IASIS HEALTHCARE	**POLICY TITLE**: Subject Screening and Enrolling
MANUAL NAME: Clinical Operations	**POLICY NUMBER**: CR 1.2.2 ☐ 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 tracking the list of potential, consented, and enrolled subjects, to document the fair and unbiased screening and enrolling of subjects for each study and to ensure that enrolled subjects have easily available identification information in the event that they need to be contacted.

SCOPE:

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

DEFINITIONS:

Not Applicable

PROCEDURE:

Subject Logs:

- Every potential subject with whom an informed consent discussion is conducted is listed on a subject screening log, whether or not they agree to participate.
- Every subject who signs the informed consent form is tracked to indicate whether the subject was enrolled (i.e., randomized to treatment).
- A copy of every signed informed consent form for any subject participating in research being conducted at an IASIS facility is sent to the ICARE Office of Research.
- Every subject who is randomized to treatment is listed on a subject identification log.
- Every subject who is randomized to treatment for a study being conducted at an IASIS facility has an IASIS Patient Enrollment Notification Form completed and submitted to the ICARE Office of Research.
- The above subject screening, enrollment, and identification information is documented in one of two ways:

1) if the sponsor has a preferred method for tracking this information, this method is followed.
2) if the sponsor does not have a preferred method, the attached form is used or similar form.

Responsibility:

- The study coordinator is responsible for ensuring that all screening, enrollment and identification logs are kept up to date.
- The study coordinator is responsible for ensuring the scheduled submission of the screening and/or enrollment logs to the designated contact as instructed by the sponsor.
- The Principal Investigator or his/her designee is responsible for completing and submitting the proper Patient Enrollment Notification Form and a copy of signed Informed Consent Forms for any and all subjects participating in studies being conducted at any IASIS facility.

SUBJECT SCREENING AND ENROLLMENT LOG

Sponsor: ____________________________ Protocol #: __________________________

Scrng #	Date	Initials	Source*	Consented?	Randomized?	Enrllmt #
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	
				⑨ yes ⑨ no**____	⑨ yes ⑨ no***____	

***Source Codes:**

1 = PI
2 = Other clinician
3 = DA employee
4 = Friend/family
5 = Newspaper ad
6 = Radio ad
7 = Flyer
8 = Yellow pages
9 = Other (list)

****Codes for Consent Failures:**

1 = Did not meet I/E criteria
2 = Logistics (e.g., transportation, scheduling issues, etc.)
3 = Doesn't want to participate in ANY study
4 = Doesn't want to participate in THIS study
5 = Study staff declined (e.g., due to concerns about mental capacity)
6 = Other (list)

*****Codes for Dose Failures:**

1 = Did not meet I/E criteria
2 = No show
3 = Withdrew consent
4 = Other (list)

SUBJECT IDENTIFICATION LOG

Sponsor: _____

Protocol #: _____

#	Initials	Name	Address	Phone #'s

I-CARE
IASIS CENTER for the ADVANCEMENT of RESEARCH and EDUCATION

RESEARCH PATIENT SCHEDULING AND CHARGE FORM

- Schedule a research test or procedure
- Schedule a research component of a Standard of Care (SOC) Visit
- Schedule a SOC services for a research participant

***Use ONE form per visit**

I-CARE:	**Phone:**	**Email:**
Name of Study:		**Principal Investigator:**
ClinicalTrials.gov #:		**Sub Investigator:**
Location/Facility:		**IRB:**
CMS Approval	**IDE No**	

Research Participant Information

Last Name:	**First Name, MI:**
Date of Birth:	**Subject ID:**

Health Care Provider Information

Ordering Physician:	**Study Coordinator:**	**Phone #/Email**

Insurance Provider Information

Billing Commercial Payor *	☐	
Billing Medicare *	☐	
Billing I-CARE Contract Account	☐	

	Billing				
Test, Procedure, or Service Requested	Com.	Medicare	I-CARE	Q0 / Q1	**Date of Service**
	☐	☐	☐		
	☐	☐	☐		
	☐	☐	☐		
	☐	☐	☐		
	☐	☐	☐		
	☐	☐	☐		

***Claims to include Research Modifiers and/or Z codes and ClinicalTrials.gov registration number.**

Form completed by: Date:

REFERENCES: Food and Drug Administration

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