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| **Purpose:** This form is designed to help facilitate the reporting of events that occur in human subject research, including unanticipated problems, adverse events, non-compliance, protocol deviations, etc. |

**Instructions:** Use this form to report events to the IRB no later than 7 days of the investigator becoming aware of the occurrence. *Investigators should contact Research Compliance Services (RCS) immediately upon discovery of an unanticipated problem involving risks to subjects or others.* In addition to RCS, guidance on reporting unanticipated problems can be found at the Office for Human Research Protections (OHRP) [website](http://www.hhs.gov/ohrp/policy/advevntguid.html).

Please submit by email this form and all applicable research materials to [ResearchCompliance@uoregon.edu](mailto:ResearchCompliance@uoregon.edu). If you have any questions, please contact RCS by [email](mailto:ResearchCompliance@uoregon.edu) or phone (541-346-2510). RCS will communicate to the investigator the determination of the event review and/or any further actions required by the IRB.

Save this form to your computer before proceeding.

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| 1. General Information | |
| **Principal Investigator:** | **Today’s Date:** |
| **Faculty Advisor:** | **Protocol Number:** |
| **Study Title:** | |

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| 1. Event Reporting | | | |
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| * 1. Date(s) of Event: | | | |
|  | | | |
| * 1. Date(s) of Discovery (if different from above): | | | |
|  | | Explain, if different: | |
|  | | | |
| * 1. Is this study funded/sponsored? | | | |
|  | | Yes  No | |
| **If “Yes”, has this event been reported to the funder/sponsor?** | | | |
|  | | | Yes  No Please Explain**:** |

| 1. Event Details | | | | |
| --- | --- | --- | --- | --- |
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| * 1. Type of Event (check all that apply). | | | |
| Protocol deviation | | | Change in FDA labeling or marketing of drug/device |
| Protocol violation | | | HIPAA violation |
| Breach of confidentiality of data | | | Physical harm/injuries/death to participants |
| Interim findings or safety monitoring report | | | Psychological, social or economic harm to participants |
| Complaint (participant or other) | | | Unexpected number of participant withdrawals |
| Incarceration of a participant | | | Threat to participant safety |
| Other: | |  | |
|  | | | |
| * 1. Describe the event (attach additional pages or supplementary information as necessary): | | | |
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|  | | | |
| * 1. Location of event: | | | |
|  | | | |
| * 1. Are there other research sites associated with this study? | | | |
|  | Yes  No If “Yes”, list additional sites: | | |
|  | | | |
| * 1. Number of participants involved: | | | |
|  | | | |
| * 1. Has/have the participant(s) been withdrawn from further participation? | | | |
|  | Yes  No Please explain: | | |
|  | | | |
| * 1. Is the study still open to enrollment? | | | |
|  | Yes  No | | |
|  | | | |
| * 1. If the study is closed to enrollment, are currently enrolled participants still undergoing study procedures? | | | |
|  | Yes  No  n/a If Yes, explain: | | |
|  | | | |
| * 1. If the study is closed to enrollment, is long term follow-up to occur? | | | |
|  | Yes  No  n/a If Yes, explain: | | |
|  | | | |
| * 1. Has study enrollment or other activities been suspended or terminated by the investigator or study sponsor? | | | |
|  | Yes  No If “Yes”, explain and indicate by whom: | | |

| 1. Event Severity (in the judgment of the Principal Investigator) | | |
| --- | --- | --- |
|  | |
| * 1. What is the estimated seriousness of the event? | |
|  | Mild-for example, does not limit or interfere with daily activities; expected to resolve quickly with no physical, psychological, social, or economic consequences; minimal impact to participants, etc. |
|  | Comments: |
|  | Moderate-for example, enough discomfort to interfere with daily activities; treatment of symptom(s) may be needed; expected to resolve but short term physical, psychological, social, or economic consequences are possible, etc. |
|  | Comments: |
|  | Severe-for example, life-threatening; event results in significant symptoms that prevents normal daily activities; may require hospitalization or invasive intervention; long term physical, psychological, social, or economic consequences are possible, etc. |
|  | Comments: |
|  | Fatal |
|  | Comments: |
|  | |
| * 1. The event was unexpected or unanticipated: | |
|  | Yes  No Please explain: |
|  | |
| * 1. The event was related or possibly related to participation in the research: | |
|  | Yes  No Please explain: |
|  | |
| * 1. The event suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized: | |
|  | Yes  No Please explain: |

| 1. Corrective Action (implemented and/or proposed by the Principal Investigator) | | |
| --- | --- | --- |
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| * 1. What, if any, corrective actions have already been taken to mitigate the event and/or eliminate apparent immediate hazards to subjects? | |
|  | Comments: |
|  | |
| * 1. Should the Research Plan be amended (example: change in inclusion/exclusion criteria, change participant enrollment numbers, additional procedures for monitoring participants, change in recruitment/consent processes, etc.)? | |
|  | Yes  No Please explain: |
|  | |
| * 1. Should the recruitment documents(s) be revised? | |
|  | Yes  No Please explain: |
|  | |
| * 1. Should the consent document(s)be revised? | |
|  | Yes  No Please explain: |
|  | |
| * 1. Should currently enrolled participants be notified or re-consented? | |
|  | Yes  No Please explain: |
|  | |
| * 1. Should previously enrolled participants be notified? | |
|  | Yes  No Please explain: |
|  | |
| * 1. Should targeted training of research personnel be provided? | |
|  | Yes  No Please explain: |
|  | |
| * 1. Are there any other corrective actions proposed? | |
|  | Yes  No Please explain: |

*[Remainder of page intentionally left blank; signature page to follow.]*

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| 1. Investigator and Faculty Advisor Signatures |
| * I certify the information provided in this Event Review Form correct and complete. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |

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| **Principal Investigator Signature Date**   * *Electronic signatures acceptable. You may type in the name of the Principal Investigator* * *If the person emailing this form is not the Principal Investigator, the Principal Investigator must be copied on the form submission.* | |
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| **REQUIRED FOR STUDENT RESEARCH**   * By signing this form, the faculty research supervisor attests that (s) he has reviewed the event form and has discussed the event, the causes and the corrective action with the PI. | |

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|  | *Click here to type name or insert electronic signature.* |  | *Click here to enter a date.* |  |

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| Faculty Advisor Signature Date   * *Electronic signatures acceptable. You may type in the name of the Faculty Advisor.* * *If the person emailing this form is not the Faculty Advisor, the Faculty Advisor must be copied on the form submission.* |