

DON - HRPP

From: DON - HRPP <Human.Research@med.navy.mil>
Sent: Wednesday, May 05, 2010 3:51 PM
To: DON - HRPP
Cc: DON - HRPP
Subject: DON HRPP E-Gram - Human Research Protection Official (HRPO) Nomination Process and Requirements
Attachments: #5 Sample ONR Checklist Process Briefing Slides 9 Mar 10.ppt; #6 Sample ONR HRPO Basic Checklist 21 Jan 10.doc; #7 Sample ONR HRPO Additional Checklist 9 Mar 10.doc; #8 Sample ONR HRPO letter to Contracting Officer 12 Apr 10.doc; #1 HRPO Nomination Letter Template 12 Apr 10.doc; #2 Federal Register Volume 74, Number 144 Wednesday, July 29, 2009.pdf; #3 Background HRPO Briefing Slides 22 Mar 10.ppt; #4 HRPO CITI Training Directions 30 April 10.pdf

To: Institutional Officials, IRB Chairs, IRB Administrators and HRPP POCs.

As a follow-up to the DON HRPP E-gram of 13 October 2009, "Defense Federal Regulation Supplement-Rule," the DON HRPP developed the following information to support Human Research Protection Official (HRPO) processes at your commands.

Attachments provided are:

[1] HRPO Nomination Letter Template; [2] DFARS Clause Federal Register Notice; [3] Background HRPO Briefing Slides; [4] HRPO CITI Training Directions; [5] Sample ONR Checklist Process Briefing Slides; [6] Sample ONR HRPO Basic Checklist; [7] Sample ONR HRPO Additional Checklist; [8] Sample ONR HRPO Letter to Contracting Officer.

Attachment [1] is used for nominating a command HRPO and HRPO training materials are provided in Attachments [2],[3] and [4]. Attachments [5] through [8] reflect the "HRPO Model" being implemented at the Office of Naval Research (ONR). These attachments are offered as examples to assist commands in establishing their own HRPO review process and procedure to ensure compliance with the DFARS 252.235-7004 and SECNAVINST 3900.39D

Three steps for implementation of a command HRPO Program are as follows:

STEP 1: Nominate and Appoint the HRPO - Nominate a military or government employee(s) for appointment as the Command HRPO. The HRPO position will likely be a collateral or additional duty for the nominee. Qualified candidates could be selected from any of several command positions including program management, legal, financial management, or Command Human Research Protection (HRP) office positions. Prior human research protection experience is not required. Some Commands may already have staff assigned to Human Research Protections functions. These persons may also be nominated for the HRPO position, but that decision is at the discretion of the Command. A Contracting Office staff member may also be considered, but the HRPO must not be the same Contracting Officer that is awarding the contract under HRPO review. Commands should ensure that the selected HRPO has the ability to perform the function and has completed the required training, described below in Step 2.

The HRPO Nomination Letter, Attachment [1] template, should be used to submit the HRPO nomination to the DON HRPP. Commands HRPO nominations can be sent electronically to: human.research@med.navy.mil.

The DON Surgeon General (SG) or DON HRPP Director will approve the nominee for an indefinite period of time. If the appointed HRPO is no longer able to perform their duties the Command should submit a new nomination package.

STEP 2: HRPO Nominee Completes Requirements - Prior to nomination, the HRPO should review Attachment [2] DFARS clause - see Federal Register notice at <http://edocket.access.gpo.gov/2009/E9-17949.htm> and Attachment [3] Background HRPO Briefing Slides. The HRPO nominee must complete the HRPO training on the Collaborative Institutional Training Initiative (CITI) website. See Attachment [4] for directions to access the DON HRPO learner's group module.

STEP 3: Establish a Command Process for HRPO Review - Samples of the ONR-based "HRPO Model" documents are provided for review and information in Attachments [5] through [8].

For question concerning DFARS or the HRPO Model, please contact Ms. Ivana Sustersic at Ivana.Sustersic@navy.mil.

Thank you

DON HRPP

Sent on behalf of

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