



IP-008
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INFORMATION PAPER
SUBMISSION OF REPORTABLE EVENTS TO R2O2

Information Papers published by the OUSD(P&R), R2O2 contain background information on specific issues raised to this Office, policies covering the issues and the OUSD(P&R), R2O2 interpretation of those policies. These papers include policy interpretations that are enforceable within and among all institutions in the OUSD(P&R).

Policy

In accordance with Title 32 Code of Federal Regulations Section 219.103(b)(5), “Assurances applicable to federally supported or conducted research shall at a minimum include...Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.” Department of Defense Instruction (DoDI) 3216.02, Enclosure 2, Sections 3.f.(5) and (7) require Heads of OASD and DoD Components to provide in a timely manner to the ASD(R&E), “Any allegation of serious or continuing noncompliance related to research involving human subjects that has been substantiated by inquiry or investigation and any subsequent actions taken based on the findings...” and “Any substantiated unanticipated problems involving risks to human subjects or others (UPIRTSO).”

Implementation Requirements

Section 23 of the OUSD(P&R) Human Research Protection Program (HRPP) Operating Instruction (OI), dated September 29, 2014, requires the Human Protections Administrator (HPA) to “report all incidents of significant or continuing noncompliance, research-related unanticipated problems involving risks to subjects or others, suspensions or terminations of IRB approval, and unanticipated serious adverse events in writing to the [Component Headquarters] CHQ within three business days of verifying or substantiating the report or initiating the action.” The OI allows for this to be an initial report, which should include a description of the problem or incident; a description of steps already taken to address the problem or incident; and a recommended plan to address the problem or incident. The template attached should be used for this initial submission.

Once the IRB or HPA establishes and implements a corrective action plan, a final report must be submitted by the Institutional Official to the Component Designated Official (CDO), through the R2O2. The final report must include a description of the event; an analysis of the cause of the event; a description of steps taken to address the cause and reduce the likelihood of reoccurrence; and, when applicable, the relevant portion of the minutes of the meeting where the IRB discussed the event. The CDO may determine that the actions taken were sufficient and appropriate, or the CDO may choose to require further action. Once the CDO has determined an appropriate way forward, the CDO will report the event(s) to ASD(R&E), as required by DoDI 3216.02.

Definitions

ASD(R&E)	Assistant Secretary of Defense (Research and Engineering)
CDO	The Deputy Assistant Secretary of Defense (Health Readiness Policy and Oversight) and the senior official with the authority and responsibility for implementing the OUSD(P&R) HRPP management plan.
CHQ	Component Headquarters. The R2O2 is the CHQ.
DoDI	Department of Defense Instruction
HPA	Human Protections Administrator. The individual who coordinates or directs the institution's HRPP under the authority and direction of the Institutional Official.
OASD	Office of the Assistant Secretary of Defense
OI	Operating Instruction
Reportable Events	Occurrences required to be reported to appropriate institutional officials, DoD Component officials, and/or ASD(R&E) in accordance with 32 CFR 219, DoDI 3216.02, and/or DoD Component policies (e.g., (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval).
Serious Adverse Event	An unfavorable and unintended occurrence associated with the conduct of a research project.
Serious Noncompliance	Failure of a person, group, or institution to act in accordance with DoDI 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.
UPIRTSO	Any incident, experience, or outcome that meets ALL three of the following conditions: 1. Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied. 2. Is related or possibly related to participation in the research (in DoDI 3216.02, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research). 3. Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

