

Naval Medical Research Unit Six

Monitoring & Oversight



Policies and Procedures for Monitoring and Overseeing NAMRU-6 Human Subject Research

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Policies and Procedures for Monitoring and Overseeing Human Subject Research at Naval Medical Center Research Unit Six

The purpose of this policy and procedure manual is to establish a monitoring and oversight plan at the Naval Medical Research Unit Six (NAMRU-6) for human subject research that is reviewed by the Naval Medical Research Unit Six (NAMRU-6) IRB.

NAMRU-6 researchers, as well as the Institutional Official, should also refer to the NAMRU-6 *“Institutional Review Board: Policies and Procedures for the Protection of Human Subjects in Research,”* which provides additional guidance for reviewing and approving human subject research.

For additional reference materials and resources, NAMRU-6 personnel are welcome to contact the NAMRU-6 Research Administration Program.

- a. **Background.** As required by its Assurance for the Protection of Human Research Subjects, NAMRU-6 is responsible for the performance of all research covered by its Assurance, including full responsibility for compliance with applicable Peruvian and U.S. regulations and laws, U.S. Department of Defense directives, and U.S. Department of Navy instructions and guidance.
- b. **NAMRU-6 Policy.** NAMRU-6 relies in part on the Institutional Review Board (IRB) at the Naval Medical Research Center (NMRC) and partly on its own IRB for review and approval of ongoing research involving human subjects. NAMRU-6 designates the Director, Research Administration Program (RAP) to monitor and oversee IRB-approved human subject research and report the results of this monitoring to the Commanding Officer and NMRC/NAMRU-6 IRBs. NAMRU-6 maintains documentation for its oversight responsibility, including a current Assurance and correspondence with the IRB.
- c. **Procedure.** NAMRU-6 monitors and oversees human subject research by holding monthly IRB meetings and reviewing research protocol documentation, not less than once per year, to:
 1. Verify that investigators have met and documented the initial and continuing education and training requirements by including the documentation in the research protocol submission to the NMRC/NAMRU-6 IRB.
 2. Verify that investigators have reported promptly any amendments to the research to the NMRC/NAMRU-6 IRB and have not initiated them without IRB approval, except when necessary to eliminate apparent immediate hazards to subjects or others.
 3. Address conflicts of interest that may occur after the initial IRB-approval for those involved in conducting, managing, or supporting human subject research.

4. Report to the Commanding Officer and the NMRC/NAMRU-6 IRB any unanticipated problems involving risks to subjects or others and serious adverse events; and any serious or continuing non-compliance by investigators. The Commanding Officer has responsibility to report such problems, events, and non-compliance to the NAMRU-6 Institutional Signatory Official and to applicable regulatory officials.
5. Verify that investigators have provided a copy of the IRB-approved and informed consent document with all signatures to each subject at the time of consent, unless the IRB specifically has waived this requirement.
6. Verify that investigators maintain, at a minimum, the following research protocol documents:
 - Research protocol, including all supporting documents (data abstraction forms, recruitment materials, advertisements, etc.) approved by the IRB.
 - Informed Consent Document, if applicable, approved by the IRB.
 - Approval letter, including IRB approval, to start the research.
 - Continuing review reports, amendments, other reports (unanticipated problems or adverse events), and the final report.
 - Letters approving continuing review and amendments.
 - All correspondence between investigators and the IRB.
7. Consider standards for evaluating subject case histories, product accountability records, and other documentation required by FDA regulations.
8. Verify that research documents are secured to maintain privacy and confidentiality as described in the research protocol.
9. Ensure that publications and presentations are properly cleared through the NAMRU-6, NMRC, if applicable, and others as appropriate, using DON HRPP guidelines.