OMB No. ####-####
Approved for use through ### ##, ####

Office for Human Research Protections' Incident Report Form

Applicability: The U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46 require that organizations engaged in or reviewing nonexempt HHS-conducted or supported human subjects research establish and follow written procedures for ensuring prompt reporting to OHRP of the following: (1) any unanticipated problems involving risks to subjects or others; (2) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and (3) any suspension or termination of IRB approval (pre-2018 Requirements at 45 CFR 46.103(b)(5) and 45 CFR 46.113, and the 2018 Requirements at 45 CFR 46.108(a)(4) and 45 CFR 46.113).

Submission of this form is required for any incident report made to OHRP in accordance with 45 CFR part 46. If an organization is unable to utilize this form, please email OHRP at IRPT.OS@HHS.GOV to discuss alternatives.

1. Report Status	2. Report Type (check all that apply):	3. If Unanticipated Problem (check all that apply):
This report is a(n): ☐ FULL REPORT ☐ INITIAL REPORT ☐ FOLLOW-UP REPORT If follow up, initial report #:	☐ UNANTICIPATED PROBLEM ☐ SERIOUS NON-COMPLIANCE ☐ CONTINUING NON-COMPLIANCE ☐ SUSPENSION OF IRB APPROVAL ☐ TERMINATION OF IRB APPROVAL	☐ RISK OF BREACH OR BREACH OF CONFIDENTIALITY ☐ ANY OTHER INCIDENT

4. Category of the Incident Related to Non-Compliance, Suspension, or Termination (check all that apply):
   - A. ☐ Research conducted without IRB approval
   - B. ☐ Issues related to informed consent or assent
   - C. ☐ Failure to follow IRB-approved protocol
   - D. ☐ Issues related to the IRB
   - E. ☐ Other

5. FWA or IORG number of reporting organization:	6. FWA(s) of the Institution(s) Conducting the Research (separated by commas):

7. Study Title(s):
   1.
   2.
   3.

8. Protocol Number(s):	9. Principal Investigator(s):	10. Research Sponsor(s):	11. Award Number(s):
1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.

12. Brief Description of the Research (if applicable):

13. Detailed Description of the Incident:

14. Corrective Action Plan Description:

15. Corrective Action Plan Category (check all that apply):
   - A. ☐ Re-seeking consent or notifying subjects
   - B. ☐ Revising IRB policies and procedures
   - C. ☐ Revising protocol or consent form
   - D. ☐ Educating or training for IRB members/staff, investigators, research staff, or institutional officials
   - E. ☐ Suspending or revoking principal investigator's privileges to conduct human subject research
   - F. ☐ Audit plan for research
   - G. ☐ Suspended or Terminated study
   - H. ☐ Other

The submitting organization certifies that the information provided above is correct.	18. Name and address of the organization submitting this form:
16. Name of FWA Signatory Official or IORG Senior/Head Officer: 17. FWA Human Protections Administrator (HPA) Name or IORG Information Provider:	
19. Name of Person Submitting this Form:	20. Submitter's Email:
21. Submitter's Phone Number *(with area code)*:	22. Date:

OMB No. ####-####
Approved for use through ### ##, ####

Statement of Burden

Instructions for Completing this Form

Please answer all required questions. Individuals completing this form may also review the "Guidance in Reporting Incidents to OHRP" for additional information.

1. **Report Status**
   - FULL REPORT: Select this if this is an initial report that is complete and will not require a follow-up report.
   - INITIAL REPORT: Select this if this is an initial report that will require a follow-up report to be completed. This may be required for instances where the institution has not implemented a corrective action plan or has not completed gathering all information but is required to report incidents as required by the pre-2018 Requirements at 45 CFR 46.103(b)(5), and the 2018 Requirements at 45 CFR 46.108(a)(4). An initial report number will be provided by OHRP for follow-up reports.
   - FOLLOW-UP: Select this if this is a follow-up report to a previously submitted initial report. Provide the initial report number provided by OHRP.

2. **Report Type (check all that apply)**
   - UNANTICIPATED PROBLEM: Select this option if the incident is unexpected and related or possibly related to the research and poses additional risks to subjects or others. If this item is selected, question #3 must be completed.
   - SERIOUS NON-COMPLIANCE: Select this option if the incident involves serious noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB. If this item is selected, question #4 must be completed.
   - CONTINUING NON-COMPLIANCE: Select this option if the incident involves continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB. If this item is selected, question #4 must be completed.
   - SUSPENSION: Select this option if the IRB suspended the study or suspended enrollment of subjects. If this item is selected, question #4 must be completed.
   - TERMINATION: Select this option if the IRB terminated the study. If this item is selected, question #4 must be completed.

3. If Unanticipated Problem, (check all that apply)

This item should be completed only if UNANTICIPATED PROBLEM is selected in #2.
   - RISK/BREACH OF CONFIDENTIALITY: Select this option if the incident led to a risk of breach or breach of confidentiality.
   - ANY OTHER INCIDENT: Incidents that are unexpected and related or possibly related to the research and that pose additional risks to subjects or others.

For more guidance on unanticipated problems, review "Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)"

4. **Category of Incident**

This item should be completed only if SERIOUS NON-COMPLIANCE, CONTINUING NON-COMPLIANCE, SUSPENSION, or TERMINATION is selected in #2.

Select all options that accurately describe the incident that is being reported:

A. Research conducted without IRB approval
B. Issues related to informed consent or assent
C. Failure to follow IRB-approved protocol
D. Issues related to the IRB
E. Other

5. **Federalwide Assurance (FWA) Number or Institutional Organization (IORG) number of the reporting institution**

Enter the FWA number or IORG number of the organization submitting this form. In some cases, the organization reporting an incident may not be the same as the organization conducting the research. Organizations with both an IORG number and an FWA number should enter the FWA number.

6. FWA(s) of the Institution(s) Conducting the Research

Enter the FWA number(s) of institution(s) conducting the research. Include all institutions affected by the incident, separated by commas. OHRP will notify the Signatory Official(s) and Human Protections Administrator(s) of each institution listed.

7. Study Title(s)

If applicable, enter the study title(s) that was affected by the incident.

8. Protocol Number(s)

If applicable, enter the protocol number(s) assigned by the institution that was affected by the incident.

9. Principal Investigator(s)

If applicable, enter the name(s) of the principal investigator(s) leading the research that was affected by the incident.

10. Research Sponsor(s)
If applicable, enter the name(s) of the funding source(s) of the research.

11. Award Number(s)
If applicable, enter the grant number(s) or contract number(s) associated with the research that was affected by the incident.

12. Brief Description of the Research
If applicable, provide a brief description of the research or research protocol. The description should be enough to provide sufficient context for understanding the incident. Please provide an attachment if additional space is needed.

13. Detailed Description of the Incident
Provide a detailed description of the unanticipated problem, serious or continuing non-compliance, or rationale for the suspension or termination. Include the date(s) and location(s) of the incident. Please provide an attachment if additional space is needed.

14. Corrective Action Plan Description
Provide the corrective actions the institution is taking or plans to take to address the unanticipated problems or non-compliance. Please provide an attachment if additional space is needed.

15. Corrective Action Plan Category
Select all options that describe the corrective action plan that will be or have already been implemented:

A. Re-seeking consent or notifying subjects
B. Revising IRB policies and procedures
C. Revising protocol and/or consent form
D. Educating or training for IRB members/staff, investigators, research staff, or institutional officials
E. Suspending or revoking principal investigator's privileges to conduct human subject research
F. Audit(s) plan for research
G. Suspended or terminated study
H. Other

16. Name of the FWA Signatory Official or IORG Senior/Head Officer
If Box 5 uses an FWA number, provide the name of the signatory official of the organization submitting this form. If Box 5 uses an IORG number, provide the name of the Senior/Head Officer.

17. Human Protections Administrator (HPA) Name
If Box 5 uses an FWA number provide the name of the Human Protections Administrator of the organization submitting this form. If Box 5 uses an IORG number, provide the name of the Information Provider.

18. Name and address of the organization submitting this form
Enter the name and address of the organization submitting this form.

19. Name of Person Submitting this form
Enter the name of the person submitting this form.

20. Submitter's Email
Enter the email address of the person submitting this form.

21. Submitter's Phone Number
Enter the phone number of the person submitting this form. Use the following format: xxx-xxx-xxxx.

22. Date
Enter the date the form is being submitted.