REPORTABLE NEW INFORMATION (RNI) FORM

The term **Reportable New Information (RNI)** has been adopted to represent a broad categorization of events including Unanticipated Problems, Adverse Events, Protocol Deviations/Violations, Noncompliance, audit or monitoring results, newly identified risks, etc. that may be reportable per University policy and federal regulatory requirements.

Use this form to report events, including Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO), which fit the definition of promptly reportable events. See Section 1 below for description of events that require prompt reporting. The IRB defines ‘prompt’ to be **within 5 working days of discovery of the event**.

If an event does not meet the criteria outlined below, report it to the IRB in summary form at the time of continuing review.

1. **REPORTABLE EVENTS – REPORT TYPE**

1.1. Events listed below require prompt reporting to the DU IRB. Indicate the type of information that is being reported.

- Unexpected death of a locally enrolled subject whether considered related to the research or not. Death is considered unexpected if the risk is not listed in the consent form or is not listed the protocol narrative. **(IRB must be notified in writing within 24 hours of event)**

- Adverse event (any harm experienced by a subject regardless of whether the event was internal (on-site) or external (off-site) and regardless of whether the event meets the FDA definition of “serious adverse event”), which in the opinion of the principal investigator is both unexpected and related.

- Information that indicates a change to the risks or potential benefits of the research. For example: Interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits might be different from those initially presented to the IRB.

- Paper is published from another study that shows that the risks or potential benefits of your research might be different from those initially presented to the IRB.

- A breach of confidentiality.

- Incarceration of a subject in a protocol not approved to enroll prisoners. Complete Appendix D: Research involving Prisoners and submit with this report form.
Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.

Audit, inspection, or inquiry by federal agency.

Event that requires prompt reporting to the funding agency or sponsor.

Sponsor, investigator, or institution imposed suspension or premature termination for risk.

Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.

Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

Allegation of investigator or study team non-compliance or finding of investigator or study team non-compliance.

Other information that the PI determines is related to the research and indicates that participants or others might be at increased risk of harm; or that may affect a subject’s willingness to continue to participate.

2. **PROBLEM/EVENT INFORMATION**

2.1. Date of problem/event: **CLICK HERE TO ENTER A DATE.**

2.2. Date PI/study team was aware of problem/event: **CLICK HERE TO ENTER A DATE.**

2.3. Location of the problem/event:

   - On-site (under DU PI oversight)
   - Off-site (under oversight of the PI at another institution)

2.4. Include relevant information about the location of the event: **CLICK HERE TO ENTER TEXT.**

2.5. Description of the problem/event including the nature and severity of the problem: **CLICK HERE TO ENTER TEXT.**

2.6. Describe the likely impact of the event on the risk to the study subjects or others: **CLICK HERE TO ENTER TEXT.**
2.7. The event or problem potentially unfavorably affects:
- Rights/welfare of subject(s)
- Safety or privacy of subject(s)
- Integrity of research data
- Willingness of subject(s) to continue participation
- Other: [Click here to enter text.]

3. Reporting and Actions

3.1. Will the participant(s) continue in the study?
- Yes  No

3.2. Has the study been put on hold because of this problem/event?
- Yes  No

   If ‘YES’ has the entire research team been notified?
   - Yes  No

3.3. In your opinion, should currently enrolled subjects be notified of this problem/event?
- Yes  No

   If ‘YES’, attach a copy of the notice and provide a description of the notification process:
   [Click here to enter text.]

3.4. Should the consent form or any study procedures be modified as a result of this problem/event?

   - Yes, revised documents attached
   - No, insufficient data to make determinations
   - No, isolated incident
   - No, already noted in the study materials

3.5. What actions, if any, have been taken to address the situation? If none, mark the box below NONE.
   [Click here to enter text.]

3.6. What corrective actions are proposed to be taken?
   [Click here to enter text.]

3.7. Will any sponsors, collaborators, or other agencies need to be notified?
   - Funding agency
   - Sponsor/Department
Collaborators
DU Sponsored Programs
Other: Click here to enter text.

Name of Person Reporting Event: Click here to enter text.
Role in Project: Click here to enter text.