**FORM F – Accident/Exposure/ Noncompliance Incident Report**

**Idaho State University, Office for Research**
**Institutional Biosafety Committee (IBC)**

1651 Alvin Ricken Drive, Pocatello, ID 83201-8286
Phone: 208-282-1336

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This form should be used to report any laboratory accidents, exposures, or noncompliance with NIH Guidelines and ALL serious adverse events (SAE) that are **both** related or possibly related to the use of the human gene transfer product **and** unanticipated in either nature, severity, or frequency.

## *PLEASE TYPE THIS FORM*

| **DATE REPORT COMPLETED:** | **IBC Protocol No.** |
|---|---|
| **1. PRINCIPAL INVESTIGATOR:**<br>Name (Last, First): Campus OR Work Phone Number: Email Address: | |
| **2. IBC PROJECT TITLE:** | |
| **3. Report Involves the following (check all that apply) and answer applicable sections below** | |
| ☐ **Accident** | ☐ **Noncompliance with NIH Guidelines** |
| ☐ **Exposure** | ☐ **IBC reportable SAE** |
| ☐ **Major protocol violation/deviation involving human rDNA or synthetic nucleic acid transfer use** | ☐ **External reportable event- as determined by DSMB, DMC or other oversight committee** |
| ☐ **Any findings from laboratory animal testing that suggest a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity** | |

| **4. Description of Accident, Exposure, or SAE** |
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| **Date of the event** | |
| **Nature of Agent(s) involved (*Be specific regarding rDNA, Infectious Agent, Toxin*)** | |
| **Nature of Accident or Exposure (*Describe in Detail*)** | |
| **Location** | |
| **Personnel Involved (*List all those potentially exposed*)** | |
| **Dates of exposure to human rDNA or synthetic nucleic acid transfer product** | |
| **Dose at each exposure** | |
| **Was this the dose(s) specified in the protocol?** | ☐ **Yes** ☐ **No. If no, why?** |
| **Who has the incident be reported to (*Check all that apply*)?** | ☐ PI ☐ IBC ☐EH&S ☐ IACUC ☐ Other |

**5. If applicable, provide a description of the protocol noncompliance as it relates to NIH Guidelines.**

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| **6. If applicable, describe the SAE and its relation or possible relation to the use of the gene transfer product.** |
| **7. If applicable, provide a description of the protocol violation/deviation or noncompliance as it relates to the human gene transfer use.** |
| **8. If applicable, provide a description of the External Reportable Event.** |
| **9. If applicable, provide a description of new laboratory findings in animals.** |

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| **10a. Signature**<br>I have personally reviewed the information contained in the incident report and agree that it is complete and accurate. | |
| **Signature of Principal Investigator** | **Date** |

OR

| **10b. Signature**<br>Form Submitted by<br>☐ Environmental Health & Safety Office<br>☐ Assistant VP for Research Outreach & Compliance<br>. | |
|---|---|
| | **Date** |