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| Event Report  The purpose of this form is to inform the IRB about a reportable event related to a project.   |  |  | | --- | --- | | Instructions: | Submit this form within seven (7) days of event discovery.  Sections marked with an asterisk ( \* ) are required.  Sections marked with a double asterisk ( \*\* ) are required if applicable. | | C:\Users\cbcholka\AppData\Local\Microsoft\Windows\INetCache\Content.Word\UNM_OfficeInstitutionalReviewBoard_Horizontal_RGB.PNG  1805 Sigma Chi NE | Tel: (505) 277-2644  Website: irb.unm.edu | Email: [IRBMainCampus@unm.edu](mailto:IRBMainCampus@unm.edu) |

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| Project Identification | | | |
| *\* IRB reference number:* |  | *\* Project title:* |  |

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| Principal Investigator of Record | | | | | | | | | | | | |
| \* The Principal Investigator of record is: *(select one)* | | | | | Principal Investigator | | | Responsible Faculty | | | | |
| \* Name: |  | | | | | \* Phone: |  | | | \* Email: |  | |
| \* Department: | |  | | \* University Status (e.g. tenure track or visiting faculty, instructor, staff, etc.): | | | | | | | |  |
| \* Affiliation: | | Main Campus | UNM Branch Campus: | | | | | | External Partner: | | | |

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| Additional Contact Person | | | | | | | | | | |
| \*\* The contact person for this project is: *(select one)* | | | | Student Investigator | | | Project Coordinator | | | |
| \*\* Name: |  | | | | \*\* Phone: |  | | \*\* Email: |  | |
| \*\* Department: | |  | \*\* University Status (e.g. undergraduate, master’s or PhD student, staff, etc.): | | | | | | |  |

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| Project Information | | | | | | | | | |
| *\* Is the project funded?* | No | | Yes | | *\*\* If yes, has the funder been notified of the event?* | | | No | Yes |
| *\* What is the enrollment status of this project?* | Open to enrollment | | | | | Closed to enrollment | | | |
| *\* Identify project activities that are happening as of today:* | |  | | Project is collecting data through participant interactions or interventions | | | | | |
|  | | Project is limited to data analysis | | | | | |
| *\*\* For projects closed to enrollment but still collecting participant data, please describe in detail the procedures that continue:* | | | | | | | | | |
| *\* Provide participant enrollment statistics:* | *Total enrolled to date =* | | | | | |  | | |

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| Event Overview | | |
| *\* Date you became aware of the event:* | |  |
| *\* Identify the categories that represent the event: (check all that apply)* | | |
|  | **New or increased risk:** Information that indicates a new or increased risk of harm, or a safety issue. For example:   1. New information (e.g. an interim analysis, safety monitoring report, publication in the literature, funder report, or researcher finding) indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk. 2. Protocol violation that harmed participants or others, or that indicates participants or others might be at increased risk of harm. 3. Complaint from a participant or other that indicates participants/others might be at increased risk of harm or at risk of a new harm. | |
|  | **Unanticipated problem involving risk to participants or others:** Any incident that, in the opinion of the researcher, is unexpected, possibly related to the research procedures, and suggests that participants or others are at a greater risk of harm than was previously known.   1. A harm is “**unexpected**” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, or characteristics of the research population (e.g. not listed as risk in consent form). 2. A harm is “**possibly related**” to the research procedures if there is a reasonable possibility that the incident, experience, or outcome was more likely than not to have been caused by the research procedures. | |
|  | **Noncompliance:** Noncompliance with the federal regulations governing human research, institutional policies, or the requirements and determinations of the IRB (such as not following IRB approved processes). | |
|  | **Audit:** Audit, inspection, or inquiry by the IRB, a federal or other oversight agency, or funding agency. | |
|  | **Confidentiality breach:** Breach of research data confidentiality; loss or destruction of research data not in accordance with IRB approval. | |
|  | **Unreviewed change:** Any accidental or unintentional change to the IRB-approved protocol that involved risks or has the potential to recur. | |
|  | **Incarceration:** Interaction with or collection of data from an incarcerated individual in a project not IRB approved to involve prisoners. | |
|  | **Complaint:** Complaint of a participant that cannot be resolved by the research team. | |
|  | **Suspension:** Premature suspension or termination of the research by the funder, researcher, or institution. | |
| Event Details | | |
| *\* Provide a* ***detailed description of the event.***  *\* Provide a* ***corrective action plan to prevent recurrence of the event.***  *\*\* List any specific requests from the IRB.*  *NOTE: Use as much space as needed to fully explain the information required.* | |  |

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| In the opinion of the Principal Investigator… | | |
| *\* Was this event unanticipated?* | No | Yes |
| *\* Did the event cause harm or place participants or others at increased risk of harm?* | No | Yes |
| *\* Is it more likely than not that this event was caused by participation in the research?* | No | Yes |
| *\* Should the consent document and/or protocol be revised?* | No | Yes |
| *\*Should enrolled participants be re-consented?* | No | Yes |
| **IMPORTANT!** If an amendment to the project is needed, please submit a separate application package with revised document(s) for IRB review. | | |

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| Certification | | | |
| \* Signature below certifies that the information provided on this form is accurate. | | | |
| Principal Investigator of Record | | Student Investigator | |
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| \* Signature | \* Date | Signature | Date |