Mastering Clinical Research

For previous presentations and upcoming schedule, visit:

- https://apps.winship.emory.edu/intranet/clinicaltrials/mcr.php
SOP Updates

Tatiana Kurilo, MPH, CCRC
Quality Management and Education
Outline

• Pregnancy Test for Clinical Trial Subjects

• SOP Update:

  SOP 3.4: Preparing for a subject visit
  Effective March 30, 2015!

  SOP 3.2: Determining Eligibility for Clinical Trials
Internal QM audit of charts that require pregnancy test per protocol (baseline and subsequent).

• 48 female pre-menopausal study subjects from all Working Groups (except GU) were selected

• Baseline/Screening Pregnancy Test was missed on 4 subjects. Test was not ordered or we do not have proof it was ordered.

• From 15 female pre-menopausal study subjects that required subsequent pregnancy tests per protocol, test was missed in 6 subjects

• In those 6 cases Pregnancy Test was missed on 15 occasions
  * Deviations submitted to sponsor and IRB

• The reasons for not ordering the test vary from honest mistake to just simply not ordering. In some cases the study team stated that the test was ordered, but it was not supported by any proof.
When we **do NOT** order Pregnancy Test for the baseline assessment?

- Subject is MALE
- Subject is FEMALE that is Not a FCBP (Female of Childbearing Potential):
  - Hysterectomy
  - Postmenopausal
Postmenopausal

• Postmenopausal is defined as:
  ❖ Age ≥ 55 years and one year or more of amenorrhea
  ❖ Age < 55 years and one year or more of amenorrhea, with estradiol < 20 pg/ml
  ❖ Age < 55 with prior hysterectomy but intact ovaries, with estradiol < 20 pg/ml
  ❖ Prior bilateral oophorectomy
Pregnancy Test **MUST** be done if

- Subject is FCBP
- Tubal Ligation and Spouse’s successful vasectomy do not waive pregnancy test requirement
SOP 3.4: Preparing for a subject visit

• **Purpose:** To define the processes required to prepare for an enrolled subject's clinic visit to ensure that all study activities are completed and the study visit goes smoothly without unnecessary delays or duplication of services

• **Scope:** All Winship staff involved in the management of subjects who participate in cancer-related clinical research trials
SOP 3.4: Preparing for a subject visit

Assigned CRC/CRN:

• Prepares study calendar for on-study subjects
• Coordinates scheduling/ordering of all study procedures/tests per study protocol and notifies study subject of the upcoming appointment(s)
• Checks the subject's clinic schedule to ensure that all study procedures/tests are ordered and required supplies are available, and necessary instructions are communicated to the clinic staff
• Submits precert orders for commercially supplied drug(s) when applicable
SOP 3.4: Preparing for a subject visit

• Prior to a subject’s lab visit:
  – Prepares the research tubes with instructions and makes arrangements for collection of research tests
  – Communicates all upcoming specimen processing needs through the appropriate system of communication
  – Notifies the Winship research laboratory staff of any anticipated specimen handling needs in advance, especially for visits requiring special handling or a long time commitment
SOP 3.4: Preparing for a subject visit

• Prepares appropriate study visit form
• Prepares to order study medication, determining who is allowed to sign the pharmacy order by reviewing Oncore® and ensuring that a delegated Investigator is available for signing pharmacy orders
• Checks to ensure proper access to the Interactive Voice Response System (IVRS) is available, if applicable
SOP 3.2: Determining Eligibility for Clinical Trials

• **Scope:** This policy and procedure will apply to all clinical trials that enroll patients for treatment

• **Scope:** All Winship staff involved in the management of subjects who participate in cancer-related clinical research trials
1. When a potentially eligible patient is identified, the research nurse, clinical research coordinator or physician responsible the study will gather all supporting documentation **PRIOR** to completion of the eligibility checklist.
SOP 3.2: Determining Eligibility for Clinical Trials

2. The eligibility checklist will be completed with source documents attached. Any questions about eligibility criteria will be reviewed with the investigator. There will be no eligibility waivers for sponsor-investigator studies.
SOP 3.2: Determining Eligibility for Clinical Trials

3. The eligibility package will be reviewed by the CRC/CRN, PRIOR to presenting it to the physician investigator for review and sign-off.

• ALL source documents being used to determine eligibility must be available for review with the Eligibility Checklist, including source documentation from outside facilities.
SOP 3.2: Determining Eligibility for Clinical Trials

4. The PI/investigator who is to sign off on the eligibility checklist MUST REVIEW all documents.

5. Once CRC/CRN and the PI/investigator have reviewed and signed the Eligibility Checklist, then the patient can be registered/randomized according to the study protocol.

6. For studies involving subsequent steps of determining eligibility, the process will be the same as verifying eligibility for the initial enrollment.

7. The PI/investigator is strongly encouraged to sign and date each component of eligibility.
Questions..
Study Order Template
Pregnancy and Lab Changes

Cathy Sharp RN, MN, OCN
Clinical Research Nurse IV
**Cycle 1 orders**

This Order Is Not Valid Unless This Section Has Been Completed:

Have dosage adjustments, as specified per study protocol guidelines, been made on any medications listed on this order?
- [ ] YES
- [ ] NO

Diagnosis: **Multiple Myeloma**

1 Cycle = 28 Days

<table>
<thead>
<tr>
<th>Cycle#</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 8</th>
<th>Day 15</th>
<th>Day 16</th>
<th>Day 22</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>(nursing assessment/labs only)</td>
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<tr>
<td>Date and Time Order Written</td>
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</tbody>
</table>

### Labs:

- **On C1D1** administer study drug if:
  - ANC > 1500 (If BMDBx ≥ 50% plasma cells, then ANC > 1000)
  - Platelets > 75,000 (If BMDBx ≥ 50% plasma cells, then PLT ≥ 50,000)
  - AST/ALT ≤ 3X ULN
  - T. Bilir ≤ 1.5 mg/dL
  - Serum creatinine ≤ 2.5 mg/dL or creatinine clearance ≥ 30 mL/min

- Is patient of child bearing potential? **Yes**
- **No**
- If yes, pregnancy test confirmed to be negative? **Yes**
- **No**
- Confirmed by MD RN CRC Initial Date
- If menses irregular, required on Days 1 and 15

- **On C1D15** administer study drug if:
  - ANC > 1000 if ≥ 50% plasma cells in BMDBx
  - Platelets > 50,000 if ≥ 50% plasma cells in BMDBx
  - If ≥ 50% plasma cells in BMDBx, may proceed to treat if judged by investigator to be in best interest of patient
  - AST/ALT ≤ 5X ULN
  - T. Bilir ≤ 3X ULN
  - Creatinine ≤ 3X ULN

### Nursing Considerations:

Perform as outlined in table below

- **BOI** = Beginning of Infusion
- **EOI** = End of Infusion

<table>
<thead>
<tr>
<th>Cycle 1 Day 1</th>
<th>Tasks to be Performed</th>
<th>Date/Time Performed</th>
</tr>
</thead>
</table>

Verify study required labs have resulted and/or are pending:

- CBC with Diff
- CP-Comp
- Mg
- Alk Phos
- LDH
- PT
- APTT
- Is patient of child bearing potential? **Yes**
- **No**
- If yes, pregnancy test confirmed to be negative? **Yes**
- **No**

**All information provided and calculations have been independently confirmed by the following licensed healthcare providers**

Print Licensed Medical Professional Name: [Signature]
Print Attending Physician Name: [Signature]

Date: [Signature]
Date: [Signature]

Last Updated: 8/25/14 K98
Approved by MD on: 8/18/14
**INVESTIGATIONAL PROTOCOL:**
A Multicenter Phase 2 Study of Single-agent Filanesib (ARRY-520) in Patients With Advanced Multiple Myeloma

**Primary Investigator:** Sagar Lonial, MD

**Research Nurse:**

**Research Coordinator:**

**Pre-dose**
1) ECG – resting and semi recumbent
2) PK sampling

**BOI**
Initiate Filanesib infusion

**EDI**
End of Filanesib Infusion

<table>
<thead>
<tr>
<th>Cycle 1 Day 2</th>
<th>Tasks to be Performed</th>
<th>Date/Time Performed</th>
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<tr>
<td>BOI</td>
<td>Initiate Filanesib infusion. MUST BE GIVEN (b) 4 HOURS OF PREVIOUS DAY INFUSION</td>
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<tr>
<td>EOI</td>
<td>End of Filanesib Infusion</td>
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<tr>
<th>Cycle 1 Day 8</th>
<th>Tasks to be Performed</th>
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<tbody>
<tr>
<td>BOI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EOI</td>
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</table>

<table>
<thead>
<tr>
<th>Cycle 1 Day 15</th>
<th>Tasks to be Performed</th>
<th>Date/Time Performed</th>
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<tbody>
<tr>
<td>Pre-dose</td>
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</tr>
<tr>
<td>BOI</td>
<td></td>
<td></td>
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<tr>
<td>EOI</td>
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<th>Date/Time Performed</th>
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<tbody>
<tr>
<td>BOI</td>
<td>Initiate Filanesib infusion. MUST BE GIVEN (b) 4 HOURS OF PREVIOUS DAY INFUSION</td>
<td></td>
</tr>
<tr>
<td>EOI</td>
<td>End of Filanesib Infusion</td>
<td></td>
</tr>
</tbody>
</table>

**All information provided and calculations have been independently confirmed by the following licensed healthcare providers**

Print Licensed Medical Professional Name: ____________________________

Print Attending Physician Name: ____________________________

Date: ____________________________

Date: ____________________________

(Licensed Professional Signature/Contact #)

(Attending Physician Signature/Contact #)

Corrected by:

RN: ____________________________

RN: ____________________________

Last Updated: 6/25/14 KIS

Approved by MD on: 8/18/14
For Existing Orders – Please Use Labels
Questions..
Process for Identifying Required Labs

SUSAN MAIO, MS, CCRC
CLINICAL RESEARCH COORDINATOR IV
WINSHIP CANCER INSTITUTE
CLINICAL TRIALS OFFICE
• When preparing for the patient’s visit, the CRC/CRN will verify the patient’s cycle and day for the upcoming visit.

• The CRC/CRN will then refer to the protocol’s schedule of events as well as the narrative in the protocol to identify which labs are required for the upcoming visit.
• Once all protocol-required labs are identified for the patient’s upcoming visit, the CRC/CRN will order the labs using EML or appropriate scheduling form. A copy of the EML/scheduling form must be kept in the patient’s research chart.

• On the day of the patient’s visit, the CRC/CRN will check PowerChart to ensure labs were drawn and are resulted or pending.
## Process for Identifying Required Labs

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Status</th>
<th>Details</th>
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<tbody>
<tr>
<td>Adrenocorticotropic</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>C-Reactive Protein (CRP)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
<td></td>
</tr>
<tr>
<td>Complete Blood Count</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Comprehensive Metabolic Panel</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Cortisol Level (Cortisol)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Differential Auto (Auto)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Lactate Dehydrogenase</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Magnesium Level (Mg)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Phosphorus Level (Phosphorus)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Thyroid Stimulating</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Thyroxine Free (Free T3)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Triiodothyronine Free (Free T3)</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<tr>
<td>Estimated GFR, Africa</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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</tr>
<tr>
<td>Estimated GFR, Non A</td>
<td>Timed Study, 03/23/15 5:00:00, Blood</td>
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<table>
<thead>
<tr>
<th>Radiology</th>
<th>Details</th>
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<tbody>
<tr>
<td>MRI Brain w/ + w/o C-</td>
<td>Routine, 05/29/15 11:30:00, Melanoma, Melanoma</td>
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<tr>
<td>CT Abdomen + Pelvis</td>
<td>Routine, 05/29/15 9:00:00, Melanoma, Oral Contrast, Melanoma</td>
</tr>
<tr>
<td>CT Chest w/ Contrast</td>
<td>Routine, 05/29/15 9:00:00, Melanoma, Melanoma</td>
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<tr>
<td>CT Neck Soft Tissue</td>
<td>Routine, 05/29/15 9:00:00, Melanoma, Melanoma</td>
</tr>
<tr>
<td>CT Abdomen + Pelvis</td>
<td>Routine, 04/17/15 8:00:00, Melanoma, Oral Contrast, Melanoma</td>
</tr>
<tr>
<td>CT Chest w/ Contrast</td>
<td>Routine, 04/17/15 8:00:00, Melanoma, Melanoma</td>
</tr>
<tr>
<td>CT Neck Soft Tissue</td>
<td>Routine, 04/17/15 8:00:00, Melanoma, Melanoma</td>
</tr>
<tr>
<td>MRI Spine Cervical w/ + C-</td>
<td>Routine, 12/05/14 17:30:00, Melanoma, Melanoma</td>
</tr>
</tbody>
</table>
In the event a patient has labs that were ordered, but not drawn, send an email notification

To: Jessica Gabriel
cc: Dr. Jonathan Kaufman,
    Dr. Bassel El-Rayes,
    Kathleen Rodger
    Pam Bourbo

The email should contain the patient’s name, DOB, and what labs were missed.
Questions?
POST QUESTION 1
When required by protocol the baseline Pregnancy Test must be done for all Female clinical trial subjects of Childbearing Potential.

A  True
B  False
POST QUESTION 2

If the spouse of a Female clinical trial subject of Childbearing Potential had a successful vasectomy the baseline pregnancy test is not needed.

A  True    B  False
POST QUESTION 3
To be compliant with SOP 3.4 CRC/CRN will check the subject’s clinic schedule to ensure that all study procedures and tests are ordered and required supplies available prior to the subject’s visit.

A True  B False
To be compliant with SOP 3.2 the PI:

A. Will ask CRN/CRC if he/she carefully reviewed the eligibility checklist before presenting and then sign off on it.

B. Does not need to sign off on eligibility checklist, it is CRC’s Responsibility to make sure subject is eligible.

C. Must review all eligibility documents and then sign off on the eligibility checklist.
POST QUESTION 5
Pregnancy test results must be assessed prior to dosing and results initialed and dated on the Pharmacy Orders by:

A. PI or Sub-I of study
B. MD, RN or CRC
C. Infusion nurse only
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