Mastering Clinical Research

October 19, 2016
7:30 am
Mastering Clinical Research

Pre-Test Questions
1. The PI or sub-I as listed on the DOA will review safety laboratory values prior to dispensing of study drug?

A. TRUE

B. FALSE
2. In order for a deviation to meet IRB reporting criteria for impacting safety, it must have resulted in harm to a subject.

A. TRUE
B. FALSE
3. Per Winship policy, when are CRC/CRNs required to assess subject’s reproductive status on the Birth Control Form?

A. When subject looks young enough to be able to have children
B. When protocol requires pregnancy test
C. When subject is a female
D. Reproductive status assessment must be done for all Winship clinical trials subjects
4. Which order set(s) need to be signed by the principal investigator or the sub-investigator?

A. Drug order set
B. Nursing consideration order set
C. Both order sets must be signed
5. If the investigator assesses an eligibility violation as non-reportable, it does not require reporting to the IRB.

A. TRUE
B. FALSE
Research Matters
Pharmacy Order Committee
Updates

Cathy Sharp, CRN, MN, OCN, CCRP
Cabell Pietras, CCRP
Introductions

Chair:
Hematology—Cathy Sharp
Solid Tumor—Cabell Pietras

Administrative Assistant:
Stephanie Wamsley

Members:
Dr. Gaddh
Pharmacists
CRC/CRN from each working group
Infusion Center Nurses
Audit Findings

Pregnancy Sticker

• Must be on orders for all female subjects
• MUST be completed
• New language to include pharmacists sign-off

Is patient of child bearing potential? Yes ☐ No ☐
If yes, pregnancy test deemed to be negative Yes ☐ No ☐
Confirmed by Licensed Med. Professional __________ __________
Initial Date

• If pregnancy test not indicated per protocol, write on sticker that test is not required.
• IDS will not proceed if sticker is not on order or information not completed.
Dose Adjustments Statement

- Must be completed
- Statement means have dose adjustments EVER been made during course of treatment
- Removing this statement in future order sets
Infusion Nurse Signatures

• Finding: RN’s only signing page of dose calculations
  —signature line on every page
• New orders will only have signature line on page 1
• SOP 6.2 (Study drug orders for IDS Study Drugs) modified to state:

  “Infusion Nurses will sign the drug order set on page one which signified they have reviewed all pages of the order set as well as confirmed all dose calculations”
1. Change of wording of research lab draws on orders (i.e. PK, PD, PBCS, etc) to “Research Labs”
2. Patient allergies—only listed on page 1
3. CRC/CRN name and Pic—only on page 1
4. Is Informed Consent signed?—only on page 1
Separating Order Sets

Drug Order

Nursing Considerations Order

Rationale

1. Simplify drug order to improve patient safety
2. Cleaner format—aligns with SOC orders
3. Fewer drug order sets
4. Reduced pharmacist work load
5. Updates to pharmacy orders in more timely manner
Drug Order

Drug Orders to Include:

• Retreatment criteria
• Drug/Dosing Information
• Pre-Meds/Fluids
• Concomitant Medications
• Infusion Reaction Information
• Prohibited Medications

**Nursing Considerations:** See separate “Nursing Considerations” document ☐ Yes ☐ No
Nursing Considerations

Tables include all required research activities

- All labs required at each visit
  - Check boxes to ensure all labs are drawn
  - Completed by CRC/CRN or Infusion Center RN
- Procedures
- Research Labs
- Vital Signs
- ECG’s

N.C. order sets will be uploaded in Oncore and updated by Infusion Nurses and CRC/CRN’s.
Thank You!

Questions?
Winship Clinical Trials
SOP Updates

Tatiana Kurilo, MPH, CCRC
Quality Management and Education
Outline

• Pregnancy Test Guidelines
• **SOP 3.2** Determining Eligibility for Clinical Trials
<table>
<thead>
<tr>
<th></th>
<th>Total Number of Cases</th>
<th>Missed Baseline Test</th>
<th>Missed Subsequent Test(s)</th>
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<tbody>
<tr>
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<td>48</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>July 2015</td>
<td>33</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>October 2015</td>
<td>25</td>
<td>3</td>
<td>1</td>
</tr>
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<td>January 2016</td>
<td>16</td>
<td>1</td>
<td>0</td>
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<tr>
<td>July 2016</td>
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<td>0</td>
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</tr>
<tr>
<td>September 2016</td>
<td>16</td>
<td>0</td>
<td>0</td>
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</table>

Next audit is scheduled for December 2016
When we do NOT order Pregnancy Test for the baseline assessment?

- Subject is MALE
- Not required per Protocol
- Subject is FEMALE that is Not a FCBP:
  - Hysterectomy
  - Postmenopausal
Postmenopausal

- Postmenopausal is defined as
  - Age $\geq$ 55 years and one year or more of amenorrhea
  - Age $<$ 55 years and one year or more of amenorrhea with:
    - EMORY LAB: estradiol $<$ 20 OR estradiol $<$ 40 with FSH $>$ 40 in women not on estrogen replacement therapy
    - OUTSIDE LAB: check estradiol and FSH (when applicable) reference ranges parameters for Postmenopausal status
Pregnancy Test **MUST** be done when required per Protocol if

- Subject is FCBP
- Amenorrhea following cancer therapy does not rule out child bearing potential
- Contraceptive methods such as: tubal ligation and spouse’s successful vasectomy do not waive pregnancy test requirement
Pregnancy Test verification for Research Orders

- **Only Licensed** medical professionals are allowed to sign off the pregnancy test verification
  - Medical Doctor (MD)
  - Doctor of Pharmacy (PharmD)
  - Clinical Research Nurse (CRN)
  - Registered Nurse (RN)
  - Advanced Practice Providers (APP), such as, Nurse Practitioner (NP) or Physician's Assistant (PA)

Is patient of child bearing potential? Yes  No
If yes, pregnancy test deemed to be negative Yes  No
Confirmed by Licensed Med Professional __________ Date__________

Initial  Date
For Existing Orders – Please Use Labels
SOP 3.2: Determining Eligibility for Clinical Trials

• Greater than Minimal Risk Clinical Trials
  – The investigator (PI, co-I or sub-I) who is delegated this task on the DOA log will determine eligibility for the study subjects

• Minimal Risk Clinical Trials
  – A member of a study team (licensed healthcare professional or Clinical Research Coordinator) who is delegated this task on the DOA log will determine eligibility for the study subjects
Determining Eligibility for Greater than Minimal Risk Clinical Trials

- CRC/CRN will gather all supporting documentation **PRIOR** to the completions of the eligibility checklist
- The eligibility checklist will be completed with source documents attached
- **ALL** source documents being used to determine eligibility must be available and reviewed by the investigator prior to signing the Eligibility Sign-Off Form
- Once the investigator has reviewed the eligibility checklist and signed the Eligibility Sign-Off Form, **then** the patient can be registered/randomized according to study requirements
- For studies involving subsequent steps of determining eligibility, the process will be the same as verifying eligibility for the initial enrollment
Eligibility Determination
Greater than Minimal Risk Clinical Trials

PART I
I have prepared and reviewed supporting documentation regarding the eligibility determination for patient ______________________________ prior to registration on protocol ______________________________.

CRC or CRN

Print Name __________________ Signature __________________ Date/Time __________________

PART II
I have reviewed supporting documentation regarding the eligibility determination for patient ______________________________ prior to registration on protocol ______________________________.

☐ I have found this patient DOES NOT meet all inclusion/exclusion criteria and may NOT be enrolled in the Clinical Trial named above.

Eligibility criteria patient did not meet: ______________________________

☐ I have found this patient MEETS all inclusion/exclusion criteria and may be enrolled in the Clinical Trial named above.

PI or Sub Investigator

Print Name __________________ Signature __________________ Date/Time __________________
Form 3.2 Signatures for Eligibility

Eligibility Determination

Minimal Risk Clinical Trials

I have reviewed supporting documentation regarding the eligibility determination for patient

______________________________ prior to registration on protocol

______________________________

☐ I have found this patient DOES NOT meet all inclusion/exclusion criteria and may NOT be enrolled in the Clinical Trial named above.

Eligibility criteria patient did not meet: _____________________________

☐ I have found this patient MEETS all inclusion/exclusion criteria and may be enrolled in the Clinical Trial named above.

Study Team Member (who is delegated this task on DOA)

Print Name: __________________ Signature: __________________ Date/Time: __________________
**Who Can Determine Eligibility for the Study Subjects**

<table>
<thead>
<tr>
<th>Clinical Trial</th>
<th>Investigator (PI or co-I)</th>
<th>Licensed Professional (not investigator)</th>
<th>CRN</th>
<th>CRC</th>
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</thead>
<tbody>
<tr>
<td>Greater than Minimal Risk Interventional</td>
<td>* YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Minimal Risk Interventional And Non-Interventional</td>
<td>* YES</td>
<td>* YES</td>
<td>* YES</td>
<td>* YES</td>
</tr>
</tbody>
</table>

* If delegated this task on the delegation of authority log
Reminders

• Reproductive status assessment must be done for **ALL** Winship clinical trials subjects – Birth Control Form is available on Winship Intranet

• Please read eligibility requirements carefully

• All Winship Clinical Trials SOPs, policies, procedures, forms and tools are available On the Winship intranet under Clinical Trials: https://apps.winship.emory.edu/intranet/clinical trials/index.php
Questions