

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 This report is a(n): <input type="checkbox"/> FULL REPORT <input type="checkbox"/> INITIAL REPORT <input type="checkbox"/> FOLLOW-UP REPORT If follow up, initial report #:	2. Report Type (check all that apply): <input type="checkbox"/> UNANTICIPATED PROBLEM <input type="checkbox"/> SERIOUS NON-COMPLIANCE <input type="checkbox"/> CONTINUING NON-COMPLIANCE <input type="checkbox"/> SUSPENSION OF IRB APPROVAL <input type="checkbox"/> TERMINATION OF IRB APPROVAL	3. If Unanticipated Problem (check all that apply): <input type="checkbox"/> RISK OF BREACH OR BREACH OF CONFIDENTIALITY <input type="checkbox"/> ANY OTHER INCIDENT
4. Category of the Incident Related to Non-Compliance, Suspension, or Termination (check all that apply): A. <input type="checkbox"/> Research conducted without IRB approval B. <input type="checkbox"/> Issues related to informed consent or assent C. <input type="checkbox"/> Failure to follow IRB-approved protocol D. <input type="checkbox"/> Issues related to the IRB E. <input type="checkbox"/> 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): 1. 2. 3.	10. Principal Investigator(s): 1. 2. 3.	11. Research Sponsor(s): 1. 2. 3.
12. Award Number(s): 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. <input type="checkbox"/> Re-seeking consent or notifying subjects B. <input type="checkbox"/> 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. <input type="checkbox"/> Revising research policies and procedures D. <input type="checkbox"/> Revising protocol or consent form E. <input type="checkbox"/> Educating or training for IRB members/staff, investigators, research staff, or institutional officials F. <input type="checkbox"/> Suspending or revoking principal investigator's privileges to conduct human subject research G. <input type="checkbox"/> Audit plan for research H. <input type="checkbox"/> Suspended or Terminated study I. <input type="checkbox"/> 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 (<i>with area code</i>):	23. Date:

Statement of Burden

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0477. The time required to complete this information collection is estimated to average 30 minutes per report. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.