IASIS HEALTHCARE	**POLICY TITLE**: IRB – IEC Approval
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.1.2 ☐ Addendum to Corporate Policy ☐ Form Available In I-REPP System
SECTION (as applicable): Clinical Research	**POLICY OWNER**: Tedd Adair, Vice President of Clinical Operations and Chief Clinical Officer
ORIGINATION DATE: 01/01/2011	**FINAL APPROVAL DATE**: April 30, 2016

POLICY:

When obtaining IRB/IEC approval of all required study materials, to ensure that all relevant study materials are submitted to an IRB/IEC that meets FDA requirements and that approval is received before they are used to conduct the study activities.

SCOPE:

This procedure applies to all clinical trials conducted at any ICARE location.

DEFINITIONS:

Not Applicable

PROCEDURE:

"IRB" refers to an Institutional Review Board; "IEC" refers to an Independent Ethics Committee. These terms may be used interchangeably.

IASIS Healthcare Approved IRBs
Every clinical trial conducted at an IASIS facility must be reviewed and approved by one of the following IRBs:

- Western Institutional Review Board
- Schulman Associates IRB
- Quorum IRB
- University of Utah (only for GYN Research Network Studies)
- Midwestern University (only for Residents in an IASIS Affiliated Residency Program)
- Other IRBs pre-approved by IASIS Legal Department (only when an IASIS Affiliation Agreement exists, such as Affiliated Nursing Schools)

IRB/IEC Membership:
Documentation is requested from the IRB/IEC to demonstrate that it meets the following regulatory requirements regarding IRB/IEC membership criteria:

- At least 5 members
- Varying backgrounds to ensure adequate review
- Qualified through experience and expertise (professional competence)
- Demographically and/or culturally diverse to ensure sensitivity to community concerns
- Knowledgeable in regulations, law, and professional standards of practice
- At least one male and one female member
- More than one profession represented
- At least one member whose primary concerns are in the scientific area
- At least one member whose primary concerns are in nonscientific areas
- At least one member who is not otherwise affiliated (and whose immediate family members are not affiliated) with the institution

IRB/IEC Procedures:
Documentation is requested from the IRB/IEC to demonstrate that it meets the following procedural regulatory requirements:

- the IRB/IEC follows written procedures for:
    - conducting its initial and continuing review of research
    - determining which projects require review more often than annually
    - ensuring prompt reporting of changes in research activity, unanticipated problems involving risk to subjects, noncompliance with requirements, and suspension or termination of approval
- the IRB/IEC prepares and maintains adequate documentation of IRB activities
- the IRB/IEC records are retained for at least 3 years after the completion of the research

Documentation to confirm that the IRB meets regulatory requirements for IRB/IEC Membership and Procedures may include:

- written IRB standard operating procedures
- statement included on official IRB correspondence to the investigative site (e.g., the initial approval letter)
- other equivalent method of documentation that has been approved by the ICARE Research Supervisor confirming that these regulatory requirements have been met

Submissions to the IRB/IEC for Initial Review:
All of the following are submitted to the IRB/IEC for approval:

- most recent version of the study protocol
- informed consent form that includes:
    - a statement that the study involves research
    - an explanation of the purposes of the research
    - the expected duration of the subject's participation
    - a description of the procedures to be followed
    - identification of any procedures which are experimental
    - a description of any reasonably foreseeable risks or discomforts to the subject

- a description of any benefits to the subject or to others which may reasonably be expected from the research
- a disclosure of the appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- a statement describing the extent to which confidentiality of records will be maintained and noting the possibility that the FDA may inspect the records
- an explanation as to whether any compensation and whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained (for research involving more than minimal risk)
- the ICARE approved standard injury statement
- an explanation of whom to contact for answers to pertinent questions about the research and subjects' rights and whom to contact in the event of a research-related injury
- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits or rights to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits or rights to which the subject is otherwise entitled

When appropriate, one or more of the following elements shall also be included in the informed consent form:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of
- the research which may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study

- assent form (for use with minors only)
- amount and method of subject compensation and/or reimbursement for out-of-pocket expenses such as those for transportation, parking, meals, etc.
- recruitment materials (e.g., advertisement), if used
- scripts, videos, or any other patient education materials, if used
- any other written information to be provided to the subjects
- if individually identifiable health information (e.g., surgery or office schedules, medical records, etc.) will be used or reviewed to "pre-screen" potential participants prior to the informed consent discussion, a request for approval of a waiver of authorization to use this protected health information is also submitted to the IRB

Vulnerable Populations

If the site is anticipating enrollment of participants from any vulnerable population (e.g. children, pregnant women, human fetuses, neonates, prisoners, handicapped, mentally disabled, economically or educationally disadvantaged), the investigator must propose to the IRB special protections that will be implemented to ensure that the rights and welfare of research participants classified as "vulnerable" are protected, or request guidance/instruction from the IRB on appropriate safeguards for the special population.

IRB/IEC Approval:

Before beginning any study procedures,

- IRB/IEC approval must be received in writing
- Verification must be obtained that:
    - no IRB/IEC members participating in the review had a conflict of interest; this will be accomplished by obtaining and reviewing the list of the participating members
    - the research was approved during a meeting at which a majority of the members of the IRB/IEC were present, including at least one member whose primary concerns are in nonscientific areas (except when an expedited review procedure is used)
    - the research was approved by a majority of the members present at the meeting
- A copy of the IRB/IEC approval must be on file in the ICARE Office of Clinical Research

Expedited review by the IRB may be requested for minor changes in previously approved research; however, the IRB must make the final determination that such information falls into an appropriate category eligible for expedited review per relevant federal regulations.

Before using or reviewing any individually identifiable health information to "pre-screen" potential participants prior to the informed consent discussion, IRB or Privacy Board approval of a waiver of authorization must be received in writing. Documentation of this approval must include:

- A statement identifying the IRB or Privacy Board (PB) and the date on which the waiver was approved
- A statement that the IRB/PB has determined that the waiver satisfies the following three criteria:
    - The use of the protected health information involves no more than a minimal risk to the privacy of individuals
    - The research could not practicably be conducted without the waiver, and
    - The research could not practicably be conducted without access to and use of the protected health information
- A brief description of the protected health information for which use or access has been determined to be necessary by the IRB/PB
- A statement that the waiver has been reviewed and approved under either normal or expedited review procedures
- Signature of the chair or other member as designated by the chair of the IRB/PB

Changes to Research Activities:
After initial IRB approval is obtained, no changes may be made without IRB approval except where necessary to protect the rights, safety, and/or welfare of the subjects. Any proposed changes to IRB-approved research activities or IRB-approved documents must be approved in writing by the IRB prior to implementation.

Responsibility:
- The Principal Investigator/assigned party is responsible for ensuring that documentation of regulatory compliance is requested of all IRB's/IEC's used by IASIS.
- The Principal Investigator/assigned party, with assistance from other applicable operations staff, is responsible for ensuring the timely submission of documents for IRB/IEC/PB approval.
- The study coordinator is responsible for ensuring that all relevant documents are approved in writing (along with the appropriate verifications) before beginning any study procedures, including any "pre-screening" activities.
- The study coordinator is responsible for ensuring that IRB approval of changes to research activities or IRB-approved documents is received in writing prior to implementation.

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration Federal Code Title 21 Part 56

Review/Revised Date:	Title:	Description of Change or Location of Change in Document:
04/30/2016	Tedd Adair VP of Clinical Operations & CCO	Scheduled review; converted to ISO Policy Template