



DON Human Research Protection Program

# Department of the Navy Human Research Protection Program (DON HRPP)

IRB Meeting Minutes

July 2013

Unclassified

Statement A: Approved for public release; distribution is unlimited



# Regulatory Requirements



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32 CFR 219.115

(a) An institution, or when appropriate, and IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:



# Regulatory Requirements

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(2) Minutes of IRB meetings which shall be sufficient detail to show

- attendance at meetings;
- actions taken by the IRB;
- the vote on these actions including the number of members voting for, against, and abstaining;
- the basis for requiring changes in or disapproving research; and
- a written summary of the discussion of controverted issues and their resolution.



# Documentation of Attendance at Meetings



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Attendance at meetings includes:

- Existence of a quorum
  - A quorum is defined as more than half of the IRB members listed on the membership roster.
  - A quorum also includes a member whose primary concerns are in a non-scientific area (i.e., a non-scientist).
  - A quorum also includes a member whose primary concerns are in a scientific area.

For example, if there are 11 members on an IRB, a quorum for this IRB is 6 members.



# Documentation of Attendance at Meetings



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Presence and voting status of alternate members:

- IRBs shall designate at least one alternate for the non-affiliated member. (DoDI 3216.02, Enclosure 3, Section 3.a.(7)(b))
- No other members are required to have an alternate, however, an IRB may assign alternates for any member of the board.



# Documentation of Attendance at Meetings



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Presence and voting status of alternate members  
(con't):

- When an alternate member is present and voting in place of the primary member for whom the alternate member substitutes, this should be documented in the minutes.
  - If the primary member and their alternate are both present at the meeting, only one may count towards quorum and only one may vote.



# Documentation of Attendance at Meetings



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- Members who leave the meeting due to conflict of interest (COI) or other reason:
  - “No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.” [32 CFR 219.107(e)]
  - IRB members with a COI, must leave the IRB meeting during discussion and voting.



# Documentation of Attendance at Meetings



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- Members who leave the meeting due to conflict of interest (COI) or other reason (con't):
  - Document the member's temporary absence during discussion and voting and reason for the COI.
  - Document the time in and time out for any member who leaves for COI or any other reason and the time returned, if applicable. Include the effect the absence has on the quorum.



# Documentation of Attendance at Meetings



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- Consultants
  - Document the presence of any consultant in attendance.
  - Document the consultant's qualifications.
  - Document why the consultant is present.
  - Document the information provided by the consultant.



# Documentation of Attendance at Meetings



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- Members attending the IRB meeting via teleconference/videoconference:
  - Document that each member attending via teleconference/videoconference received all pertinent material prior to the meeting.
  - Document that each member attending via teleconference/videoconference had the opportunity to equally and actively participated in the discussion.



# Documentation of Attendance at Meetings



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- Prisoner representative:
  - Document the presence of the prisoner representative IRB member, if applicable.



# Documentation of Attendance at Meetings



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- Children's advocate:
  - Dept of Education funding for children with disabilities:
    - “If an Institutional Review Board (IRB) reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must have at least one person primarily concerned with the welfare of these research subjects.” 34 CFR 350.4(c)(2)



# Documentation of Actions Taken by the IRB



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Actions taken by the IRB include:

- Recommend approval, require modifications (to secure approval), or recommend disapproval (32 CFR 219).
  - Document one of the three possible determinations (applies to initial review, continuing review and amendments).



# Documentation of Actions Taken by the IRB



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Actions taken by the IRB include:

- For each protocol, recommend approve, require modifications in (to secure approval), or disapprove (32 CFR 219).
  - Modifications can be one of two types.



# Documentation of Actions Taken by the IRB



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- Two types of modifications:
  - The first are those modifications where the IRB is able to make all of the determinations on the criteria required for approval under 32 CFR 219.111 and the IRB chair need only to acknowledge the modifications were made.
  - The second are those modifications where the IRB does not have enough information to make all of the determinations on the criteria required for approval at 32 CFR 219.111 and the modifications need to be reviewed by the convened IRB.



# Documentation of Actions Taken by the IRB



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- IRB requested modifications made and returned to the IRB:
  - Document the previous IRB requested modifications
  - Document the PI response
  - Document whether IRB requested modifications have been met.



# Documentation of Actions Taken by the IRB



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- For both initial and continuing review, the determination of approval period and justification for the determination:
  - The approval period is appropriate to the degree of risk.
  - The approval period cannot be less than once per year.



# Documentation of Actions Taken by the IRB



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- Determination of level of risk (minimal or greater than minimal):
  - Document the level of risk (minimal risk or greater than minimal risk).
  - Document justification for the determination of level of risk.



# Documentation of Actions Taken by the IRB



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- Determination that requirements for approval at 32 CFR 219.111 have or have not been satisfied:
  - Document the IRB determination that the following requirements are satisfied:
    - Risks to subjects are minimized and reasonable in relation to anticipated benefits.
    - Selection of subjects is equitable.
    - Informed consent is obtained and documented (unless the IRB approves alteration or waiver).
    - Measures to protect the privacy and confidentiality of data, when appropriate.
    - Adequate provisions for monitoring the data to ensure subject safety.
    - Additional safeguards have been included in the study to protect the rights and welfare of any vulnerable populations.



# Documentation of Actions Taken by the IRB



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- Determination that the informed consent document contains all of the basic elements of consent and additional elements as appropriate:
  - Elements found at 32 CFR 219.116



# Documentation of Actions Taken by the IRB



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- Document IRB findings for waiver or alteration of some or all of the elements of informed consent:
  - The research involves no more than minimal risk to subjects,
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects,
  - The research could not practicably be carried out without the waiver or alteration, and
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.



# Documentation of Actions Taken by the IRB



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- Document IRB findings for waiver of documentation of informed consent:
  - The only record linking the subject and the research would be the consent and the principal risk would be the potential harm resulting from a breach of the confidentiality.
- OR
  - The research presents no more than minimal risk of harm to subjects and involves no procedures of which written consent is normally required outside of the research context.



# Documentation of Actions Taken by the IRB



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- Documentation of suspension or termination of IRB approval of research.
- Document the basis for the IRB determination to suspend or terminate research.
- Document the basis for IRB determination that research satisfies the conditions of all applicable sections of 45 CFR 46, Subpart B and DoDI 3216.02 Enclosure 3, Section 7.a. for the additional protections for pregnant women, human fetuses and neonates involved in research.



# Documentation of Actions Taken by the IRB



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- Document the basis for IRB determination that research satisfies the conditions of all applicable sections of 45 CFR 46, Subpart C and DoDI 3216.02, Enclosure 3, Section 7.b. for the additional protections pertaining to biomedical and behavioral research involving prisoners as subjects.



# Documentation of Actions Taken by the IRB



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- Document the basis for IRB determination that research satisfies the conditions of all applicable sections of 45 CFR 46, Subpart D and DoDI 3216.02, Enclosure 3, Section 7.d. for the additional protections for children involved as subjects in research.
  - Document IRB determination of the need for the appointment of an advocate for children who are wards.
  - Document IRB determination of the requirement for one or both parents to give permission.
  - Document IRB determination of the requirement for child assent.



# Documentation of Actions Taken by the IRB



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- Document the IRB consideration of scientific review of research.
- If the research will take place in a foreign country, document:
  - Confirmation that all applicable national laws and requirements of the foreign country have been met,
  - Permission of the host country has been obtained, and
  - Ethics review by country (if there is no host country representation on the local Naval IRB.)



# Documentation of Actions Taken by the IRB



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- Document IRB determination of non-compliance with human subject research protections and any corrective actions required by the IRB.
- Document IRB approval of independent research monitor by name and approval of a written summary of the monitor's duties, authorities, and responsibilities.



# Documentation of Actions Taken by the IRB



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- Document IRB review of protocol amendments.
  - Document consideration of change to risks to subjects.
- Document IRB review of all adverse events.
  - Document IRB determination of corrective action, if any.
- Document IRB review of unanticipated problems involving risks to subjects or others (UPIRTSO).
  - Document whether the event meets the three criteria (DoDI 3216.02):
    - Unexpected in terms or nature, severity or frequency,
    - Related or possibly related to participation in the research, and
    - Suggests that the research places subjects or others at a greater risk of harm than previously known
  - Document IRB determination of corrective action, if any.



# Documentation of Actions Taken by the IRB



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- Document IRB determinations required by FDA regulations (if applicable):
  - Non-significant risk device determinations.
  - Approval of Humanitarian Use Devices.
  - Emergency use exemption (“compassionate use”) approval.



# Documentation of the Vote on IRB Actions



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- Document the number of members voting for, against, and abstaining.
- Document any recusals and the reason for the recusal, especially for COI.
- Document circumstances when an alternate member is voting for a primary member.



# Documentation of Controverted Issues and Resolution



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- Controverted issues are those that are disputed or opposed to by reasoning.
- IRB minutes should provide a summary of the discussion of the controverted issues and their resolution.
- The summary should be in sufficient detail for someone not present at the meeting to determine how the IRB arrived at its decision.



# Documentation of Other IRB Meeting Events



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- Time of the start and end of the meeting.
- Vote and approval of previous meeting minutes.
- Education:
  - Often, to meet continuing education requirements, IRBs will conduct educational sessions as part of their meeting.
  - Any educational session should be summarized in the minutes.



# Documentation of Other IRB Meeting Events



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- Announcements:
  - Many IRBs use the minutes as the method for the requirement to notify IRB members of the expedited actions taken by the Chair/Vice Chair since the last IRB meeting.
  - The minutes can also be used to inform IRB members of exempt determinations.



# Questions



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

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