COLLEGE of CENTRAL FLORIDA
–an equal opportunity college–

# HUMAN RESEARCH PROTECTION INSTITUTIONAL REVIEW BOARD

# IRB ADVERSE EVENT/UNANTICIPATED PROBLEM/INCREASED RISK REPORT

**NOTE: The form is subject to the disclosure requirements of Florida Sunshine Laws.**

**IRB Number of Currently-Approved Research Protocol:** _____

**Title of Currently-Approved Research Protocol:** _____

## SECTION 1

**To be completed by the principal investigator.**

**Principal Investigator:** _____

**Address:** _____ **Telephone:** _____

**PI Signature:** _____ **Date:** _____ MM/DD/YY

**PI Supervisor/ Administrator Signature:** _____ **Date:** _____ MM/DD/YY

## SECTION 2

**Investigators must report all adverse events that were not included in protocol, consent or program materials, including:**

- **Unexpected adverse events** where participants are exposed to a reportable event – an actual harm is not required (e.g., breach of confidentiality, loss of records or computer-based participant information, loss of employability, loss of insurability, criminal or civil litigation, embarrassment, humiliation, discrimination, stigmatization);
- **Serious adverse events** (e.g., resulted in death, was/is life threatening, required hospitalization, resulted in persistent or significant disability or incapacity, any medical event that requires treatment to prevent any of the previous medical outcomes); and
- **Expected adverse events of moderate or greater severity associated with the research study.**

**Adverse events must be reported to the IRB within five (5) working days of occurrence or knowledge of occurrence. All Adverse Event/Unanticipated Problem/Increased Risk Report Forms are subject to the disclosure requirements of Florida Sunshine Laws and are reviewed by the full IRB for discussion and recommendation at the next scheduled IRB meeting, or earlier.**

**Check one:** ☐ Initial Report ☐ Follow-up Report

**Location of Adverse Event:**

| |
|---|
| |

**Check all that apply:**

- ☐ Unexpected
  - ☐ Breach of confidentiality
  - ☐ Loss of records or computer-based participant information
  - ☐ Loss of employability
  - ☐ Loss of insurability
  - ☐ Criminal or civil litigation
  - ☐ Embarrassment
  - ☐ Humiliation
  - ☐ Discrimination
  - ☐ Stigmatization
  - ☐ Other: (specify) _____
- ☐ Serious
  - ☐ Resulted in death
  - ☐ Was/is life threatening
  - ☐ Required hospitalization
  - ☐ Resulted in persistent or significant disability or incapacity
  - ☐ Any medical event that requires treatment to prevent any of above
  - ☐ Other: (specify) _____
- ☐ Related/possibly related to research

**Describe the event:**

If you have any remaining questions about CF's IRB process, contact the IRB chair at ie@cf.edu.

Date Received by IRB Chair or Designated Representative: _____ Date Distributed to IRB: _____

IRB Recommendation:
Date: _____

- ☐ Changes to Consent Form
- ☐ Reconsenting
- ☐ Referral to: (specify) _____
- ☐ Other: (specify) _____