Investigator Responsibilities

1. Submits a completed Human Subjects Protocol (HSP) to the IRB for review with the following information:
   a. A rationale for the requirements in 21 CFR 50.24(a)(1)-(4) in POL019
   c. Definition of the length of the therapeutic window and the scientific evidence for its basis as proposed in the investigational plan or research protocol;
   d. A commitment to attempt to contact within the therapeutic window a legally authorized representative (LAR) for each subject when informed consent by the subject is not feasible or, if subject consent is feasible, asking the LAR for consent rather than proceeding without consent;
   e. A commitment to attempt to contact within the therapeutic window the subject’s family member who is not a LAR, when informed consent by the subject is not feasible and the LAR is not reasonably available, asking if the family member objects to the subject's participation in the study;
   f. Proposed procedures for:
      i. Obtaining informed consent from subjects or their LAR in situations where use of such procedures and documents is feasible;
      ii. Providing an opportunity for a family member to object to a subject’s participation in the clinical investigation or research;
      iii. Informing, at the earliest feasible opportunity, each subject—or if the subject remains incapacitated, a LAR of the subject, or if a LAR is not available, a family member—of the subject’s inclusion in the research, the details of the research and other information contained in the informed consent document;
      iv. Informing the subject—or if the subject remains incapacitated, a LAR of the subject, or if such a LAR is not reasonably available, a family member—that (s)he may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
      v. Informing the subject about the research as soon as feasible;
Providing information about the research to the subject’s LAR or family member, if feasible, in the event the subject is entered into research with waived consent and the subject dies before a LAR or family member can be contacted;

- Description of the proposed additional protections of the rights and welfare of the subjects for the study;
- Plan for tracking and summarizing all attempts to obtain informed consent from LAR and family members and making this information available to IRB at continuing review.

- Submits informed consent documents to be used with subjects and LAR in situations where informed consent process is feasible (see POL013 policy on, PRO113 procedure for informed consent process);

- Submits information to be used when providing a family member an opportunity to object to a subject’s participation;

- For FDA-regulated research, provides IND or IDE number and holder for protocols that clearly identify the protocol as one that may include subjects who are unable to consent;

- Provides a summary of all efforts to obtain informed consent from subjects’ LAR and family members at the time of continuing review.

**IRB Responsibilities**

The IRB for clinical investigations subject to FDA regulations:

- Approves the activity and a waiver of informed consent process requirements at 45 CFR 46.116(a), (b) and 46.408, if applicable;

- Finds and documents that:
  - The research activity is subject to 21 CFR Part 50;
  - The research activity has a separate IND or IDE which clearly identifies that the protocol(s) would include subjects who are unable to consent;
  - With concurrence of a licensed physician member or consultant unaffiliated with the investigation, the requirements for an exception to informed consent process for research in emergency circumstances are met in relation to the protocol(s) (21 CFR 50.24(a), (b));

- Determines it is unable to approve the activity because the activity does not meet the criteria for exemption provided in 21 CFR 50.24(a) or for other relevant ethical concerns:
  - Documents these findings; and
  - Provides the findings promptly to the clinical investigator and sponsor.
• Retains the IRB determinations and documentation related to the investigation for at least 3 years after completion of the investigation and makes the records accessible to FDA for inspection and copying.

The IRB for research not subject to FDA regulations:

• Approves the activity and a waiver of informed consent process requirements at 45 CFR 46.116(a), (b) and 46.408, if applicable;

• Finds and documents that the research is not subject to FDA regulations at 21 CFR Part 50; and

• Finds, documents, and reports to OHRP that the conditions in HHS Emergency Research Consent Waiver Section (b) are met.

OIRB Responsibilities

The Senior Staff:

• Works with investigator to obtain necessary information for protocol review;

• Assists investigator with arrangement of consultation with community representatives about proposed conduct of the clinical investigation, when appropriate;

• Tracks findings and determinations of IRB to ensure satisfaction of federal requirements;

• Reviews communications to the investigators of the IRB findings;

• Reviews the minutes of the IRB meeting to assure sufficient information is included to meet the DHHS and FDA regulatory requirements;

• Drafts letters to OHRP to report IRB approval of Waiver to Informed Consent Process in Research Planned for Emergency Settings.

The Administrative Staff:

• Drafts communications to the investigators of the IRB findings and determinations;

• Mails communications to the investigators and sponsors, if necessary;

• Prepares the minutes of the IRB meeting, including the necessary information to document the IRB findings and determinations to meet DHHS and FDA regulatory requirements;

• Mails letters to OHRP to report IRB approval of Waiver to Informed Consent Process in Research Planned for Emergency Settings for research not under FDA regulation.
Sponsor Responsibilities

The Sponsor for research regulated by the FDA:

- Promptly reports a determination that the IRB is unable to approve the research because it finds that the activity does not meet the criteria in the exception provided under 21 CFR 50.24(a) or other relevant ethical concerns to:
  - The FDA;
  - Other clinical investigators participating or asked to participate in this research or a substantially equivalent research study; and
  - Other IRBs that have been asked to review this research or an equivalent research study.

Approved on **October 29, 2010**, by:

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director