



THE SCHOOL BOARD OF BROWARD COUNTY, FLORIDA
STUDENT ASSESSMENT & RESEARCH
IRB & Research Review Process

Adverse Event Report Form

The Principal Investigator is obligated to report unanticipated problems or adverse events related to subject participation that occur in the context of ongoing or closed IRB-approved research projects. All items on pages 1 and 2 must be completed. Use "N/A" to indicate "Not Applicable."

Principal Investigator Name: _____ IRB#: _____

Company/University Name: _____

Title of Research Project: _____

Faculty Advisor (if PI is a student): _____

Most current approval date: _____ Most current approval expiration date: _____

Name of Individual Reporting the Problem: _____

Phone: _____ Email: _____

Relationship to Study: PI/co-investigator Participant/family member
 Research team member Other: _____

Method of Initial Reporting to the BCPS IRB (check all that apply):

This report form (date submitted): _____

Email/fax/letter (date sent): _____

Conversation with staff member (date of conversation): _____

Other: _____

Type of Problem (check all that apply):

Unanticipated problem involving study-related activities, procedures, materials, recruitment, etc.

Adverse, unpleasant, negative, or harmful event experienced by a participant

Violation of approved protocol (variance from IRB-approved protocol, NOT approved in advance)

Other: _____

Adverse Event Report Form (continued)

Description of Problem

1. Description of event or sequence of events. (Attach additional pages if necessary or documentation if available.)

2. Reason for event:

3. Name of individual(s) involved and relationship to study:

4. Date and time of event: _____

5. Risk (i.e., reporter's assessment of probability of harm/magnitude of harm) resulting from problem in relation to level of risk in original application (check all that apply):

For individual participants

- Decreased risk
- Unchanged risk
- Increased risk

For the study in general

- Decreased risk
- Unchanged risk
- Increased risk

6. Other comments including reporter's request action to be taken:

Adverse Event Report Form (continued)

IRB Assessment Form (This form is to be completed by an BCPS IRB representative)

**IRB Representative
Receiving the Report**

**IRB Representative
Conducting the Assessment**

Name: _____
IRB Position: _____
Date Report Received: _____
Phone: _____
Email address: _____

1. Date and time of assessment was initiated: _____

2. Description of assessment, items reviewed, etc. (Attach additional pages if necessary or documentation if available.)

3. Assessment of risk (i.e., assessor's opinion of probability of harm/magnitude of harm) resulting from problem in relation to level of risk in original application:

For individual participants

For the study in general

- Decreased risk
- Unchanged risk
- Increased risk

- Decreased risk
- Unchanged risk
- Increased risk

4. Assessment Findings:

- Inaccurate report, no unanticipated problem occurred
- Problem had no adverse effect on protocol or participants, no further action necessary
- Problem did not increase risk but follow-up action is needed
- Problem increased risk; follow-up action is needed
- Problem indicates immediate danger to participants, *immediate follow-up required*
- Other: _____

5. Description of assessment findings:

Adverse Event Report Form (continued)

SBBC IRB Assessment Form (continued)

6. Recommended actions (check all that apply):

- Inform PI of the outcome of the assessment
- Inform participants impacted by the problem of the assessment and recommendations
- Inform all participants impacted by the problem, assessment, and recommendations
- Modify informed consent form/procedures and distribute to participants impacted by the problem
- Modify informed consent form/procedures and distribute to new participants
- Modify research protocol and seek approval for changes with BCPS IRB
- Suspend research project pending resolution of recommendations
- Terminate approval for research project
- Other: _____

7. Attach documentation of recommended actions for submission to BCPS IRB for approval (e.g., Change Request and rationale).

8. Signatures: This form must be signed by the BCPS IRB representative conducting the assessment, the IRB Chair and the Principal Investigator. If the recommendations include notification of other institutional officials, those officials must also sign this form.

_____ BCPS IRB Assessor (please print)	_____ Signature of BCPS IRB Assessor	_____ Date
_____ BCPS IRB Chair (please print)	_____ Signature of BCPS IRB Chair	_____ Date
_____ Principal Investigator (please print)	_____ Signature of Principal Investigator	_____ Date
_____ Sponsoring Institution Official (please print)	_____ Signature of Sponsoring Institution Official	_____ Date