Successful Human Subject Research

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Oversight During Research

HRPO

– HRPO Approval prior to any research
– 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 criteria
  - Enrollment of eligible subjects must be documented—Inclusion/Exclusion Checklist
  - Criteria Too narrow will not yield enough subjects
  - Enrolling outside of criteria violates protocol
Research/Protocol Design

- Interventions/Observations
  - Subjects must have all expected interventions or observations performed and documented
  - Reasons for not performing observations or interventions must be documented
  - Can the protocol be executed as written
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

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*
Did the subject sign & date the signed consent form? Did research team member sign & date consent document? Never backdate a consent form. 

• *If subject or researcher failed to date the consent form, write a note-to-file*
Consent Form Issues
(continued)

IRB approval stamp is not on bottom of the consent form
Hand written changes can not be made to an approved consent form
STUDY LOGS

• 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
DSMB Report

Submit a copy of the **DSMB REPORT** to the HRPO at continuing review
Source Documents

Q. What are source documents?

A. It’s wherever data is first recorded (original records or certified copies)
Q. Why are source documents needed?

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

Source documents include:

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

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
Assistance for Successful Research

- Educational Programs
  - Ethics Lectures
  - Training Grant programs

- Staff Training Program

- Research News
  - [http://researchnews.wustl.edu](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
# INCLUSION/EXCLUSION FORM

**DATE OF VISIT**

___/___/____

**TRIAL NAME:**

**SUBJECT ID#** ___ ___-___ ___ -

**SUBJECT INITIALS:** _______

## Inclusion Criteria

- **Must have**
  
<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
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## Exclusion Criteria

- **Must NOT have**
  
<table>
<thead>
<tr>
<th>Yes</th>
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Prepared By

__________________________________ Date Signed________

Signature

Reviewed/Approved By

________________________ Date Signed __________
Data Collection Forms

- Subject/ID name on each page
- Date of observations
- Signature of observer
- PI review assurance (initials/date)
- If an observation not made, indicate why with a note