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Successful human subject research

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Successful Human Subject Research

Sarah Fowler-Dixon, Ph.D.
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HRPO & the QA/QI Office
2011

Oversight During Research

HRPO

- Continuing Review: Informed Consent and Protocol Lapses
 - Consent document can only be used through the date of expiration to enroll new subjects.
 - Must be renewed at least annually
 - Protocol lapses occur when you allow a protocol to expire prior to renewal
 - No new participants may be enrolled.
 - No continuation of treatment may take place without written HRPO authorization
 - No federal funds may be expended on human research if protocol allowed to lapse

Top 3 Issues Around Successful Research

➤ Design

- Inclusion/Exclusion Criteria
- Testing/Observation Regimen

➤ Consent Issues

- Prior to Research
- Obtained in HRPO approved manner

➤ Record Keeping

- Documentation of all encounters with subject

Research/Protocol Design

- Inclusion/Exclusion Criteria
 - Each enrolled subject must meet
 - Enrollment of eligible subjects must be documented
- Interventions/Observations
 - Subjects must have all expected interventions or observations performed and documented

Consent Issues

- Expect to find one consent per subject having data collected
- Consent document must be appropriately signed and witnessed
- Consent must be obtained in manner approved by HRPO
 - Children
 - Phone Consent
 - Legally Authorized Representative

Consent Form Issues

(continued)

Did the subject receive a copy of the signed consent form?

As a good practice, if mailed, send 2 copies & document. One comes back to you. Participant keeps the other.

Consent Form Issues

The latest version is not being used

- *Check approval and expiration dates on consent form*

Consent Form Issues

(continued)

Did the subject receive a copy of the signed consent form?

- *Document the fact that subject received a signed copy of the consent form*

Consent Form Issues

(continued)

Did the subject date
the signed consent form?

Never backdate a consent form

- *If subject failed to date the consent form,
write a note-to-file*

Consent Form Issues

(continued)

IRB approval stamp is **not** on the consent form

Consent Form Issues

(continued)

Hand written changes can not be made to an approved consent form

Record Keeping

Binder for regulatory documents

- *An industry sponsored study will require more regulatory documents*

TYPES OF STUDY LOGS

(NOT ALL ARE NEEDED FOR ALL STUDIES)

- Enrollment Log
- Staff Signature Log
- Delegation of Responsibility Log
- Monitoring Log
- Drug Dispensing/Accountability Log

Drug Accountability/Dispensing Log

- Protocol identifier
- Subject identifiers (initials/study number)
- Randomization and/or kit number
- Date dispensed & amount dispensed
- Date returned & amount returned
- Initials of person dispensing/receiving

Data and Safety Monitoring Board (DSMB) Report

Failure to submit a copy of the **DSMB
REPORT** to the HRPO at continuing
review

Investigator Brochure (IB)

Why is the IB not on file?

Reason #1: It's too big to keep in the regulatory binder

Solution #1: Write a signed and dated note-to-file indicating where it is located.

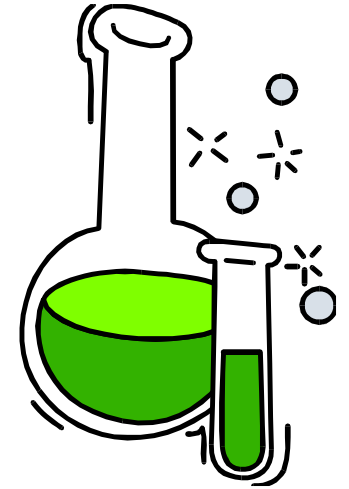
Investigator Brochure

Why is the IB not on file?

Reason #2: We're studying a marketed drug.

Solution #2: Obtain a copy of the package insert.

Investigator Brochure



Why do I need a copy of the IB?

To provide safety and efficacy data from pre-clinical and clinical trials to support human exposure by the route, at the dosages, for the duration, and in the population to be studied.

Source Documents

(Not submitted to IRB. Developed by study team or industry sponsor.)

Source documents include:

1. hospital records
2. lab notes
3. memos
4. subject diaries
5. evaluation checklists
6. pharmacy dispensing records

Source Documents

(examples include)

7. X-rays
8. copies of transcriptions certified after verification as being accurate and complete
9. microfiches
10. photographic negatives
11. microfilm or magnetic media
12. recorded data from automated instruments

Source Documents

Q. Why are source documents needed?

A. To document the existence of the subject and substantiate integrity of trial data collected.

Source Documents

Q. What are source documents?

A. It's wherever data is first recorded
(original records or certified copies)

Assistance for Successful Research

- Educational Programs
- Staff Training Program
- Research News
 - <http://researchnews.wustl.edu>

Organizational Offices and Points of Contact Available to Help

- Human Research Protection Office
 - 314-633-7400; <http://hrpo.wustl.edu>
- Grants & Contracts
 - 314-747-4134; <http://grantsandcontracts.wustl.edu>
- Research Office
 - 314-935-5889; <http://wuro.wustl.edu>
- Sponsored Project Accounting
 - 314-935-xxxx; <http://spa.wustl.edu>
- Center for Clinical Studies
 - 314-747-4000; <http://ccs.wustl.edu>