



DON Human Research Protection Program

Department of the Navy Human Research Protection Program

**Modifications Required to
Secure Approval**

February 2013

Unclassified
Statement A: approved for public release;
distribution is unlimited



IRB Determinations



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Possible IRB determinations when reviewing human subjects research protocols:

- Approve
- Require modifications to secure approval
- Disapprove



Modifications Required to Secure Approval



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Two types of modifications:

- Those that must go back to the convened board
- Those that can be approved by the Chair

Which is appropriate, and when?



Modifications Required to Secure Approval



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If all sections of 32 CFR 219.111 are not fulfilled:

- the study cannot be approved with modifications required to secure approval.
- The study must go back to the convened board.



Chair May Review for Recommendation of Approval



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If the board requests:

- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted
- Submission of additional documentation (e.g., certificate of ethics training)
- Precise language changes to protocol or informed consent documents
- Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy



Requires Convened Board Review



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If the board requests any of the following:

- “Clarify...”
- “How...”
- “Provide more information...”
- “Explain....”
- “Describe...”



Examples: Mods To Be Reviewed by Convened IRB



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- Clarifications requested for stopping criteria
- Questions about the statistical methodology
- Questions about how referrals will be obtained
- Questions about how privacy will be maintained
- Name and/or qualifications of the medical monitor
- Concerns about the plan for research related injuries
- Questions about military enrollment
- Lack of all recruitment materials
- Lack of all study related materials (Investigator's Brochure, Device Manual)
- Questions about how participants will be identified
- Questions about measures to ensure subject privacy



Questions

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Please contact DON HRPP with any follow-up questions or concerns.

Phone: 703-681-9629

Email: human.research@med.navy.mil

Director, DON HRPP:
CAPT William Deniston