Mastering Clinical Research

For previous presentations and upcoming schedule, visit:

• http://winshipcancer.emory.edu/mcr
1. The Principal Investigator is responsible for maintaining a list of qualified individuals to whom he/she has delegated study related duties.

A  TRUE

B  FALSE
2. The DOA Log will be updated by the PI over the course of the study and reviewed for completeness.

A. Monthly
B. Quarterly
C. At Tumor Board meetings
D. At the time of the continuing review
3. According to SOP 5.2, Opening a Clinical Trial to Accrual: When is it appropriate to start enrollment to a new Winship therapeutic clinical trial?

A. When a new study receives IRB approval.

B. When a new study receives eNOA and SIV is completed.

C. After Quality Management has reviewed the signed Opening Clinical Trials Checklist and notified study team by e-mail that the study is open to accrual.
4. According to Multi-Site SOP 10.3: The Site Initiation Meeting (SIM) can occur **prior** to receiving **all** regulatory documents from the participating site as long as the site has local IRB approval.

A. TRUE

B. FALSE
5. The Sponsor-Investigator has how many business days from receipt of Eligibility documents from a Participating Site to review and sign-off?

A 2
B 1
C 3
D 0.75
Overview of Winship CTO
Standard Operating Procedures

Tatiana Kurilo, MPH, CCRC
Quality Management and Education
Outline

• Revised SOPs:
  SOP 8.3 Delegation Of Authority
  SOP 5.2 Opening a Clinical Trial to Accrual

• Protocol Training for Nursing Units at Winship Cancer Institute
8.3 Delegation of Authority

• **Purpose:** To document the delegation of authority by the Principal Investigator

• **Scope:** All Winship investigators and staff involved in the management of subjects who participate in cancer-related clinical research involving drugs, biologics, devices or invasive procedures

• **Responsibilities:** The Principal Investigator is responsible for maintaining a list of appropriately qualified individuals to whom the investigator has delegated significant study related duties
# DELEGATION OF AUTHORITY LOG

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<tr>
<th>Protocol Title</th>
<th>IRB Number</th>
<th>Principal Investigator</th>
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<table>
<thead>
<tr>
<th>Name (please print)</th>
<th>Trial Role</th>
<th>General Duties (see Tasks)</th>
<th>Initials</th>
<th>Signature</th>
<th>Dates of Duties</th>
<th>*PI Signature &amp; Date</th>
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**Tasks**

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<td>Medical History</td>
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<td>Administration of Investigational Product</td>
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<td>Physical Exam</td>
<td>8</td>
<td>Case Report Form (CRF Completion)</td>
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<td>Investigational Product Accountability</td>
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<td>Specimen Collection/Shipping</td>
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<td>5</td>
<td>Review Lab and Procedure Results</td>
<td>10</td>
<td>Collect Vital Signs</td>
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<td>Other:______________________________</td>
<td>20</td>
<td>Other:______________________________</td>
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</table>

*I have delegated the identified duties and will directly supervise the named personnel in the performance of protocol requirements.

PI Signature ___________________________ Date ______________

I have reviewed the Delegation of Authority Log for completeness & accuracy.

PI Signature (Sign at CR__) ___________________________ Date ______________
PI Signature (Sign at CR__) ___________________________ Date ______________
PI Signature (Sign at CR__) ___________________________ Date ______________

Winship Clinical Trials Office
Version Date: 3/15/2014
8.3 Delegation of Authority

• The DOA Log must be completed before the study is initially open to accrual.

• The DOA Log will be reviewed and updated by the Principal Investigator over the course of the study and reviewed for completeness at the time of the continuing review to ensure it is updated and maintained.

• Review of the Delegation of Authority Log should be documented with the signature and date of review by the Principal Investigator.
5.2 Opening a Clinical Trial to Accrual

• **Purpose:** To define the steps that must be taken prior to opening a clinical trial

• **Scope:** This SOP applies to all individuals and clinical trials conducted by the Winship Cancer Institute and its affiliate sites who participate in Therapeutic Clinical Research
5.2 Opening a Clinical Trial to Accrual

- The following must be completed and documented on the Opening Clinical Trials Checklist PRIOR to subject enrollment:
  
  - IRB approval with release of consent document
  - eNOA received
  - Study orders approved by the PI and available
  - Study drugs available in the investigational pharmacy
  - All lab supplies available
  - Site initiation completed
  - Case report forms available
  - Documentation of study specific training provided to ALL individuals with delegated responsibilities including infusion staff
  - DOA log completed and signed by principal investigator
  - Regulatory documents completed
## OPENING CLINICAL TRIALS CHECKLIST

### Study Information
- **Study Number:**
- **Sponsor:**
- **Type of Study:**
  - Investigator Initiated/Emory sponsor
  - Industry Sponsor
  - NCI/Cooperative Group
  - Other:

### Regulatory Items
- **IRB Number:**
- **IRB Approval Date:**
- **IRB Expiration Date:**
- **Protocol Version #:**
  - Current Signed 1572 or □ N/A
  - Delegation of Authority Completed
  - eIRB Study Personnel Accurate

### Billing Information or □ N/A
- ERMS Access Available
- eNOA Received

### Investigational Drug or □ N/A
- Study Drug Received/Available
- Orders PI Approved and available
- Smartkey Number:

### Supplies and Equipment or □ N/A
- Lab Supplies Received/Available
- Lab Manual Reviewed & Copy in CTO Lab
- Biomedical Engineering Inspection (e.g. ECG)

### Training
- □ SIV
- □ Study Personnel Not at SIV Trained
- □ In-service, if applicable

### CRFs
**CRFs Available**
- □ Electronic Database: __________________
- □ Paper

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**Printed Name, Research Staff**

**Signature**

**Date**

**Printed Name, Any CTO Assistant Director, or QM/Edu Coordinator**

**Signature**

**Date**
5.2 Opening a Clinical Trial to Accrual

• Following completion of the required steps, one of the Assistant Directors or a Quality Management coordinator will review documentation and sign the Opening Clinical Trials Checklist

• When the CTO Quality management has completed the review of the signed checklist they will send an email to the principal investigator and the study team informing them that the study is open to accrual and restating the accrual targets
Protocol Training for Nursing Units at Winship Cancer Institute

There is a strong push to activate NCI clinical trials within 4 weeks, as well as to decrease the activation timeline for all other clinical trials; therefore, adjustments have been made to the nurse training procedure and sign-off.

- Ambulatory Infusion Center (AIC) Nurses will identify 2 timeslots a week of 30 minutes each that can be dedicated for protocol training.

- Nurse training should be conducted at all Winship sites listed as participating in the trial (Winship Clifton Rd, EUHM, ESJH) before the checklist will be signed by the Director of Nursing, Winship Cancer Institute.
Protocol Training for Nursing Units at Winship Cancer Institute

Nurse training will occur in two steps.

1. Initial Training: This is high level training to meet the standard for the Director of Nursing to be able to sign off on the study within a timely manner. This training will include a brief summary of the study highlighting the title, phase and type of study, very basic eligibility of patient population and overview of study regimens/treatments. Pharmacy orders will be presented if available.

2. Detailed Training: This training will occur closer to the start of the study on the unit. The schedule will be determined based on the first enrollment of a patient. This training will include: protocol specific education and Pharmacy orders will be presented.
Training for Nursing Units Schedule

- G-Bay - Monday and Friday 8:00 - 8:30 am

- Phase I – Tuesday 7:15 - 7:45 am and Thursday 3:00 - 3:30 pm

- Midtown and ESJH slots – to be announced
Winship CTO SOPs and Forms can be found on Winship Intranet:

https://apps.winship.emory.edu/intranet/clinical_trials
Questions..
Multi-Site SOPs
(Management of Sub Sites for Investigator Initiated Trials)

Nikki Brumbelow, MS, CCRC
Multi- Site Coordinator
### Multi-site studies update

**Actively enrolling:**
- WCI 1524-08
- WCI 1777-09
- WCI 1871-10

**Not yet recruiting:**
- WCI 1937-10
- WCI 1549-08
- Winship 2434-13
- Winship 2572-13
- RAD2412-13

**Closed to recruitment, Maintenance:**
- WCI 1591-08 (R2V2)
Multi-Site: Standard Operating Procedures

APPROVED SOPs:
- 10.1 Regulatory Process
- 10.2 Site Pre-Initiation
- 10.3 Site Initiation
- 10.4 Enrollment Process
- 10.8 Reporting Identified Sites for OnCore Access
- 10.9 OnCore Security and Access
- 10.10 Central Subject Registration

PENDING SOPs:
- 10.5 Routine Monitoring
- 10.6 SAE/UP Reporting Process
- 10.7 Close-out Visit
Multi- Site: Common Findings

Common findings have shown areas to:

• Improve on communication
• Ensure sites are adequately trained

Action:
Encourage PIs to be actively involved and establish accountability with the PIs at each site.
Multi-Site SOP 10.1 Regulatory Process

Assemble regulatory packet

Create an amendment to include Participating Site

Send SIS, SFF, and CDA to Participating Site

IRB approval at Emory

Send Start-up letter and regulatory packet to PS
Multi-Site SOP 10.1 Regulatory Process Cont.

- Prepare and send sub contract request to RAS
- Work with Participating Site on site specific changes to protocol/consent
- Review submitted documents and upload into OnCore reg. binder
- Notify MSC
Winship Regulatory staff creates the study reference materials in electronic form and uploads into OnCore.

Once the Participating site has local IRB approval, the MSC will coordinate with OnCore support staff to grant the Participating Site permission to access these documents.
Multi-Site SOP 10.3 Site Initiation

A. The Site Initiation Meeting (SIM) will be conducted only after local IRB approval has been obtained, the site contract and budget have been finalized, and all applicable regulatory documents have been received by Winship.

The MSC will complete the following:
- Confirm that OnCore is ready for use.
- Coordinate scheduling of the SIM and availability of space for Winship staff
- Create the agenda and provide it to the participating site staff prior to the SIM.
- Provide a follow up SIM report no later than 10 working days after the SIM.
## Expected Site Attendees:

<table>
<thead>
<tr>
<th>Winship Staff:</th>
<th>Participating Site Staff:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor- Investigator (presenter)</td>
<td>Principal Investigator (if not possible, a site co-investigator must be in attendance)</td>
</tr>
<tr>
<td>Primary Study Coordinator/Nurse (presenter)</td>
<td>Study Coordinator/Nurse</td>
</tr>
<tr>
<td>Regulatory Specialist assigned to the study (presenter)</td>
<td>Regulatory staff</td>
</tr>
<tr>
<td>Laboratory staff, if applicable (presenter)</td>
<td>Laboratory staff, if applicable</td>
</tr>
<tr>
<td>MSC (presenter)</td>
<td>All other study staff identified on the Delegation of Authority Log</td>
</tr>
<tr>
<td>Data Manager</td>
<td>Data Manager</td>
</tr>
<tr>
<td>Pharmacist, if applicable</td>
<td>Pharmacist</td>
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</table>
Topics for Discussion

- Protocol Overview
- Subject Recruitment
- Study Calendar
- Case Report Forms
- Drug Supply
- Laboratory Logistics
- Serious Adverse Event/Adverse Event Reporting
- Good Clinical Practice (GCP) and regulatory requirements
- Data and Safety Monitoring
- Monitoring
- Audits
- Record Management
- Randomization/unblinding
- Communication
Multi-Site SOP 10.4 Enrollment Process

Participating sites may begin subject enrollment following completion of the Site Initiation process and receipt of an activation notification.

The Participating Site(s) are responsible for the following:
- Pre-screen and consent subjects
- Document subject information via the CSR form and send to the CSR
- Complete the Eligibility Checklist from OnCore
- Obtain verification signatures and dates from 2 delegated staff
- Submit the signed/dated Eligibility Checklist (with all supporting documentation) at least 2 business days prior to scheduled first treatment date
- Enter all data in OnCore

The MSC and/or S-I are responsible for the following:
- review the submitted documentation within 1 business day from receipt
  - Two signatures with date are required for eligibility confirmation.
- If eligible, MSC will notify the site and provide the subject’s enrollment number and dose and/or randomization assignment
- update subject information into OnCore
- If a subject is a SF, MSC will update enrollment status in OnCore
The study team must notify the CSR when an interested Participating Site will be pursuing participation in a particular Winship clinical trial.

OnCore support staff will complete the following:
- Enter Participating Site’s Institution in OnCore, if not already, and give permissions to the institution
- Ensure the assigned Winship regulatory specialist is trained to manage the Participating Site
- Review the SIS for staff from the Participating Site who will be responsible for entering study data
- Send an email to these individuals, attaching the OnCore Access Request Form and the OnCore Confidentiality Agreement.
1. The CSR or OnCore Team grants OnCore privileges by matching job responsibilities and privilege descriptions.

2. The Participating Site users will be assigned the role ACRA- Affiliate Clinical Research Associate.

3. An email is sent to the user, providing the link to the system, the User ID, statement to contact the registrar to obtain the temporary password by phone, instruction for resetting their password for optimum strength, and basic navigation instructions.

4. They will be assigned a strong, temporary unique password, given to the user by phone after verification of individual, and will be required to reset the password to a strong value the first time the user accesses the system (see SOP for actual requirements).

5. OnCore staff will provide user support as needed for all OnCore users.

6. Study/CRF- specific training and support should be provided by the Winship MSC and/or study team.
The study and site-specific CSR form will be provided to each Participating Site.

The CSR will send a Subject Registration Notification through the OnCore system to all study teams.

When a subject signs consent at a Participating Site, they will complete the CSR form and fax or email to the CSR with the entire signed consent/HIPAA within 24 hours or 1 business day of consent.

The CSR will register the subject and upload the signed consent/HIPAA form into OnCore.
QUESTIONS?