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USA

- The local IRB (USA IRB) will retain certain responsibilities for oversight and review of the research in order to comply with USA requirements, and all pertinent federal, state and local laws and regulations.
- Institutional policies will apply for disclosing financial conflicts of interest.
- Regulatory review and approval will be conducted by the USA Institutional Biosafety Committee and Radiation Safety Committee, as necessary.

USA IRB Responsibilities

The USA IRB is the local institution ensuring the safe and appropriate conduct of the research at USA. This includes, but is not limited to:

- Oversee requirements for human subjects training
- Monitor protocol compliance as part of its quality assurance program
- Changes in conflict of interest
- Change in PI and key personnel
- Managing any serious adverse events occurring at the institution
- Providing a mechanism by which complaints about the research can be made by local study participants or others.

USA has specific responsibilities of the local institution in relation to HIPAA, Informed Consent and Assent, and the reporting of unanticipated problems and serious adverse events, as well as participation by prisoners and individuals with impaired decision making capacity. These have been incorporated into the USA IRB administrative review process and procedures described below, and the guidelines which follow.

The USA IRB Administrative Review Process

The USA IRB administrative review process is designed to simplify local review and approval of trials requesting external IRB oversight. In addition to the initial administrative review process, the USA IRB will also initiate an annual follow-up to check on the status of the study and changes to key personnel. Since the external IRB is accountable for all continuing reviews, the USA IRB is no longer required to conduct reviews of amendments; continuing reviews; reviews of recruitment or educational materials intended for use by current or potential study participants; and review of adverse events.

Reporting Unanticipated Problems

- **Local** unanticipated problems occur at and are limited to a specific institution. The local institution is responsible for managing these according to our FWA procedures. If USA IRB determines that an unexpected incident, event, or outcome meets the regulatory definition of unanticipated problem, it is