

THE NEMOURS FOUNDATION POLICY AND PROCEDURE MANUAL	
SUBJECT: Use of External Institutional Review Boards	No. HSP-002
EFFECTIVE DATE: June 1, 2006	SUPERCEDES: Version August 23, 2007
SECTION: NOSHP	DEPARTMENT: NOHSP
NAME/TITLE: Paul E. Garfinkel, MSH, CIP – Director, NOHSP	
SIGNATURE:	DATE APPROVED: May 9, 2006 DATE REVIEWED / REVISED: August 23, 2007 DATE REVIEWED / REVISED: May 1, 2008

1. **PURPOSE:** Rarely, Nemours may utilize external IRB's to review human subjects research. This will most frequently occur when research is conducted by Nemours investigators at a partner institution not owned by Nemours. This policy establishes the process by which Nemours may encumber the services of a non-Nemours Institutional Review Board for the review of research conducted by Nemours investigators.
2. **POLICY:** In order to assure the provision of adequate review of human subjects research conducted under the auspices of any Nemours entity, Nemours may utilize the services of external IRBs upon the execution of an IRB Authorization Agreement by both institutions.
 - 2.1. Nemours retains the ultimate responsibility for assuring the protection of human participants in research conducted under its auspices regardless of the venue of IRB review.
 - 2.2 Individual Nemours Investigators may not independently seek the services of an external IRB outside of the terms of existing IRB Authorization Agreements between Nemours and another institution
3. **DEFINITIONS:** A glossary of terms and concepts found in the Nemours HSP policies and procedures is located on the NOHSP website.
 - 3.1. **IRB Authorization Agreement:** A legal agreement prescribed by OHRP that describes the obligations of both parties when one relies upon the other for IRB review services. (The OHRP template for this Agreement is found here: <http://www.hhs.gov/ohrp/humansubjects/assurance/filasuri.htm>.)
 - 3.2. **Institutional Official:** The Nemours Corporate Officer designated by policy with the regulatory oversight of Nemours research and human research participant programs, including signatory authority on behalf of Nemours on related documents.
4. **PROCEDURES:**
 - 4.1. When it is recognized that Nemours requires the services of an external IRB the Institutional Official will negotiate an IRB Authorization Agreement with the other institution.
 - 4.1.1 The Director, NOHSP will obtain and review a copy of the external IRB's policies and procedures in order to assure that the IRB meets Nemours' standards for the protection of human research subjects.

- 4.1.2. The Agreement will specify the nature of the research that will be delegated to the external IRB.
 - 4.1.3. As appropriate, an additional agreement or memorandum of understanding may be negotiated with the other institution / IRB for the purpose of specifying additional details of the relationship that are not addressed in the IRB Authorization Agreement.
 - 4.2. All Agreements will be submitted to Nemours Legal Services for review and approval.
 - 4.3. The Institutional Official shall be the signatory official for the agreements on behalf of Nemours.
 - 4.4. Copies of all executed agreements shall be maintained in NOSHP and Nemours Legal Services files.
 - 4.5. Such agreements will include a requirement that the external IRB notify NOHSP on a timely basis of any disciplinary actions, sanctions, or reporting to federal or state regulatory agencies regarding any Nemours Associate.
 - 4.6. The Director of NOSHP will assure the adequacy of reviews performed by external IRBs via:
 - Periodic review of applicable minutes and IRB/Investigator correspondence. And/or
 - Cross-membership on the Nemours' and the affiliated IRB.
5. **REGULATORY REFERENCES:** [HSP-016 IRB Jurisdiction](#), [45 CFR 46.103\(b\)\(2\)](#), [45 CFR 46.103\(d\)](#), [45 CFR 46.114](#), [21 CFR 56.114](#).
6. Element 1.2.B: The Organization provides the appropriate number of IRBs for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner. An Organization may use the IRBs of another Organization to meet the needs of its research program.