

Questions and Answers Regarding Human Research Protection Official (HRPO) Duties

The following questions were asked in conjunction with the HRPO training that was provided on 22 October 2015.

Q1: Who should appoint and supervise the HRPO? We don't have a Contracting Officer at our command. We rely on a KO at NAVMEDLOGCOM. Our current local instruction has our HRPO appointed by our IO (who is also our CO). The requirement for HRPO comes from 48CFR 252.235-7004, which is the contracting/acquisition side, but requirements of the duties are coming from the IRB regulations.

A1: HRPO program oversight is addressed in question #4. Your local instruction is fine, except that per DON HRPP policy, your IO/CO nominates the HRPO and that nomination is approved by the Director, DON HRPP. Please see DON HRPP's website for the nomination letter template. The duties of the HRPO are found in DoDI 3216.02 (Enclosure 3, section 4).

Q2: Who is responsible to determine if a contract or agreement needs HRPO review? We have several different contracts and agreements with one of them being a service contract. That service contract is a one year contract with up to 5 option years. Each option year can have over 50 Technical Direction Letters; some with Human Subject Research tasks, and some without. Again, we don't have a Contracting Officer (KO) at our command. We rely on a KO at NAVMEDLOGCOM for that contract. We have a local Contract Officer Representative (COR). Are the KO and COR required to do training sufficient to determine if the contract/agreement/or modification contains an element of human subject research?

A2: The IO of any institution supporting non-DOD conducted research is responsible for establishing a process to meet the requirements of the SECNAVINST 3900.39D and DODI 3216.02. There is no DON requirement to make the KO or COR responsible for making those determinations. The Program Officer (PO), Program Manager (PM) or equivalent person sponsoring the activities outlined in the contract or agreement is responsible for determining whether the contract or agreement may need HRPO review because this is part of the acquisition planning process (see Q8 below). Proceeding without proper HRPO coordination/review adds an element of execution risk, that can be mitigated through good communication between HRPOs, POs/PMs, and the contracting personnel as to what elements "may include research involving human subjects" triggering requirements under DoDI 3216.02 (Enclosure 3, section 4). In addition, under the acquisition process, the [potential] awardee must be made aware of the HRPO review and contractor requirements as outlined in 48 CFR 252.235-7004, DFARS clause and DoDI 3216.02. As indicated in Q14 below, DON HRPP will develop training for KOs and CORs to ensure that they understand when to involve the HRPO for such research.

Q3(a): Who maintains HRPO program oversight? It seems that the oversight of the HRPO is at DON HRPP. But all the paperwork is filed with the contracts.

A3(a): The command at which the HRPO resides is responsible for maintaining HRPO oversight as part of their HRPP. In addition, DON HRPP performs post approval quality assurance reviews of the command's HRPO processes at assist visits and site inspections.

Q3(b): Should DON HRPP also receive copies of the HRPO reviews?

A3(b): Only copies of the HRPO determination/approval letter need to be submitted to DON HRPP. There is no need to submit any other part of the review.

Q3(c): Who ensures that the HRPOs are sufficiently trained?

A3(c): It is a joint effort between DON HRPP and the command. DON HRPP requires HRPOs to complete training through the CITI program, which is completed prior to assuming the role. The command is responsible for selecting appropriately experienced personnel, and for providing ongoing training to ensure continued compliance with DoD and DON requirements.

Q4: Does the HRPO review requirement apply to all collaborative research that involves a non-DoD collaborator, including those in which Navy personnel are involved and the research is subject for review and oversight by a Navy IRB?

A4: Yes, HRPO review is still required of all the non-DOD collaborator's activities. A member of the Navy IRB can be nominated to be a HRPO to promote efficiency in the review process. See DON HRPP e-gram of 21 October 2015.

Q5: Does the HRPO have any responsibility toward reviewing the contract documents themselves to ensure inclusion of the required clause/equivalent verbiage as applicable? Or is it the responsibility of the contracting officer?

A5: The contracting officer is responsible for ensuring the DFARS clause/text is included in all contracts in accordance with 48 CFR 252.235-7004 and DoDI 3216.02, Enclosure 3, section 4. If the HRPO becomes aware that a contract for DOD-supported research involving human subjects is missing language required by DoDI 3216.02, Enclosure 3, section 4, the HRPO is responsible for notifying the sponsor of the activity and the contracting officer or other appropriate POC of their obligation to incorporate the appropriate language. DON HRPP recommends HRPOs maintain open and ongoing communication with contracting officers and personnel within their unit to ensure non-DOD institutions participating in DOD-supported research involving human subjects are bound by the DoDI 3216.02's requirements.

Q6: Do Intergovernmental Personnel Act agreements fall under the purview of the HRPO? If the answer is 'yes,' then, "are personnel employed through an IPA covered by the command's assurance? Or is another agreement for IRB coverage required?"

A6: No, intergovernmental Personnel Act agreements do not fit under the purview of the HRPO. IPAs working within scope of their IPA agreements are considered to be part of the command's workforce, and should be considered covered by the command's assurance.

Q7: I was asked by HR whether the requirements for the inclusion of DFARS clause in contracts applies to personal as well as to non-personal contracts. Request clarification on this. And whether there is abbreviated DFARS equivalent language need to be included in the personal contracts.

A7: There is no exception in DODI 3216.02 for personal services contracts; therefore, the DFARS clause must be used.

Q8: HRPO approval must be secured by the contractor prior to the release of an award. However, if the contractor is tasked to develop the research protocol that ultimately must be approved by an IRB and HRPO prior to initiation, how can such a contractor receive funds to develop the research protocol without receiving prior HRPO approval?

A8: This can be accomplished by segregating the tasks that "may include research involving human subjects" from those that clearly do not. The process of developing the research protocol submission alone is not research involving human subjects and does not require prior HRPO approval under DODI 3216.02 or SECNAV 3900.39D as long as such actions do not involve activities preparatory to research like accessing identifiable data or intervening or interacting with humans that "may include research involving human subjects". Funding separate contract options or task orders that do not contain any elements that "may include research involving human subjects" would not trigger the requirements for prior HRPO approval under DoDI 3216.02 (Enclosure 3, section 4).

Q9: If a service support contractor conducts research involving human subjects under research that is led by a DON Principal Investigator and approved by a DON IRB, is HRPO review still required?

A9: Yes. HRPO review is still required for research activities conducted by non-DOD institutions if they are involved in activities that "may include research with human subjects," even if the research is led by a DON PI, and the research is approved by the DON IRB. The DODI does not provide for an exception applicable to service support contractors, or distinguish between roles as PI or AI.

Q10: On 1 June 2015, ASD(R&E) released a memo with subject “Reducing Administrative Burden on a non-DoD institution relying on a DoD Institutional Review Board (IRB)” that stated that HRPO review responsibilities may be accomplished by a reviewing DoD IRB member under certain circumstances and an IRB approval letter associated with such a DoD IRB review may serve as the HRPO notification letter for the corresponding support agreement. Given the overlap in research compliance determinations between a HRPO review and a DON IRB review, can a DON IRB review and approval notice alone cover all HRPO review requirements for service support contractors who conduct research involving human subjects on research led by a DON Principal Investigator and approved by a DON IRB?

A10(a): Please see recent DON HRPP email released on 21 October 2015 with subject heading “DON HRPP Clarification of Memo Issued by Assistant Secretary of Defense (Research & Engineering) dtd 1 June 2015”. A DON IRB member involved in the IRB review of such a protocol who also fulfills the HRPO review responsibilities as identified in that memo must be an official HRPO who has been approved by the DON HRPP.

A10(b): A “DON IRB review and approval notice alone” does not automatically meet the requirements of a HRPO review. DON IRB review requirements specified within DoDI 3216.02 and SECNAVINST 3900.39D, paragraphs 8e and 8f do not include all of the review requirements specified for the HRPO review per DoDI 3216.02, Enclosure 3, sections 4c and 5. Therefore, to pass a compliance review, the DON IRB review intended to cover all requisite HRPO review requirements must clearly demonstrate that all requisite HRPO review requirements have been satisfied. Please note that the 1 June 2015, ASD(R&E) memo did not eliminate any HRPO review responsibilities, it did allow for concurrent reviews rather than serial reviews.

Q11: Can the approach for HRPO review described within the above 1 June ASD(R&E) memo also be used for collaborating non-DoD performers who receive DON IRB review services via a DoD Institutional Agreement for IRB Review (IAIR) but who are not service support contractors?

A11: Yes, the same approach specified within the above 1 June 2015 ASD(R&E) memo and clarified within the 21 October 2015 DON HRPP clarification email listed above may be followed when a HRPO who is one of the reviewing DON IRB members determines that all HRPO approval requirements are satisfied, concurrent with the DON IRB review.

Q12: Prior to the DON HRPP HRPO training held on 22 October 2015, DON HRPP released an updated set of HRPO checklists and Sample HRPO approval letter on 19 October 2015 which incorporate all of the requirements specified for DON supported research within DoDI 3216.02. Are DON HRPOs required to document their HRPO reviews using these updated materials?

A12: Use of the updated materials will help ensure compliance; however, use is not mandatory. The updated set of HRPO checklists and sample HRPO approval letter were developed to ensure full compliance with the DFARS clause 48 CFR 252.235-7004 and DoDI 3216.02; however, if a

Command has its own set of checklists and approval notice that document the minimum requirements captured within this updated set of HRPO checklists and sample HRPO approval letter, use of that Command's materials will meet the requirements.

Q13: What are the differences between DoD IRB review and HRPO review as far as review requirements and review authority is concerned?

A13: HRPO review authority is specified within DFARS clause 48 CFR 252.235-7004 and DoDI 3216.02. While there is overlap with DON IRB review requirements, HRPO review also includes various requirements that a DON IRB is not currently required to determine from a non-DoD performer. The 1 June 2015 ASD(R&E) memo addresses the extra requirements required for HRPO approval.

Q14: Will DON HRPP conduct any training for contract officers and office of research technology applications representatives (ORTAs) within the Navy to ensure that they understand the triggers for the requirement of HRPO review of DON-supported research conducted by non-DoD performers?

A14: Yes, DON HRPP will develop training for contract officers and ORTAs within the Navy to ensure that they understand when to involve the HRPO for such research.

Q15: None of the NAVMEDLOGCOM contracting officers are located within my Command. As such, as a HRPO it is difficult for me to establish a working relationship with any NAVMEDLOGCOM personnel. Is there another process that I can follow to ensure that all HRPO reviews will be requested when needed?

A15: The Commanding Officer at your Command may establish internal procedures requiring personnel responsible for submitting NAVMEDLOGCOM requests to alert the Command's assigned HRPO concerning any activities that "may include research with human subjects" and require HRPO approval. The DFARS makes it clear that HRPO review is an Acquisition Planning REQUIREMENT (See DFARS at 48 CFR Part 235.072).

Q16: Does DON HRPP have a sample HRPO Standard Operating Procedure (SOP) template that our Command may use to develop our own HRPO SOP or confirm that our HRPO SOP is complete?

A16: DON HRPP does not have an HRPO SOP template to send, however, your DON HRPP POC can work with you to help develop your command's SOP. In an ongoing effort to ensure compliance with the HRPO requirement DON Commands will submit their HRPO SOPs, HRPO checklist(s), and Sample HRPO approval letter(s) for review by DON HRPP. DON HRPP staff will provide feedback regarding whether your Command's documents satisfy the requirements and if needed, will provide additional assistance to ensure the materials are complete.