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| **Lipscomb University Institutional Review Board: Adverse Event Report Form** | | | | | | | |
| **Reporting Researcher/s:** | | | | |  | **Date:** |  |
| **Principal Investigator:** | | | | Same as above | | | |
| **Project Title:** | | |  | | | | |
| **Study Description:** Dissertation Research Grant Proposal Master's Thesis Research Faculty Research  Undergraduate Research Other: | | | | | | | |
| **Report Type:** Initial Report Follow-up Report | | | | | | | |
| **Event Outcome:** Resolved Ongoing | | | | | | | |
| Investigators must report adverse events that occur during the course of their research with human subjects to the IRB in a timely fashion. An adverse event, as defined by the Department of Health and Human Services, is “an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).” An adverse event in non-medical research can include an undesirable and unintended consequence of, or reaction to, procedures. An unanticipated adverse event can also be defined as any adverse experience whose nature, severity, and frequency of risk were not described in the information provided for IRB review or in the consent form.  Only unanticipated adverse events that are associated with a research intervention must be reported to the IRB. An adverse event is considered to be associated with a research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (i.e., a causal relationship between the reaction and research intervention cannot be ruled out by the investigator(s)).  All adverse reactions and unexpected events should be reported as soon as possible to the IRB Chairperson (via email at irb@lipscomb.edu) no later than 96 hours from the time the investigator became aware of the problem. All fatal or life-threatening events MUST be reported to the IRB within 48 hours after discovery. Investigators should file such reports in writing, using this form. All relevant documents and supporting material should be included with this form. When attaching supporting material and consent forms, participants' personal identifiers (e.g., name, social security number) should not be included.  In some instances, a serious or unexpected adverse event may necessitate an immediate change in protocol to relieve an apparent immediate hazard to research participants. In such situations, the principal investigator may implement a change in protocol in order to protect the welfare of the research participants. Investigators should be certain to describe such changes in protocol in the Adverse Event Report Form. | | | | | | | |
| 1. | Please identify the participant or participants involved in the adverse event: | | | | | | |
| 2. | Was the adverse event serious? Yes No | | | | | | |
| 3. | If the adverse event was serious, please check all that apply: | | | | | |  |
|  | | Death  Serious/life threatening injury  Persistent or significant disability/incapacity  Hospitalization  Other (describe): | | | | |  |
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| 4. | Please provide a detailed description of the adverse event. Be sure to include terms that accurately characterize the adverse event as well as any pertinent participant health history: | | | | | | |
| 5. | Was the adverse event listed as a potential risk on the consent form? Yes No N/A | | | | | | |
| 6. | Please provide a detailed description of any actions taken in response to the adverse event including any changes to study protocol: | | | | | | |

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| Signature: |  | Date: |  |
| Please submit any documents/supporting materials with this form to the Institutional Review Board via email at irb@lipscomb.edu. | | | |