**RAP Form  
Reportable New Information (RNI)**

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| **Purpose:** This is a supplemental application form to be included with your electronic application submitted through the Research Administration Portal (RAP) system to facilitate the reporting of events that occur in human subject research, including unanticipated problems, adverse events, non-compliance, protocol deviations, etc.  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.*  Additional 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). |

**Instructions:** Attach this application and, where indicated, all applicable research materials in a Reportable New Information (RNI) submission of the Research Administration Portal (RAP). Direct any questions regarding this form or human subjects research to Research Compliance Services (RCS) by [email](mailto:ResearchCompliance@uoregon.edu) or phone (541-346-2510). Save this form before proceeding.

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| 1. General Information | |
| * 1. **Name and title of the person completing this form:** |  |
| * 1. **IRB Number**   **(e.g. STUDY00000XXX)** |  |

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

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| Part III: Event Details | | | | |
| * 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 below. | | |
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| * 1. Number of participants involved: | | | | |
|  | | | | |
| * 1. Has/have the participant(s) been withdrawn from further participation? | | | | |
| Yes  No | | Explain below. | | |
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| * 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 below. | |
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| * 1. If the study is closed to enrollment, is long term follow-up to occur? | | | | |
| Yes  No  n/a | | | If Yes, explain below. | |
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| * 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 below. | | |
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| Part IV: 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. | |
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|  | 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. | |
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|  | 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. | |
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|  | Fatal | |
|  | | |
| 1. The event was unexpected or unanticipated: | | |
| Yes  No | | Explain below. |
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| * 1. The event was related or possibly related to participation in the research: | | |
| Yes  No | | Explain below. |
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| * 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 | | Explain below. |
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| Part V: Corrective Action (implemented and/or proposed by the Principal Investigator) | |
| * 1. What, if any, corrective actions have already been taken to mitigate the event and/or eliminate apparent immediate hazards to subjects? | |
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| * 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 | Explain below. |
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| * 1. Should the recruitment documents(s) be revised? | |
| Yes  No | Explain below. |
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| * 1. Should the consent document(s)be revised? | |
| Yes  No | Explain below. |
|  | |
| * 1. Should currently enrolled participants be notified or re-consented? | |
| Yes  No | Explain below. |
|  | |
| * 1. Should previously enrolled participants be notified? | |
| Yes  No | Explain below. |
|  | |
| * 1. Should targeted training of research personnel be provided? | |
|  | |
| Yes  No | Explain below. |
| * 1. Are there any other corrective actions proposed? | |
| Yes  No | Please explain: |
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