The Principal Investigator must comply with the following minimum reporting requirements. Specific reporting requirements for the protocol will be included in the HRPO Approval Memorandum. Failure to comply could result in suspension of funding.

**For all DoD-supported studies**

A. After initial IRB-approval, the DoD Human Research Protection Office/Official (HRPO) must perform an Administrative review of the research **before the activities that involve human subjects can begin.** The DoD HRPO performs an administrative review to ensure compliance with DoD regulations and requirements. The IRB approval letter and all documents part of the IRB application must be submitted and approved by the appropriate DoD Agency involved. [DoDI 3216.02 4.c.(2)]

See [here](#) for a list of Agency HRPO contacts to submit to for this Administrative review.

B. Non-DoD Institutions shall promptly notify the Human Research Protection Official (HRPO) of the funding agency the following:

- **Investigator reports:**
  - when significant changes to the research protocol **are approved by the IRB,**
  - the results of the IRB continuing review,
  - Final study reports
  - if the IRB used to review and approve the research changes to a different IRB

- **Institution (RCO) reports:**
  - when the institution is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol, and
  - all Unanticipated Problems (UPs), suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects must be promptly reported.

**The US Army (USAMRMC) and US Air Force define a substantive modification to a protocol as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc), significant change in study design (i.e. would prompt additional scientific review) or a change that could potentially increase risks to subjects.**

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**DoD Websites with HRPO contacts and Required Forms**

**Air Force** (main webpage)

Email

**US NAVY – Office of Naval Research (ONR)** (main webpage)

Human Research Protection Official (HRPO), Ms. Sevgi Bullock, via e-mail at sevgi.bullock@navy.mil.

Research Protections of DoN

For more information on ONR Research Protections, contact 703-696-8557 or ONR343@navy.mil.


**Army HRPO** (main webpage)

FAQs page
The U.S. Army Human Research Protections Office
7700 Arlington Blvd
Falls Church, VA 22042-5140
Phone 703-681-6565
Email AHRPO

**USAMRDC ORP HRPO** (US Army Medical Research and Material Command - main webpage)
Submission forms for research with Data and Specimens, cadavers, and International research).
Contact the ORP HRPO for protocol submission instructions at usarmy.detrick.medcom-usamrc_other_hrpo@mail.mil or 301-619-2165, or facsimile (301-619-7803) to the HRPO In addition to the methods above, the complete report can be sent to the US Army Medical Research and Materiel Command, ATTN: MCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.