

**Department of the Navy Human Research Protection Program
Research Protocol Documentation for
Investigators, IRBs, and Headquarters-Level Administrative Review**

Background: Department of the Navy commands, through their investigators and Institutional Review Boards (IRB), must maintain adequate documentation of human subject research protocols and IRB records. [32 CFR 219 and SECNAVINST 3900 series]

Directions: Use the following chart to determine the documentation investigators and IRBs must retain and copies of documents commands must provide to DON HRPP for headquarters-level administrative review. Not all the items apply to every research protocol. N/A = Not Applicable

Document Item	Investigator File	IRB File	Send to DON HRPP	Comments
Initial Review of New Protocol				
1. Document granting approval to start research (including granting exemption)	X	X	X	
2. Education and training documentation	X	X	N/A	Have available for HQ review upon request or at site visit
3. Scientific review and approval Document	X	X	X	
4. Approved research protocol – with version # and date	X	X	X	
5. Instruments (e.g., psychological tests)	X	X	X	
6. Questionnaires (e.g., diaries, demographics)	X	X	X	
7. Data collection forms, CRFs	X	X	X	
8. Recruiting, advertising materials, or letters of introduction	X	X	X	
9. Subject information sheets	X	X	X	
10. IRB-approved consent documents with expiration date/IRB stamp (all finals)	X	X	X	
11. Parental Permission (same as above)	X	X	X	
12. Child Assent (same as above)	X	X	X	
13. Foreign Language Translations of Consent / Assent / Parental Permission	X	X	X	
14. Other reviews (RAD Safety, RDRC, etc.)	X	X	X	
15. Survey Approval (OPNAV) *	X	X	X	* Approval usually obtained after IRB review
16. Verification Worksheet (CIP only)	X	X	X	
17. Standards of Conduct/Attestations	X	X	X	
18. Resource Requirements (CIP only)	X	X	X	
19. Departmental Impact Statement (CIP only)	X	X	X	

Document Item	Investigator File	IRB File	Send to DON HRPP	Comments
20. CVs	X	X	N/A	Have available for HQ review upon request or at site visit
21. FDA related documents, if applicable				
a. FDA letter for IND or IDE	X	X	X	
b. FDA Form 1571	X	X	X	
c. FDA Form 1572	X	X	X	
d. Investigator Brochure, Investigator Drug Brochure (IDB)	X	X	X	
22. Documents supporting Collaboration – Approval document from other collaborating institutions, when applicable	X	X	X	
23. Command Endorsements – Documents recommending endorsement of the research protocol, when applicable	X	X	X	
24. Agreements supporting research (JRRA, MOU, MOA, CRADA, etc.) as applicable	X	X	X	
25. IRB minutes - Excerpt from minutes – initial review	N/A	X	X	
Continuing Reviews				
1. Document approving continuing research	X	X	X	
2. Continuing Review Report from PI	X	X	X	
3. Original signed consent/assent/permission documents for all subjects	X	N/A	N/A	Have available for HQ review upon request or at site visit
4. Document for expedited review procedure	N/A	X	X	
5. IRB minutes (excerpt) for convened review	N/A	X	X	
Amendments				
1. Document approving amendment	X	X	X	
2. Amendments to the research protocol and/or consent documents (investigators change, changes in procedures, populations)	X	X	X	
3. Document for expedited review procedure	N/A	X	X	
4. IRB minutes (excerpt) for convened review	N/A	X	X	

Document Item	Investigator File	IRB File	Send to DON HRPP	Comments
Unanticipated Problems-Adverse Events				
1. Document with results of IRB review	X	X	X	
2. Unanticipated problems or adverse event report/form	X	X	X	
3. Document for expedited review procedure	N/A	X	X	
4. IRB minutes(excerpt) for convened review	N/A	X	X	
Statements of Significant New Findings				
Documents informing subjects (letter to subjects, addendum to consent, revised consent document, etc.)	X	X	X	
FDA Annual Report				
FDA report form or letter	X	X	X	
Suspension/Reinstatement				
1. Document reinstating research	X	X	X	
2. IRB and Command review of suspension	X	X	X	
3. Document suspending research	X	X	X	
4. Document terminating research	X	X	X	
5. IRB minutes(excerpt) for convened review	N/A	X	X	
Final Report / Withdrawal Notification				
1. Document approving final report	X	X	X	
2. Final Report	X	X	X	
3. Withdrawal notification	X	X	X	
4. Document acknowledging withdrawal	X	X	X	
5. Document for expedited review procedure	N/A	X	X	
6. IRB minutes (excerpt) for convened review	N/A	X	X	
Publications, Presentations, or Reports				
Copies of publications, presentation, reports based on the research protocol	X	X	N/A	Have available for HQ review upon request or at site visit

Document Item	Investigator File	IRB File	Send to DON HRPP	Comments
Other Documents Not Listed Above				
(Describe the document)	X	X	N/A	Have available for HQ review upon request or at site visit