Investigators Must Comply With All Of The Following:

- Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report: http://ohsr.od.nih.gov/guidelines/belmont.html
- Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.
- If translation for the consent of non-English-speaking subjects is necessary, contact the IRB prior to consenting, to assure compliance with all IRB-approved translation/interpretation procedures.

Post Approval Documentation Requirements:

DURING THE COURSE OF THE STUDY THE IRB MUST REVIEW THE FOLLOWING:

1. Protocol Modification Form (PMF): Must be used to notify the IRB of any modifications/additions to the study and/or study documents. *Pre-approval is required*, meaning, the IRB must review any and all modification/additions to the study and/or study documents and IRB approval must be granted *before* the modifications/additions to the study are implemented or the modified/new study documents are distributed to subjects.
**When study documents are modified over the course of the study, care should be taken to ensure the version most recently approved by the IRB is used.*

2. Personnel Change Form (PCF): Must be used to notify the IRB of changes to Key Study Personnel (KSP). KSP are individuals who contribute in a substantive manner to the design or conduct of a research study such as: a) Obtaining informed consent of or otherwise enrolling research subjects, b) Administering primary study interventions being tested under the research protocol, c) Conducting interviews, surveys, or other data collection activities with research subjects. KSP are usually research Investigators, Coordinators, Associates, and Assistants. The IRB also requires that all KSP have up-to-date training in Humans Subject's Protections.
Contact the IRB Office for question about accepted Human Subject's Protections training courses.

3. Website Listing Form: This form may be submitted to the IRB as a request to post basic study information on the Swedish.org website. A study must be approved by the IRB (either Swedish IRB or WIRB) before information about the study may be posted. Only basic information such as study title, the purpose of the study, eligibility criteria, and study contact information may be included. If an investigator wishes to post website information more specifically directed at recruitment of study subjects, a Protocol Modification Form (PMF) with the appropriate recruitment materials must be submitted to the IRB for review and approval.

4. Adverse Event Reporting: Unanticipated events are to be reported to the IRB. These are events where the nature, severity, or frequency of the adverse event is not identified in the investigational plan for the research study (e.g. investigator's brochure, protocol, consent form).
Contact the IRB Office for definitions of a serious unanticipated event and to verify if an event requires IRB reporting.

5. Protocol Deviations/Violations: Protocol deviations, or changes/variances in research from the current IRB-approved protocol, should be avoided. A Principal Investigator should not intentionally depart from or otherwise initiate a planned or deliberate change to the protocol unless necessary. While Principal Investigators should avoid protocol deviations, a Principal Investigator may initiate a protocol deviation without Sponsor or IRB review or approval when, in the Principal Investigator's judgment, the change is necessary to eliminate an apparent immediate hazard to the subject(s) (e.g. to protect the life or physical well-being of a subject in an emergency).
Contact the IRB to verify if an event requires IRB approval or reporting.

6. Continuing Review Progress Reports (CRPR): It is the policy of SMC to conduct continuing review of ongoing research projects not less than once per year, as required by 45 CFR 46.109(e). The IRB may, in its discretion, require review of a study more often than once per year if the IRB determines more frequent review is necessary. The IRB Office will send out a courtesy reminder email notice to the Principal Investigator and the study contact(s) approximately ***1 month before the CRPR is due in the IRB Office.***

If the CRPR is not received in the IRB Office by the due date the study is at risk of CLOSURE. Closure would occur on the study's expiration date and cause accrual and research activities to end and result in noncompliance of the Principal Investigator. The noncompliance would then be reported to the SMC Chief Medical Officer and Chief Scientific Officer. If the Principal Investigator plans to conduct research in the future with SMC, an explanation of noncompliance and a corrective action plan would require IRB review before research may be considered.

7. Study Closures: The IRB considers study statuses as they apply to local sites (the site the IRB is reviewing the study for) and local subjects. A study can be closed to enrollment, temporarily closed, or closed; final. A definition of each closure type is identified below. A PMF must be submitted to the IRB each time a study's status changes. The only exception is when a study is closed; final. When a study is closed; final, a Study Closure Form must be submitted to the IRB.
Definitions:

- **Enrollment Closed; study procedures ongoing** – Study activities continue for subjects enrolled to the study but no additional subjects will be entered into the study.
- **Enrollment Closed; follow-up ongoing** – Subjects have completed all study-related interventions and the study remains active only for long-term follow-up of subjects.
- **Enrollment Closed; data analysis only** – Study procedures and follow-up are complete and data (including identifiable subject information and/or linked information) is being analyzed.
- **Enrollment Temporarily Closed** – Study activities continue for subjects enrolled to the study but no additional subjects will be entered into the study. The IRB must be notified when the study re-opens to enrollment or if the study permanently closes to enrollment.
- **Closed; final** – All study procedures and subject follow-up are complete including data analysis of identifiable and/or linked subject information and IRB review is no longer necessary.