

Appendix B

Non-FAC Open Panel Model Guidelines

- 1) Only OHRP screened applications which meet the requirements for review under the 407 process are forwarded for review by the panel of expert consultants.
- 2) Relevant protocol and IRB documents are posted on the OHRP website for public review and a Federal Register notice is prepared that:
 - a) Invites public review and comment on the proposed research; and
 - b) Announces the date on which the panel of expert consultants will be convened and invites members of the public to attend.
- 3) Expert consultants selected from a standing pool of experts, supplemented with appropriate protocol specific experts, receive protocol materials and public comments for review.
- 4) Experts new to the expert panel consultation review process receive an appropriate orientation by OHRP staff.
- 5) A face-to-face meeting of the expert consultants is convened, with the public present for a portion of the meeting.
- 6) All experts are given an opportunity to express their opinions, review all materials, and listen to public comments.
- 7) After their convened meeting and consideration of public comments, each expert consultant writes an independent recommendation regarding the proposed research.
- 8) The individual reports from the expert consultants are posted on the OHRP website.
- 9) OHRP develops recommendations based upon all materials and forwards its recommendations and materials to the Secretary (or designee).
- 10) The Secretary (or designee) approves or disapproves the request for HHS to support the research.
- 11) OHRP notifies the referring institution in writing of the Secretary's (or designee's) decision.
- 12) At the Secretary's (or designee's) discretion, the HHS decision, detailed rationale for the decision, and supporting materials are posted on the OHRP website.
- 13) If the Secretary (or designee) approves the proposed research with stipulations, the investigator must modify the research proposal and submit it to the local referring IRB for review and approval.
- 14) The IRB submits the approved revised protocol to OHRP for final concurrence.