Dartmouth College

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

[CPHS.Tasks@Dartmouth.edu](mailto:CPHS.Tasks@Dartmouth.edu) • 603-646-6482

**CPHS Reporting Form**

**Unanticipated Problems Involving Risks to Subjects or Others (UPRs), Serious Adverse Events (SAEs), and Unanticipated Adverse Device Effects (UADEs)**

**Please complete: CPHS# PI:**

* This form should be used to report both medical and non-medical unanticipated problems involving risks.
* Reportable events may include breach of confidentiality, incarceration, and complaints. See the CPHS SOP for more info.
* Respond to each item, even if to indicate N/A or not applicable. Definitions appear on the last page of this form.
* Attach this form as supporting information on the Reportable New Information page in RAPPORT
* Please also attach any supporting documents about the event such as a memo, discharge summary, clinical notes, MedWatch or IND Safety Report, or UADE Sponsor Report on Question 7 of the Reportable New Information form in RAPPORT.
* The term “event” in this form could refer to an event or problem.
* If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding, highlighting, or by deletion.

**Timeframe for reporting events**:

**Upon notification/immediate:**  PI or sponsor has temporarily or permanently suspended current activities (due to potential harm to subjects).

**One week:** Serious events

**Ten days:** Unanticipated Adverse Device Effects (UADE)

**Two weeks**: Events that are not deemed serious but do meet the criteria outlined below

More information is provided below.**\***

1. **Criteria for reporting: SAE, UADE, and UPR**

In the opinion of the PI, was the event:

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
|  |  | Unexpected in terms of nature, specificity, severity, or frequency, given:   * What is described in the protocol, I.B., Research Plan, or consent form? * The characteristics of the population being studied? |
|  |  | Related or possibly related to participation in the research? |
|  |  | Seriously harmful, or suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, social, or economic harm)? Or a decrease in benefit? |
| ☐ | ☐ | Locally relevant:   * Event occurred on a study that is reviewed by the CPHS, or * Event occurred on a study reviewed by an external IRB, and the event or problem occurred locally, or * Report references an agent, product or procedure involved in this study |



If **all** the answers in the table above are ‘yes’, continue to next section.

If **any** of the answers are ‘no’, **stop -** and report in summary form at the time of continuing review. This event does not need to be reported as an RNI.

Reporting criteria differs based on whether the event was internal or external.

* **Internal Event:**

- CPHS is the reviewing IRB for the site where the event occurred.

- CPHS is not the reviewing IRB, but the event involved a local participant.

For internal events, continue to question 2.

## External Event:

- Event at a non-local site where the CPHS is not the reviewing IRB.

- Reports such as IND Safety Report, dear investigator letter, or a black box warning.

For external events, please answer the following about the event/problem, and the planned response:

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** |  |
| ☐ | ☐ | Has the Dartmouth PI determined any of the following are needed in response to the event:   * modifications to the protocol, consent form, or other documents. * notification of current participants. |
| ☐ | ☐ | Has the sponsor, DSMB or other party determined any of the following are needed in response to the event:   * modifications to the protocol, consent form, or other documents. * notification of current participants. |



If either answer in the table above is ‘yes’, continue to the next question, question 2.

If the answer to both questions above is ‘no’, **stop-** and report in summary form or as part of a Data Safety Monitoring Report at the time of continuing review. This event does not need to be reported as an RNI.

1. **Date of the event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ This report is a(n)** Initial Follow-up

1. **The investigator is reporting this incident to***:*

CPHS only  Sponsor  Other (e.g., program officer): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Has this event been reported to the FDA, OHRP, and/or others?** Yes No\*

*\*If no, does the sponsor intend to do so?* Yes No

1. **Study type:**  Multi-site  Dartmouth Only
2. **Is the risk of this event described in the consent form or in the investigator's brochure?**

No

Yes, but it has occurred with greater specificity

Yes, but it has occurred with greater frequency

Yes, but it has occurred with greater severity

Yes, but none of the above (Do not report to CPHS unless study modifications are planned which are directly related to this event/risk). Explain here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Describe the response as a result of this event, including the plan to protect or notify currently enrolled individuals.**
2. **Is a modification to the study planned by the sponsor or local investigator? Please describe the expected timeline.**
3. **Optional Additional Information:**

**Definitions and other information:**

**Unanticipated Problem Involving Risks to Subjects or Others (UPR):** Any incident, experience, or outcome that is unanticipated, at least possibly related, and suggests the research places subjects or others at a greater risk of harm than previously known.

**Unanticipated-** The incident, experience or outcome is not expected in terms of nature, severity, or frequency given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and consent document; and (b) the characteristics of the subject population being studied.

**Related-** there is a reasonable possibility that the incident, experience, or outcome may have been associated with the procedures involved in the research.

**Serious Adverse Event (SAE)** is an adverse event that is both serious and unexpected.

**Adverse Event** is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in research, whether or not considered related to the subject’s participation in the research.

**Serious**: Death; a life-threatening adverse drug experience; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect.

**Unexpected**: Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure or consent form.

**Unanticipated Adverse Device Effect (UADE):**

An unanticipated adverse device effect is any serious adverse effect on health or safety, or any life-threatening problem or death, caused by or associated with an investigational device. Internal Unanticipated Adverse Device Effects (UADE) reports must be made within 10 working days. The sponsor is required to report events directly to IRBs within 10 working days; for external events the Dartmouth PI does not need to report directly to the CPHS as the sponsor is required to do so- unless the Dartmouth PI is the sponsor.

**\* Prompt Reporting:** The appropriate time frame for satisfying the requirement for prompt reporting will vary depending on the specific nature of the unanticipated problem, the nature of the research associated with the problem, and the entity to which reports are to be submitted. For example, an unanticipated problem that resulted in a subject’s death or was potentially life-threatening generally should be reported to the IRB within a shorter time frame than other unanticipated problems that were not life-threatening. Therefore, please adhere to the following guidelines in order to satisfy the requirement for prompt reporting:

1. Unanticipated problems that are serious adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event.

2. Any other unanticipated problem should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.

**Additional UADE reporting information FDA requirements for sponsors:**

**Occurring at a site NOT subject to CPHS review:** Sponsors must immediately conduct an evaluation of a reported UADE, and report the results of the evaluation to the FDA, all reviewing IRBs, and participating investigators within 10 working days after the sponsor first receives notice of the effect.

[21 CFR 812.46(b), 812.150(b)(1)]

**Note:** When UADE reports are sent to the CPHS directly from the sponsor, the PI should not send an additional report to the CPHS.

References:

Dartmouth CPHS Standard Operating Procedures (SOP)

FDA January 2009 Procedural Guidance: Guidance for Clinical Investigators, Sponsors, and IRBs—Improving Human Subjects Protection. <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf>

OHRP January 15, 2007 Guidance: Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events. <http://www.hhs.gov/ohrp/policy/advevntguid.html>

For further guidance, questions, or concerns, contact the CPHS at 603-646-6482