OMB No. 0990-0477
Approved through XXXXXXXX

Office for Human Research Protections' Incident Report Form

Applicability: The U.S. Department of Health and Human Services' (HHS) Federal Policy for the Protection of Human Subjects (the Common Rule), which is codified for HHS at 45 CFR part 46, subpart A,[1] requires 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. IORG # for Reviewing IRB:
	7. FWA(s) of the Institution(s) Conducting the Research (separated by commas):

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

9. Protocol Number(s):	10. Principal Investigator(s):	11. Research Sponsor(s):	12. Award Number(s):
1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.

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

14. Detailed Description of the Incident:

15. Corrective Action Plan Description:

16. Corrective Action Plan Category (check all that apply):
   - A. ☐ Re-seeking consent or notifying subjects
   - B. ☐ Revising IRB policies and procedures

[1] The pre-2018 Common Rule (or "pre-2018 Requirements") was originally promulgated in 1991 and amended on June 23, 2005 (70 FR 36325). The 2018 Common Rule (or "2018 Requirements") was originally published on January 19, 2017 (82 FR 7149) and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).

C. ☐ Revising research policies and procedures
D. ☐ Revising protocol or consent form
E. ☐ Educating or training for IRB members/staff, investigators, research staff, or institutional officials
F. ☐ Suspending or revoking principal investigator's privileges to conduct human subject research
G. ☐ Audit plan for research
H. ☐ Suspended or Terminated study
I. ☐ Other

The submitting organization certifies that the information provided above is correct.	19. Name and address of the organization submitting this form:
17. Name of FWA Signatory Official or IORG Senior/Head Officer: 18. FWA Human Protections Administrator (HPA) Name or IORG Information Provider:	
20. Name of Person Submitting this Form:	21. Submitter's Email:
22. Submitter's Phone Number *(with area code)*:	23. Date:

Statement of Burden