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INFORMATION PAPER

Delegable Authorities and Shared Responsibilities of the Institutional Official

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 may include policy interpretations that are enforceable within and among all institutions in the OUSD(P&R).

"Responsibility is a unique concept. It can only reside and inhere in a single individual. You may share it with others, but your portion of it is not diminished. You may delegate it, but it is still with you. You may disclaim it, but you cannot divest yourself of it. Even if you do not recognize it or admit its presence, you cannot escape it. If responsibility is rightfully yours, no evasion or ignorance or passing the blame can pass the burden to someone else."
ADM Hyman Rickover

Background

The Department of Defense (DoD) Assurance (Assurance) for the Protection of Human Subjects, and its analog Federal-wide Assurance (FWA) issued by the Department of Health and Human Services, Office for Human Research Protection include specific Responsibilities of the Institutional Official (IO). The IO can delegate some of the authorities that devolve from those responsibilities, while others cannot be delegated. The specific authorities that can and cannot be delegated are not codified in regulation or DoD policy. This Information Paper provides a list of the authorities and the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Research Regulatory Oversight Office (R2O2) determination of which can be delegated and which cannot.

Policy

Title 32 of the Code of Federal Regulations (CFR), Section 219 is the DoD adoption of the Federal Regulation for the Protection of Human Subjects, and subsection 219.103(c) defines the requirement for a designated "individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy…". The aforementioned individual is the IO. DoD Instruction (DoDI) 3216.02 includes the responsibilities of the IO at DoD Institutions at Enclosure 2, Section 4. The OUSD(P&R) Operating Instruction for the protection of human subjects, Section 6 further defines the responsibilities of the IO.

Policy Interpretation and Implementation Requirements for OUSD(P&R) Institutions

In accordance with 32 CFR 219.103(c), the IO is responsible for overseeing compliance with the Federal Regulation as implemented in the DoD through DoDI 3216.02 at his or her institution. While the IO is responsible for ensuring compliance, certain authorities associated with the responsibilities can be delegated to others at the institution in order to effectively and efficiently implement and maintain its human research protection program (HRPP). R2O2 maintains the following opinion with respect to *Responsibilities* and *Authorities* at OUSD(P&R) institutions.

- *Responsibilities*: The IO can delegate some of the responsibilities enumerated in DoDI 3216.02 to others at the institution; however, the delegation does not relieve the IO of the responsibilities. Therefore, responsibilities may be "shared", but the IO cannot divest oneself of them.
- *Authorities*: Each of the responsibilities includes multiple authorities that enable the IO to enact policies, procedures and business processes to meet the required responsibilities. For those responsibilities that the IO has shared with others at the institution, he or she shall delegate the associated authorities.

The table beginning at page 3 of this Information Paper lists the IO Responsibilities found in the DoDI 3216.02, the associated authorities that devolve from them and a determination of whether the IO can delegate those authorities. When an IO delegates responsibilities and associated authorities, he/she must sign a delegation memorandum that states precisely which authorities have been delegated, to whom they have been delegated, any limitations or restrictions on further delegation, the effective date of the delegations and the terms and conditions under which those delegations may be rescinded. When there is a change in the IO at an institution, the new IO must review and reaffirm or modify the delegations in accordance with this Information Paper.

Definitions

Authority:	the power to direct others to take specific actions required to implement the institution's HRPP.
Deputy IO	in instances when multiple institutions are covered by a shared Assurance, there will be a single IO designated on that Assurance. Deputy IOs may be assigned at each institution covered by the Assurance and may serve as that institution's IO for many of the authorities associated with the IOs responsibilities.
Human Subject:	a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information. (32 CFR 219.102(f)).
Institutional Official:	a senior official within the organizational structure covered by an Assurance with responsibility and authority to commit the Institution to comply with Federal, DoD and OUSD(P&R) requirements.
Research:	a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (32 CFR 219.102(d)).
Responsibility:	defines the ultimate point of accountability covered under the Assurance.

DoDI 3216.02 IO responsibilities and associated authorities (from Enclosure 2, Section 4)

a. Establish and Maintain an HRPP to ensure the institution's compliance with DoDI 3216.02		
Associated Authorities	Delegable by IO	Delegable by DIO
1. Draft institution HRPP and implementing policies, SOPs, *etc*.	Yes	Yes
2. Periodically update the HRPP documents to ensure continued compliance and reflect changes in regulatory requirements	Yes	Yes
3. Require IRB to investigate allegations of serious or continuing non-compliance, serious adverse events and UPIRTSOs	No	No
4. Submit written reports of investigations to the Director, R2O2, including a summary of findings and recommendations	No	No
b. Provide the resources needed to ensure compliance with DoDI 3216.02		
Associated Authorities	Delegable by IO	Delegable by DIO
1. Develop an HRPP manning document and staffing plan	Yes	Yes
2. Engage in hiring actions	Yes	Yes
3. Provide adequate and sufficient space for HRPP	Yes	Yes
4. Provide adequate and sufficient information technology for HRPP	Yes	Yes
5. Commit funds to support the HRPP infrastructure	Yes	Yes
6. Ensure initial and ongoing ethics education and training opportunities for all personnel involved with human subjects research at the institution	Yes	Yes
c. Establish and maintain a DoD assurance and other appropriate Federal assurances, if the institution is engaged in non-exempt research involving human subjects		
Associated Authorities	Delegable by IO	Delegable by DIO
1. Review and sign the Assurance on behalf of the Institutions covered by the Assurance	No	No
2. Review and be responsible for the HHS/OHRP Federal-wide Assurance on behalf of the institutions covered by the Assurance that are engaged in HHS-supported research	No	No
3. Approve Individual Investigator Agreements that will cover co-investigators from non-Assured institutions under the IO's institution's Assurance when collaborating at the Assured institution	Yes (only to DIO or functional institutional equivalent if applicable)	No
4. Approve institutional agreements for IRB review with other institutions that establish reliance relationships	Yes (only to DIO or functional institutional equivalent if applicable)	No
5. Report changes in IRB roster and any new IRBs established to R2O2	Yes	Yes
d. Evaluate and improve the institution's HRPP		
Associated Authorities	Delegable by IO	Delegable by DIO
1. Maintain a system of Research Compliance and Oversight to continually monitor compliance throughout the institution and identify common deficiencies, propose solutions and take steps to implement solutions	Yes	Yes
2. Develop institution-based training programs to improve compliance among investigators and oversight staff members	Yes	Yes
3. Survey best practices throughout the HRPP community for opportunities to improve local practices and processes	Yes	Yes