**UNANTICIPATED PROBLEMS REPORT (UPR) FOR RESEARCH INVOLVING HUMAN SUBJECTS**

Instructions:

1. Illness, injuries and other adverse events that are unexpected AND pose risk to participants or others must be reported for protocols that have a Wittenberg Institutional Review Board (IRB) approval.
2. Include a statement indicating that modifications to the research plan and/or informed consent documents are or are not necessary and provide justification.
3. Unanticipated problem(s) involving risk to subjects or other should be reported as promptly as possible, but no later than five business days after the Principal Investigator became aware of the event.
4. Submit completed form and required supporting documents to irbpetition@wittenberg.edu.
5. Keep a copy of this report in your research records along with the original signed consent forms.
6. For additional information see Wittenberg’s *Policy on Reporting Unanticipated Problems in Human Subjects Research.*

1. PROJECT TITLE AND IRB TRACKING NUMBER (*type in the space below)*

2. PRINCIPAL INVESTIGATOR (Wittenberg faculty or staff member, or faculty advisor for student investigators)

Name: E-mail:

Department: Phone:

3. CO-INVESTIGATOR(S) (list all investigators by Name, Email, and Phone Number)

1.

2.

3.

4.

5.

4. EVENT INFORMATION

Date event occurred:

Date event known to Principal Investigator:

Date report is being submitted:

5. EVENT CHARACTERISTICS

Select all the appropriate characteristics that apply to the unanticipated problem or adverse event.

 Event is ongoing as of this report

 Event resulted in hospitalization, treatment or supportive care for the subject

 Event was life-threatening

 Participant remains in the study

 Risk of this event was present in consent signed by subject who experienced this event

 Consent will be modified as a result of this event (further specify in question 7 below)

 Research plan will be modified as a result of this event (further specify in question 7 below)

 This event was likely to have been caused or related to the IRB approved research study. PI makes a judgement

 about whether the risk to subjects warrants the immediate suspension of data collection.

 This event was unlikely to have been caused or related to the IRB approved research study. PI makes a judgement

 about whether to suspend data collection.

6. NARRATIVE DESCRIPTION OF EVENT

1. Describe the event and how the event affected the rights, safety or welfare of the subject or others, current status of subjects.

7. STATEMENT REGARDING MODIFICATIONS TO THE RESEARCH PLAN OR INFORMED CONSENT

1. If you plan to modify the research plan or informed consent documents, describe those modifications here and provide copies of any new/modified documents.

8. NARRATIVE DESCRIPTION OF RESPONSE TO THE EVENT

1. Once the event occurred or once the Principal Investigator was made aware of the event, describe how the researchers handled the event and subject involved, including dates and locations. Describe how all subjects were informed of the event, if necessary.

9. ASSURANCE: INVESTIGATOR(S)

SIGNATURES OF ALL INVESTIGATORS (may be signed electronically with name and date)

|  |  |
| --- | --- |
| Investigator Name(s) | Date |
| Principal Investigator:  |  |
| Co-Investigator(s): |  |
|  |  |

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**OFFICE USE**

|  |  |
| --- | --- |
| IRB REVIEW | Date |
| Result of IRB Review  |  |
| IRB Chair Signature |  |