**I. INVESTIGATORS**

|  |  |
| --- | --- |
| Principal Investigator | Co-Investigator \* |
| Name: | Name: |
| Department: | Department: |
| Address**\*\***: | Address**\*\***: |
| Phone: | Phone: |
| Fax: | Fax: |
| Email: | Email: |
| Position:  Faculty  Graduate student  Undergraduate student  Other | Position:  Faculty  Graduate student  Undergraduate student  Other |
| Funding Status:  Pending  Awarded  Non-applicable | **\***Submit the names of additional co-investigators on a separate piece of paper, including all the information requested above.  **\*\***For address, include your preferred contact address. |
| If the Principal Investigator is a student include the following:  Faculty Advisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Office Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­\_\_\_\_ Phone/email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

**II. PROJECT TITLE:**

**III. IRB APPROVAL NUMBER:**

**III. TYPE OF REPORT:**

Adverse device effect

Adverse event or injury

Breach of confidentiality

Event requiring prompt reporting (per protocol, sponsor or funding agency)

Protocol deviation, violation, or unintentional change to protocol or procedures

Subject complaint

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

Other problem or finding – specify:

**IV. ASSESSING THE EVENT**

Does the event or information represent an unanticipated problem involving risks to the 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 great risk than previously expected.

Yes  No

Explain why or why not:

**V. RESEARCH INTERVENTIONS OR INTERACTIONS**

The event involves: (check all that apply)

Drug(s)

Device(s)

Research-related procedure(s) or activity

None of the above

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

**VI. DATE(S) OF THE EVENT:**

**VII. DESCRIPTION**

Describe in detail the event or problem being reported. Attached documentation as necessary. Do not include any participants’ personally identifiable information.

**VIII. RESEARCH STATUS**

1. The research participant(s) involved is/are:

Still in study

No longer in study

Unknown

1. Research recruitment is:

Ongoing

Completed or stopped

1. Research interventions/interactions involving other participants are:

Ongoing

Completed or stopped for all participants

**IX. OTHER REPORTING**

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

Sponsor

Collaborating investigators

No other reporting

Other – specify:

**X. ACTION 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

Only the research at Walsh University is being stopped

No action is planned

Other – specify:

**Provide an Application for Change of Approved Protocol for all proposed changes.**

**XI. ASSURANCES**

I verify that the information provided in this unanticipated event application is accurate and complete.

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Principal Investigator Co-Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date