

THE NEMOURS FOUNDATION POLICY AND PROCEDURE MANUAL	
SUBJECT: Review by the Convened IRB (Full IRB Review)	No. HSP-039
EFFECTIVE DATE: November 1, 2007	SUPERCEDES: Version October 1, 2007
SECTION: NOHSP	DEPARTMENT: NOHSP
NAME/TITLE: Paul E. Garfinkel, MSH, CIP – Director, NOHSP	
SIGNATURE:	DATE APPROVED: October 13, 2006 DATE REVIEWED / REVISED: October 1, 2007 DATE REVIEWED / REVISED: April 17, 2008

1. **PURPOSE:** The purpose of this policy is to establish the procedures by which the convened Nemours IRBs conduct reviews of investigator submissions of human subjects research activities.
2. **POLICY:** All research involving human participants will be reviewed and approved by the IRB prior to the start of any research activities. Review by a convened meeting of the IRB is the default mechanism of IRB review and is the primary method for the protection of human research participants.
3. **DEFINITIONS:** A glossary of terms and concepts found in the Nemours HSP policies and procedures is located on the NOHSP website.
 - 3.1. **Quorum:** More than half of the voting IRB members (ex. $13 \div 2 = 6.5$, or 7 members), including at least one member whose primary concerns are in nonscientific areas and at least one physician member when reviewing studies of FDA-regulated articles. Review of proposed research at convened IRB meetings requires a quorum.
4. **PROCEDURES:**
 - Meeting Preparations
 - 4.1. The IRB Staff assures completion of all items on the [Checklist for Meeting Preparation](#).
 - 4.2. The IRB Chair will conduct a preliminary review of all agenda items, especially items scheduled for initial review in order to identify issues that may require action before or during the meeting.
 - 4.3. IRB members will use the Checklist for IRB Review to assure compliance with federal regulations and Nemours policy.
 - Meeting Conduct
 - 4.4. The IRB Chair is responsible for the conduct of the meeting and for assuring that review by the convened IRB complies with DHHS and FDA regulations related to IRB functions and the protection of research participants.
 - 4.5. The IRB Chair will conduct the meeting according to the [Checklist for Conducting IRB Meetings](#).
 - 4.5.1. The IRB Chair may revise the order of the agenda during the meeting in order to facilitate meeting efficiency or effectiveness and the specific needs of the IRB.

- 4.6 The IRB Coordinator will assure that all pertinent discussions, actions and determinations are recorded in the IRB Minutes by following the [Checklist for IRB Minutes](#).

Investigator presentations

- 4.7. The investigator assures that the IRB has enough information to arrive at a valid decision for the specific study under review by completing the Application located in IRBNet.
- 4.8. In general, investigators do not attend IRB meetings. However, at the discretion of the IRB Chair, an investigator may be invited to attend to present a research summary and answer specific questions from the reviewers. If this is done, the PI will:
- Be informed of the confidentiality of the proceedings.
 - Address the committee before his or her protocol is reviewed and discussed by the IRB.
 - Not be present during IRB discussion and/or voting of the any research under review.

Consultants

- 4.9. When the IRB has ethical or scientific concerns that cannot be addressed within the committee, a consultant may be requested.
- 4.10. The IRB Chair will ask the committee for suggestions, giving priority to experts within Nemours.
- 4.11. If Nemours does not have the needed expertise, the IRB Chair will obtain an external consultant.
- 4.12. Consultants will comply with Confidentiality and Conflict of Interest policies.
- 4.13. The consultant's response will be reviewed at a subsequent meeting of the IRB. The IRB's decision regarding the study in question must be tabled (deferred) until that time.

Conflict of Interest Resolution

- 4.14. When the IRB determines that the investigator or a member of the research team has a potential conflict of interest during review, a decision on the specific study under review will be deferred pending review by the Research Conflict of Interest Committee as required by the Nemours Conflict of Interest policy (#1.5.4.3)

Communication

- 4.15. The IRB will report:
- Its findings to investigators, the institution, and related committees.
 - The rationale for determinations and actions.
 - A description of how investigators may respond.
- 4.16. The IRB Coordinator will use the IRBNet on-line letters to assure compliance with this policy.

5. **REGULATORY / GUIDANCE REFERENCES:**

- 5.1. [Nemours Conflict of Interest policy #1.5.4.3](#)
- 5.2. Amdur J, Bankert E. Institutional Review Board: Management and Function. Jose and Bartlett Publishers.
- 5.3. OHRP [Guidance on Written IRB Procedures](#), 2002
- 5.4. [21 CFR 56](#) Institutional Review Boards, [21 CFR 50.50](#) Additional Safeguards for Children in Clinical Investigations: IRB Duties.
- 5.5. [45 CFR 46 Protection of Human Subjects](#)

6. **AAHRPP STANDARD REFERENCES:** Element II.2.A: The Research Review Unit has and follows written policies and procedures for conducting initial and continuing review, and procedures for handling modifications to research studies.