PHI in this form or in the eIRB RNI submission.***

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| --- | --- | --- | --- | --- |
| Report Date: | | **New** event #(s) being reported: | | |
| Principal Investigator: | | IRB Study ID #: | | |
| Title of Study: | | | | |
| Study Contact: | | Mail Code | | Ext. |
| Study Status:  Not Yet Started  Active  Closed to enrollment  Finalized (e.g. not active with the IRB) | | | | |
| # of VAPORHCS participants/records enrolled/reviewed: | # of VAPORHCS participants still in treatment: | | Total # of participants/records enrolled/reviewed at all sites: | |

*This is a cumulative log of all events for the study. To add an event, place the cursor in the first blank cell and start typing – the cell will expand to accommodate your information. To add a new row, place the cursor to in the last cell (bottom right cell) and press the Tab key.*

| **Event #** | **Date (or Date Range) Event Occurred** | **Date Team First Became Aware of Event** | **Report Category:**  **Indicate all applicable category #s (1-5) from page 1. (e.g. death/ category 1, that also constitutes an apparent UPIRTSO/ category 2)** | **For category 1 or 4:**  **Date of Immediate Reporting by Discovering Individual (as indicated above).** *If date unknown, explain.* ***If neither category 1 nor 4 applies, enter “n/a.”*** | **Concise Description of Event and Related Information *(attach separate pages with additional details, if needed)*:**   1. **Describe the event that prompted the report.** 2. **As applicable, explain why the event fits criteria for the report category(s) indicated on the form.** 3. **As applicable, explain how the event has been and/or will be addressed/resolved.** 4. **As applicable, explain how such occurrences will be avoided in the future.** 5. **If the event is an UPIRTSO or local death:**    * **Indicate the related participant #;**    * **If it is a follow-up for the same participant in a previously reported event, note that event #(s); and**    * **Note the event #s of similar events that have occurred previously with other participants.** 6. **If the event is an outside report of an *offsite* AE note the related participant # here.** | **How many times has this event occurred to date, including current event being submitted?** (*e.g. if two previous subjects didn’t sign the HIPAA authorization and this event is reporting a third subject not signing an authorization, enter “3” here)* | **Are any related modifications to protocol and/or other study documents planned?**  *(If Yes, indicate when the related request and revised documents will be submitted.)* |
| --- | --- | --- | --- | --- | --- | --- | --- |
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***Submission of this form by a member of the research team indicates that the PI is aware of the event and concurs with the content of the report.***

General Link to ORO Publications and Guidance: <https://www.va.gov/ORO/oropubs.asp>

Guidance Documents:

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

[Examples of Events in VA Human Subjects Research that Constitute Serious or Continuing Noncompliance](https://www.va.gov/ORO/Docs/Guidance/1058_01_Examples_App_Serious_Cont_NonCom_HumanRsch_03_08_21.pdf)

[Decision Chart: Reporting of Systematic Deficiencies and Noncompliance in VA Research](https://www.va.gov/ORO/Docs/Guidance/Reporting_of_Systemic_Deficiencies_and_Noncompliance_in_VA_Research.pdf)

[Decision Chart: Reporting Human Deaths, Unanticipated Problems and Accident, Injury, Illness and Exposure in VA Research](https://www.va.gov/ORO/Docs/Guidance/Reporting_Human_Deaths_Unanticipated_Problems_and_Accident_Injury_Illness_and_Exposure_in_VA_Research.pdf)

[Guidance on Reporting Deficient HIPAA Authorizations](https://www.va.gov/ORO/Docs/Guidance/Deficient_HIPAA_Authorizations.pdf)

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

[IRB Policies and Procedures (P&P)](https://www.va.gov/portlandresearch/documents/irb/irb-sop.doc) - *see “Reportable Events in Research” section*

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). ***NOTE:*** *See definition of PHI above.*

**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 (***NOTE:*** *See Identifiable Private Information definition above*); *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).