**Human Subjects Research Protocol: Problem Report**

**(Event reporting for unanticipated problems involving risks to subjects or others, adverse events, and other problems)**

# Institutional Review Board (IRB), Office of Sponsored Programs and Research (OSPR)

3904 Lonas Drive, Knoxville, TN 37909

Phone: (865) 288-8219 Fax: (865) 288-5900 [irbsubmissions@south.edu](mailto:irbsubmissions@south.edu)

|  |  |  |
| --- | --- | --- |
| **OFFICE USE** | **DATE RECEIVED:** | **PROTOCOL NUMBER:** |

**Flowchart for Reporting Events to the IRB**

**NO**

**Do not** report event unless it could affect participants’ willingness to continue in the study.

**YES**

Did the event involve risks to subjects or others?

* Includes adverse events, participant complaints, protocol deviations, other problems, and untoward events.
* May involve physical, psychological, social, legal, or economic harms.

**YES**

|  |  |  |
| --- | --- | --- |
| Was the event related to the research?   * Reasonable possibility that event was caused or affected by research procedures. * Includes events that are definitely, probably, or possibly related. |  | |
|  | **NO** |
|  |
|  |  |

Was the event unanticipated?

* Unforeseen given the nature of the research and subject population.
* Not described in the protocol, consent form, or other information given to participants.

**YES**

**NO**

**Report the event using this form.** Submit the **IRB Project Revision or Amendment Form** for proposed changes to the protocol.

Report event in summary form at continuing review and in the final study report using the **Problem Summary Sheet**.

**For more information on events that require prompt reporting and definitions of terms see *REPORTING RESEARCH-RELATED PROBLEMS* in the *South College IRB Policies and Procedures Manual for Human Subjects Research*.**

**1. PROJECT TITLE**

**2. PRINCIPAL INVESTIGATOR (If you are a**

**student, you must list a faculty advisor as the Co-PI)**

**CO-PRINCIPAL INVESTIGATOR**

**(Faculty advisor of student PI)**

Name (Last, First, MI): Name (Last, First, MI):

College Academic Title: College Academic Title:

Department Name: Department Name:

Campus Mailing Address: Campus Mailing Address:

E-mail: E-mail:

Phone: Phone:

**3. TYPE OF REPORT**

Adverse device effect ***(Report only if unanticipated.)***

Adverse event or injury ***(Report only if serious, unexpected, and related.)***

Breach of confidentiality ***(Report only if involving risk.)***

Data and Safety Monitoring Board (DSMB) report, interim analysis, or other oversight committee/monitoring report

## (Report information altering the risk/benefit profile.)

Event requiring prompt reporting ***(Report only when required by the protocol, sponsor, or funding agency.)***

Investigator’s brochure updates *(****Report revision(s) to safety information. Do not report routine updates.)***

## New information (Report information indicating an unexpected change in risks or potential benefits, e.g., literature/scientific report or other published finding.)

Protocol deviation, violation, or unintentional change to protocol or procedures ***(Report only those involving risk or with the potential to recur.)***

## Subject complaint (Report complaints indicating unanticipated risks or those that cannot be resolved by the research staff.)

Unapproved change made to the research to eliminate an apparent immediate hazard

Other problem or finding (e.g., loss of study data, a subject becomes a prisoner while participating in research) – specify:

|  |  |
| --- | --- |
| **4. ASSESSING THE EVENT** | |
| Does the event or information represent an unanticipated problem involving risks to subjects or others?  ***Unanticipated problems involving risks to subjects or others are defined as unforeseen events (given the nature of the research procedures and subject population) that suggest subjects, research staff, or others are placed at greater risk by the research than previously expected.*** | Yes No |
| Explain why or why not: | |

|  |  |
| --- | --- |
| **5. RESEARCH INTERVENTIONS OR INTERACTIONS** | |
| a. | The event involves (check all that apply): |
|  | Drug(s) |
|  | Device(s) |
|  | Research-related procedure(s) or activity |
|  | None of the above |

b. Provide the names or description of any drugs, devices, or study procedures/activities involved.

**6. SOURCE OF THE REPORT**

*Internal* (occurring in South College research, at a site under the South College IRB’s jurisdiction)

*External* (occurring in research at a site other than South College, over which a non-South College IRB has jurisdiction) If External, list the location where the research was performed and/or the event occurred.

**7. DATE(S) OF THE EVENT**

**8. DESCRIPTION**

Describe in detail the event or problem being reported. For medical events, include relevant dose, treatment, and laboratory information. ***Use complete sentences. Attach additional documents as necessary. Do not include (and remove as necessary) participants’ personally identifiable information.***

|  |  |
| --- | --- |
| **9. RESEARCH STATUS** | |
| a. | The research participant(s) involved is/are: |
|  | Still on study |
|  | No longer on study |
|  | N/A or unknown |
| b. | Research recruitment (in South College research at a site under the South College IRB’s jurisdiction) is: |
|  | Ongoing |
|  | Completed (or stopped) |
| c. | Research interventions/interactions involving other participants are: |
|  | Ongoing |
|  | Completed (or stopped) for all participants |

**10. OTHER REPORTING**

The adverse event or problem will also be reported to (check all that apply): Sponsor

Collaborating investigators

No other reporting or unknown Other – specify:

**11. ACTIONS TO BE TAKEN**

As a result of the event (check all that apply):

The protocol or study procedures will be modified. The consent form or process will be modified.

Additional information and/or follow-up will be provided to current and/or past participants. Current participants will be asked to re-consent to participation.

The research will be voluntarily placed on hold, pending more information or resolution of problem. ***(This requires immediate reporting.)***

The South College research is being stopped. ***(This requires immediate reporting.)***

No action is planned. ***Provide explanation below****:*

Other – specify:

**Provide *IRB Project Revision or Amendment Form* for all proposed changes. Include new/revised document(s), e.g., protocol, consent forms, letters or other communications for participants, etc.**

|  |  |  |
| --- | --- | --- |
| Signature of Principal Investigator |  | Date |
| Printed name of Principal Investigator | | |
| Signature of Co-Principal Investigator (if PI is a student) |  | Date |
| Printed name of Co-Principal Investigator (if PI is a student) | | |