

Unanticipated Problems Reporting Form

Instructions: Only items meeting the definition of an unanticipated problem are required to be reported to the IRB. All unanticipated problems should be reported to Compass IRB within 10 business days of discovery (except when event is a death in which case please report within 5 business days of discovery). Please read and complete all sections carefully and attach corresponding report. Any missing information may result in a delay in the review.

| | |
|---------------------------------------|--------------------|
| Sponsor: | Protocol #: |
| Principal Investigator's Name: | |
| Compass IRB #: | |

Definitions

Unanticipated problem - Any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm. The harm does not have to be a direct harm to be reportable. The harm, as assessed by the PI or monitoring agent, has presented increased risk (e.g., losing a laptop with subject data). Additionally, the harm doesn't have to be the harm to subjects it could involve risk to others (researchers, technicians, bystanders, the public, etc.). *Note: non-medical events (e.g., breach of confidentiality, emotional breakdown, loss of insurance, etc.). if unanticipated - would also be reportable to the IRB.*

Unanticipated/Unexpected- An event is unanticipated or unexpected when its specificity or severity is not consistent with the current investigator brochure, protocol, consent form, package insert or label; or unanticipated in its frequency, severity, or specificity.*

Related – An event is related to a research procedures if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

Adverse Event – Is any physical, psychological or social harm to subjects during the course of research.

Event Information

| Protocol/Research Details |
|--|
| Type of Problem / Event (check box that applies; if none of these): |
| <input type="checkbox"/> Adverse Event which in the opinion of the principal investigator is both unexpected and related. <i>**Please attach full SAE and/or UADE Report as submitted to Sponsor for review.</i> |
| <input type="checkbox"/> An unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk |
| <input type="checkbox"/> Information that indicates a change to the risks or potential benefits of the research. For example: <ul style="list-style-type: none"> • <u>an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB</u> • <u>a paper is published from another study that shows that the risks or potential benefits</u> |
| <input type="checkbox"/> A breach of confidentiality |
| <input type="checkbox"/> Incarceration of a participant in a protocol not approved to enroll prisoners |
| <input type="checkbox"/> Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant |
| <input type="checkbox"/> Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team |
| <input type="checkbox"/> Event that requires prompt reporting to the Sponsor |
| <input type="checkbox"/> Sponsor imposed suspension for risk |

| Event Details | |
|---|---|
| Briefly describe the circumstances of this event: | |
| Classify the event [e.g. pregnancy, death, adverse event, life-threatening, prolonged hospitalization, or other (and define)] | |
| Event date: | Subject Initials or Case # (if applicable) |
| Is this your initial notification of this event to the IRB? | <input type="checkbox"/> Yes <input type="checkbox"/> No** **If no, please proceed to <i>Document Attachments</i> section |
| How long did the event last? | |
| Was the event study-related? | |
| Currently enrolled subjects will be notified of this event? | <input type="checkbox"/> Yes** <input type="checkbox"/> No **If yes, describe method of notification |
| Previously enrolled subjects will be notified of this event? | <input type="checkbox"/> Yes** <input type="checkbox"/> No **If yes, describe method of notification |
| Do you expect this event to occur again? | <input type="checkbox"/> Yes <input type="checkbox"/> No Is the event effectively described in the consent form and protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Should the consent form be modified as a result of this event? | <input type="checkbox"/> Yes** <input type="checkbox"/> No If "Yes," please submit your recommended changes. |

| Subject Details | |
|---|---|
| Subject's age | Volunteer gender <input type="checkbox"/> Male <input type="checkbox"/> Female |
| Did this event involve a healthy volunteer? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Subject Status | <input type="checkbox"/> <u>Pre-Screening</u> <input type="checkbox"/> <u>Follow-Up</u> <input type="checkbox"/> <u>Dosed / Randomized</u> <input type="checkbox"/> <u>Completed</u> |

| Protocol/Research Details |
|--|
| Enrollment Status at Your Site (check one): <input type="checkbox"/> Open to Enrollment <input type="checkbox"/> Closed to Enrollment – Subjects still active or in follow-up <input type="checkbox"/> Study Completed – No further study-related activity at your site |

Indicate where this research is taking place:

- Multi-center study, but the event occurred here
- Multi-center study, but the event occurred off-site
- Single-site study, this study is only being conducted at my site

My protocol involves:

- Investigational Drug
- Investigational Device
- Other: _____

Document Attachments

| | |
|--|--|
| This event prompted a change to the Consent Document(s)? | <input type="checkbox"/> Yes** <input type="checkbox"/> No **If yes, attached version number/date is: |
| This event has prompted a change to the protocol | <input type="checkbox"/> Yes** <input type="checkbox"/> No **If yes, attached version number/date is: |
| This event has prompted a change to the Investigator's Brochure / Package Insert / User's Manual | <input type="checkbox"/> Yes** <input type="checkbox"/> No **If yes, attached version number/date is: |

Additional Information

Is there any additional information you need to share with Compass IRB? Yes No
 If "Yes," please take this space to share with us?

I hereby certify that I have fully disclosed all information pertaining to this event and that the above-referenced information is accurate.

Signature of Submitting Party:

_____ Name

_____ Title

_____ Signature

_____ Date

| | | |
|--|---|----------------------|
| COMPASS IRB INTERNAL USE ONLY: | | CIRB Staff ID: _____ |
| Is this report appropriate for review? <input type="checkbox"/> Yes <input type="checkbox"/> No | | |
| If "No," please list reason that report is inappropriate for review (e.g. does not meet definition of unanticipated problem, incomplete report): | | |
| Decision of Reviewer: | | |
| Is this event an unanticipated problem that involves risk to participants or others? <input type="checkbox"/> Yes <input type="checkbox"/> No | | |
| Is there information in this report that involves an allegation of non-compliance? <input type="checkbox"/> Yes** <input type="checkbox"/> No | | |
| If yes, must request a site audit and/or send to Full Board. | | |
| <input type="checkbox"/> No further action necessary | <input type="checkbox"/> Request Audit* | |
| <input type="checkbox"/> Request additional information* | <input type="checkbox"/> Send to Full Board | |
| <input type="checkbox"/> Call Site / Sponsor for discussion* | | |
| Comments/Notes (as needed): | | |
| _____ Signature of Board Reviewer | | _____ Date |
| * If checked, please attach all follow-up documentation to this report and resubmit to Board Reviewer. | | |

**Please mail, email to submissions@compassirb.com,
or fax this form to (480) 832-7376.**