IASIS HEALTHCARE	**POLICY TITLE**: Informed Consent
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.2.3 ☐ 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 conducting initial and amended informed consent discussions with potential and enrolled subjects, to ensure that subjects and potential subjects are treated with respect and autonomy by fully informing them about all relevant aspects of the study prior to their enrollment and making them aware of any changes during the trial that may affect their willingness to continue their participation.

SCOPE:

This procedure applies to all clinical trials conducted at any IASIS facility.

DEFINITIONS:

Study-related procedure: any procedure performed for the sole purpose of the study and that would not otherwise be performed as part of the subject's routine health care

Legally authorized representative: any individual, judicial or other body authorized under applicable law to give consent on behalf of a prospective subject for the subject's participation in research; this may include a legal guardian, a parent (for children of minority age only), and in some cases a validly designated durable power of attorney for health care.

Children: persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Assent: affirmative agreement to participate in research by persons who have not attained the legal age for consent (i.e. children) to treatments or procedures involved in research but who have mental capacity to understand and make decisions. *Mere failure to object should not,*

absent affirmative agreement, be construed as assent. The child with adequate mental capacity must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

PROCEDURE:

Initial Informed Consent Process:

Before performing any study-related procedure with a subject, the following informed consent process is completed in the order presented:

1) The study team member reviews any available information to determine if the potential subject is currently on any medications or treatments or has any diagnoses or other conditions that may interfere with the mental capacity to give informed consent. (Per HIPAA, this step is performed prior to the consent discussion only if the potential subject has given his/her written authorization or if the investigator has received written IRB/Privacy Board approval of a waiver/partial waiver of this authorization requirement. If neither of these conditions applies, this step is performed after the consent discussion if the person consents to participation).
2) The study team member meets with the potential subject to:
    a. fully and completely explain the trial
    b. inform them that the drugs/agents are being used for investigational purposes
    c. assess their mental capacity to give informed consent
    d. ensure that they understand that research participation is a choice
    e. ensure that they understand that they can freely refuse to participate and/or withdraw at any time without penalty
    f. explain how their health information would be used for the study
    g. inform them that, if they do not agree to allow their health information to be used in that way, they will not be allowed to participate in the study
    h. ensure that there is no indication that the decision about whether to participate is made with coercion or undue influence by circumstances or other people.
3) The study team member then provides ample time for the potential subject to read the most current IRB-approved informed consent form and ask questions.
4) If the potential subject agrees to participate, the consent form is personally signed and dated by the subject and the person conducting consent discussion.
5) If the consent form does not contain a detailed explanation of how the subject's health information would be used for the study, the subject also must sign a separate "Authorization to Release and Use Health Information for Research Study" form.
6) The subject is given a copy of the signed and dated written informed consent form (and "Authorization" form, if applicable).
7) The original signed consent form (and "Authorization" form, if applicable) is filed in the subject's source documents.
8) For any subject participating in a study being conducted at an IASIS facility a copy of the signed consent form (and authorization form, if applicable) is forwarded to the facility Health Information Manager/or assigned party to be placed in the patient medical record.

In special circumstances, informed consent procedures may be waived by the Institutional Review Board as determined appropriate and lawful by the IRB of record. If the IRB has made this determination for any clinical investigation, this decision will be clearly identified in written

documentation to the investigative site along with any special instructions to be followed to ensure the protection of participants' rights and safety. If this IRB decision has not been clearly communicated in writing to the site, the informed consent procedures detailed in this Guideline must be followed.

Surrogate Consent:
If the subject is unable to provide his/her own consent (e.g., due to age or mental capacity), the above informed consent procedures and any ongoing consent procedures may be completed with the subject's legally authorized representative according to state law and relevant institutional policies.

Inability to Read:
If a subject is unable to read or if a legally authorized representative is unable to read, the following additional informed consent procedures are followed:

- An impartial witness is present during the entire informed consent discussion.
- After full and complete explanation on all pertinent aspects of the trial and after oral consent is given, the subject or the subject's legally authorized representative signs and dates the consent form if he/she is capable.
- The witness signs and personally dates the consent form to attest that the information in the consent form and any other written information was accurately explained to, and apparently understood by the subject or their legal representative and that informed consent was freely given by the subject or their legal representative.

Non-English Speaking Participants:
When the study subject population includes non-English speaking participants, the IRB-approved informed consent form must be translated into a language the subject understands according to relevant IRB procedures. The translated document must receive IRB approval prior to use. A copy of the translated consent document must be given to the subject, and the above informed consent procedures and discussion must be conducted in a language the subject understands. The same procedures apply to any revisions to the consent form.

Vulnerable Populations:
For research in which some subjects are likely to be vulnerable to coercion or undue influence (e.g. children, prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons), additional safeguards are included to protect the rights and welfare of these subjects. In many cases, these will include or consist of additional protections in the consent process (e.g., requiring a witness, requiring independent assessment of the capacity to consent, requiring a patient advocate, etc.). As indicated in Guideline 1.1.2, the investigator must have IRB approval to enroll vulnerable subjects and must comply with the IRB-approved additional safeguards for these subjects.

In research involving children, the following additional procedures are performed.
Assent with Children: Because children are not able to give legal consent, consent discussions and procedures are conducted with the subjects legally authorized representative as described above. In addition, the following assent procedures are also conducted when possible based on the child's mental capacity as determined appropriate by the IRB:

- The study team member meets with the minor to explain the trial in a way targeted to the minor's age and mental capacity.
- The minor is given ample time to read the IRB-approved assent form and ask questions.
- If the minor agrees to participate, the assent form is personally signed and dated by the minor and the person conducting the assent discussion.
- The minor is given a copy of the signed and dated assent form.

When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the subject's participation in the research is no longer regulated by the requirements regarding parental or guardian permission and subject assent. In such cases, the investigator will seek and obtain the legally effective informed consent for the now-adult subject for any ongoing interactions or interventions with the subject as described previously in this SOP.

Ongoing Informed Consent:

The study team is responsible for ensuring ongoing consent throughout the subject's participation in the study. This includes informing subjects of new information as it becomes available so that they can reassess the risk/benefit ratio. When the IRB approves a new version of the consent form, and the changes reflect only minor administrative changes (e.g., correcting a typo, changing an address, etc.), the subjects do not need to be re-consented with that version. When new information becomes available and/or when there is a proposed change to the research protocol, the following procedures are followed:

- The informed consent form is modified to reflect the changes and submitted to the IRB for approval (see Guideline on interim reports to the IRB).
- The subject is re-consented with the revised consent form following the same procedures described under *Initial Informed Consent Process*.
- The following guidelines are used to determine when to notify subjects about the new information and/or protocol change:
    - The subject is contacted immediately if:
        - the new information or protocol changes alter the risk/benefit ratio AND the subject's knowledge of this information would enable them to change their behaviors in a way that potentially reduces the risks (e.g., the medication has been found to have additional health risks, and the subject is currently taking the study medication).
    - The subject is informed at the next scheduled visit (whether the visit is in person, by telephone, or some other form of contact) but before any other visit activities are performed, if:
        - the new information or protocol changes alter the risk/benefit ratio but there is nothing the subject can do to reduce the risks (e.g., the medication has been found to have additional health risks, but the subject is not currently taking the study medication) OR
        - there is no change to the risk/benefit ratio (e.g., increase in study sample size).
- The study team member performs the following phone contact procedures if re-consent is required under one or more of the following circumstances:
    - The subject has completed all "in person" visits
    - The subject needs to be contacted immediately for re-consent per conditions described above

- The subject needs to be re-consented for any other reason in between "in person" visits
  - The subject is contacted by phone and notified of the new information (see previous section to determine whether the subject should be contacted immediately or at their next scheduled activity).
  - If the subject is still interested in participating in the study, he/she is invited to come to the office to sign the new consent form. If the subject does not want to come to the office, he/she is instructed to sign and return a copy that is mailed to the subject according to the following procedures:
    - Two copies of the new consent form, an addressed and stamped return envelope, and a cover letter are sent to the subject via registered mail with return receipt (or any other comparable delivery method that documents receipt)
    - The cover letter instructs the subject to sign, date, and return one copy of the consent form and to keep the other copy for his/her records.
  - If the subject signs and returns the consent form, the person who conducted the phone re-consent discussion signs and dates the form (the date should be the current date, not the date the subject signed).
  - All of the above procedures are documented, including whether the subject gave verbal consent to continue participation during the phone discussion.

For studies involving assent with minors, the assent form will be revised as appropriate to reflect any changes and submitted to the IRB for approval. Because minors are not able to give legal consent, re-consent discussions and procedures are conducted with the subjects legally authorized representative using the revised IRB-approved informed consent form according to the ongoing consent procedures described above. In addition, re-assent discussions and procedures are conducted with the subject when possible based on the minor's mental capacity.

Exceptions:
Permitted exceptions to the above informed consent procedures include:

1. When <u>ALL</u> of the following are true:
   - The patient is in a life threatening situation
   - The patient is unable to communicate their consent to participate
   - There is insufficient time to contact the patient's legally authorized representative
   - There is no alternative method to save the patient's life

2. When an investigational in vitro diagnostic device is used during a potential terrorism event or other potential public health emergency to:
   - identify a potentially life-threatening chemical, biological, radiological, or nuclear agent,
   - facilitate the treatment of individuals exposed to such an agent, and/or
   - report test results to a public health authority as appropriate.

In such instances, all of the following criteria must be true:

- The human subject is confronted by a life-threatening situation necessitating the use of the investigational in vitro diagnostic device to identify a chemical, biological, radiological, or nuclear agent that would suggest a terrorism event or other public health emergency
- Informed consent cannot be obtained from the subject because:
  - There was no reasonable way for the person directing that the specimen be collected to know, at the time the specimen was collected, that there would be a need to use the investigational in vitro diagnostic device on that subject's specimen; and
  - Time is not sufficient to obtain consent from the subject without risking the life of the subject.
- Time is not sufficient to obtain consent from the subject's legally authorized representative
- There is no cleared or approved available alternative method of diagnosis, to identify the chemical, biological, radiological, or nuclear agent that provides an equal or greater likelihood of saving the life of the subject

When an investigational in vitro diagnostic device is used as described above, the investigator is responsible for complying with all relevant IRB procedures and federal regulations pertaining to IRB and/or public health agency notifications within the required timeframe.

Responsibility:

- The PI is responsible for ensuring that all subjects are informed that the drugs/agents are being used for investigational purposes and that they are informed of all relevant information about the study.
- The PI or an appropriately trained member of the study team is responsible for conducting informed consent/assent discussions and completing the consent/assent process and documentation as described above.
- All study team members are responsible for complying with any special instructions given by the IRB pertaining to informed consent/assent of research participants classified as “vulnerable”.
- The study coordinator is responsible for maintaining the original executed informed consent/assent form in the source documentation to ensure that it is available for review by those authorized to audit study records.
- The PI and authorized research team members are responsible for ensuring compliance with all IRB procedures and federal regulations in instances when the requirements for exceptions to the above informed consent procedures have been met.

FORM REFERENCES:

Not Applicable

REFERENCES:

Food and Drug Administration 21 CFR 50.20 , 50.25 (a), and 50.25 (b)

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