| IASIS HEALTHCARE | POLICY TITLE: Subject Screening and Enrolling |
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| 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 # |
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*Source Codes: **Codes for Consent Failures: ***Codes for Dose

Failures:

- 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)

- 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)

1 = Did not meet I/E criteria

3 = Withdrew consent

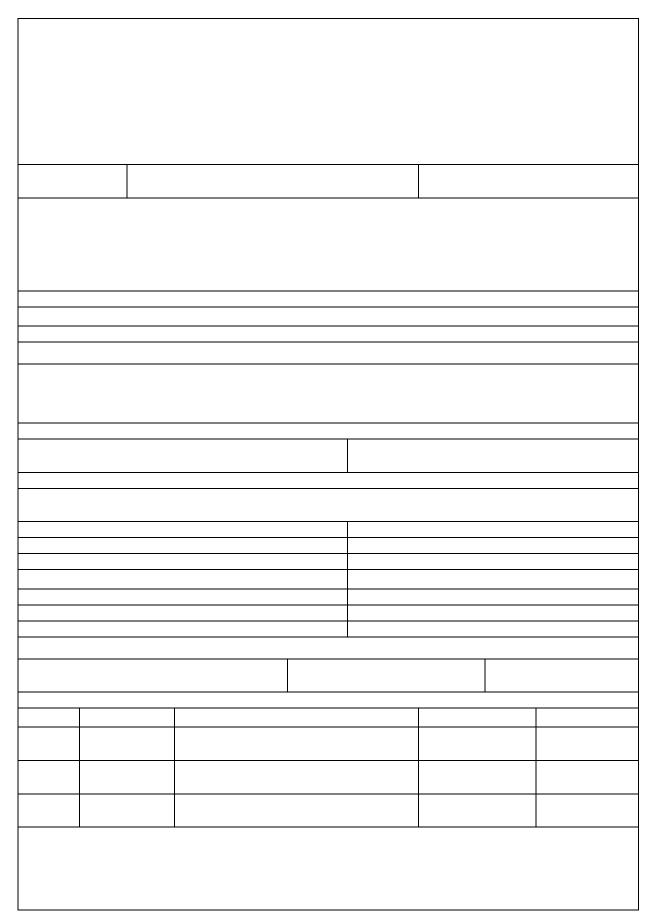
2 = No show

4 = Other (list)

SUBJECT IDENTIFICATION LOG

| Sponsor: | | | |
|-------------|--|--|--|
| Protocol #: | | | |

| # | Initials | Name | Address | Phone #'s |
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| | 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 |
| | CCO | |