Mastering Clinical Research

For previous presentations and upcoming schedule, visit:

• https://winshipcancer.emory.edu/education/continuing-education/mastering-clinical-research.html
Pre Questions
Question 1: The first monitoring visit for a participating site must occur within 3 months (or per protocol if sooner) from date of first subject enrollment.

A. True
B. False
Question 2: The Sponsor-Investigator has how many working days, from receipt of the draft remote monitoring visit report, to return his review to Multi-Site Coordinator (MSC)?

A. 2
B. 4
C. 5
D. 1
Question 3: Who is responsible for notifying the research team and MSC when a site is ready to close-out?

A. Primary Winship Coordinator
B. Winship Regulatory Specialist
C. Sponsor-Investigator
D. Donald Duck
Question 4: To be compliant with the SOP on Study Drug Orders for IDS study drugs all orders will have the signature of a second licensed staff member verifying the BSA and dosing calculations. This licensed staff member does not have to be on the 1572.

A. True  
B. False
Question 5: The CRC responsible for a study does not have to be a licensed healthcare professional to provide subject education regarding the study drug because they know the protocol in-depth.

A. True
B. False
Question 6: Subjects should be registered in ERMS:

A. within 48 hours of consenting
B. 30 minutes after consenting
C. on the same day that a subject provides consent
D. when time permits
Multi-Site SOP Training

10.5 Routine Monitoring
• effective 10/6/14

10.7 Close-Out Monitoring
• effective today (10/22/14)

All Multi-Site SOPs can be found on the Intranet with the Winship Clinical Trials SOPs

This presentation will also be uploaded to the Winship website under Education and Training
10.5 Routine Monitoring

**Monitoring Schedule**

- After first subject is enrolled, visit to occur within first 3 months (or per protocol), on-site or remote per SI

- Site visit to occur at least once a year or once if study duration is < 12 months. DSMC can override this requirement

- Additional visits occur remotely and quarterly.
## 10.5 Routine Monitoring

### Monitoring Visit Preparation

#### Confirmation letter
- Sent at least 1 week prior to visit and includes list of subjects to be reviewed
- Based upon findings, more subject charts may be chosen to review

#### Study documents
- Participating site to ensure all study documents are up to date and available for review during visit
- For remote visits-source to be uploaded into OnCore at least 1 business day prior to scheduled visit

#### Site Master File/Regulatory
- MSC to review SMF at Emory prior to on-site visit.
- All essential documents to be reviewed on-site at participating site
10.5 Routine Monitoring

During Monitoring Visit

For on-site visits, MSC and participating staff to sign Site Visit Log

MSC to review 100% of:
- ICF
- Drug records
- SAEs
- I/E
- Primary endpoints

At end of visit, all study-related issues to be communicated to site

Queries to be issued in OnCore for monitoring visits and monthly data review. Resolution timeline per protocol or no later than 4 weeks
10.5 Routine Monitoring

Post- Monitoring Visit

Draft follow-up report generated and sent to S-I within 5 working days of visit completion.
S-I to review and return to MSC within 5 working days of receipt
Final report to site within 14 working days of visit concluded.

Final report distributed to DSMC Monitoring Manager who determines if findings should be escalated to DSMC for full committee review.

A copy of all monitoring letters to be filed in SMF and regulatory binder at the participating site.
10.5 Routine Monitoring

Written documentation must be provided if discrepancies cannot be resolved.

Subject data to be entered ASAP or no more than 30 days after each visit completion.

ADDITIONAL MONITORING ACTIVITIES
10.7 Close-Out Monitoring

• **Definition**: A site monitoring process conducted after a site has been closed for any reason

• **Objective**: To review Site Investigator’s Files to ensure all required documents and records are on file, confirm disposition of investigational products, and review regulatory requirements including records retention.
10.7 Close-Out Monitoring

S-I communicates to Winship research team and MSC when a participating site needs to be closed out for any reason.

MSC schedules close out visit and notifies site in writing at least 10 working days prior to visit. Notification letter includes: Place (onsite or remote), time, date, participants, and scope.

Participating site will ensure all necessary documents are available and up-to-date. If visit is remote, site is directed to upload all documents into OnCore and/or mail to the MSC prior to the visit date.
10.7 Close-Out Monitoring

MSC will send a draft close-out monitoring report within 5 working days to the SI. SI to review and return to MSC within 5 working days of receipt. Final report sent to the Participating Site staff within 14 working days of visit.

Participating Site to resolve all issues/queries within deadline provided by MSC.

Participating site responsible for following their institutions guidelines for closing out the study with their IRB.
QUESTIONS?
Winship Clinical Trials SOP Update

Tatiana Kurilo, MPH, CCRC
Quality Management and Education
Outline

Revised SOPs:

• SOP 6.2 Study Drug Orders for IDS study drugs
• SOP 6.3 Drug Accountability for non IDS study drugs

Changes are effective on October 22, 2014!

• SOP 3.9 Management of Subjects on Study

Changes are effective on November 3, 2014
Terminology change

• **Study Drug** instead of **Investigational Drug**

**Definition:**
Study (Investigational) drug is a drug or biologic agent that is used in clinical investigation.
6.2 Study Drug Orders for IDS study drugs

• **Purpose:** To standardize the process of ordering, dispensing and delivering study drugs for oncology clinical trials within Winship Cancer Institute by IDS

• This procedure applies only for study drugs dispensed by **Emory University IDS Pharmacy**
SOP 6.2 Procedure

• Research Order Committee develops order templates and approves them prior to use

• The study PI will review and provide **final** approval of study drug orders

• All orders for studies incorporating multi-step registration/randomization will reflect the completion of final step
SOP 6.2 Procedure...

All preprinted orders and prescriptions will have 2 signatures:

1) **MD** who has been confirmed as an investigator or sub-investigator on the 1572 form
   *Prescription has been reviewed carefully for:
   • Dose
   • Route of administration
   • Time and Duration of therapy

2) **Licensed** staff member who does not have to be listed on the 1572.
   *Verified:
   • BSA
   • Dosing calculations are correct
SOP 6.2 Procedure...

Initial orders to pharmacy

Should be submitted to IDS with:

1. ERMS registration
2. Signed signature page of the Informed Consent Form
3. Signed page verifying Eligibility by the investigator
4. Enrollment or randomization confirmation which indicates dose level
SOP 6.2 Procedure...

- For self-administered study drugs, IDS dispenses the exact amount of drug to complete the cycle (no excess)
- Copies of order for a study drugs will be maintained in the subject’s study record
- All study drug which is self-administered will be documented on the Dosing and Compliance Form (available on Winship Intranet)
- Drug dispensed by IDS may be transported and delivered to the subject by an unlicensed healthcare professional.
- Licensed healthcare professional are the only ones who can provide the subject education regarding the study drug
SOP 6.2 Procedure

• Study drug dispensed by IDS and returned by the subject will be documented (bottle/container count and pill count of open containers) and must be maintained in a secured area until returned to the Investigational pharmacy.

• The **Dosing and Compliance Form** maintained in the **patient research chart**. It **is NOT** required to be provided to IDS with returned study drug/bottle/containers.
6.3 Drug Accountability for non-IDS study drugs

Purpose:

• To standardize the process of ordering, dispensing and delivering all study drugs not dispensed by the IDS for oncology clinical trials within Winship Cancer Institute

• This procedure applies only for study drugs NOT dispensed by Emory University IDS Pharmacy
SOP 6.3 Procedure

• All preprinted orders and prescriptions will have the written signature (or electronic signature for electronic orders) of the signing MD who has been confirmed as the investigator or sub-investigator on the 1572 form

* Prescription has been reviewed carefully for:
  • Dose
  • Route of administration
  • Time and Duration of therapy
SOP 6.3 Procedure...

- **Licensed** healthcare professional are the only ones who can provide the subject education regarding the study drug.
- Study drug which is self-administered will be documented. A drug diary or injection chart will be included as indicated by the study protocol.
- Study Drug dispensed by an outside Pharmacy and returned by the subject will be documented.
3.9 Management of Subjects on Study

• **Purpose:** Standardization of activities of subjects participating in clinical trials to ensure that subjects receive safe care while meeting regulatory and compliance requirements

• **Scope:** All Winship Investigators and staff involved in the management of subjects who participate in cancer-related clinical trials
SOP 3.9 Procedure-Screening...

• CRC/CRN will:
  – Register subject into ERMS on the **SAME day** that a subject provides consent. This will trigger the Winship Central Subject Registration process

• Oncore® Registrar will:
  – Perform Central Subject Registration which includes verification of consent document versions, and signature/enroller check, and entry into Winship’s Oncore® Clinical Trial Management System

• Research study sites not permitted to use ERMS will:
  – Forward subject information directly to Central Subject Registrar at Winship via an approved process
SOP 3.9 Procedure-Screening

• CRC/CRN will:
  – Register/randomize subjects after eligibility has been confirmed and documented
  – Update Oncore® to reflect eligibility status and date
  – Provide eligible subjects with contact information
  – Provide the subject with a study treatment calendar and a copy of the calendar will be placed in the subject’s research record
  – Document in Oncore® and ERMS screen failures
SOP 3.9 Procedure- Intervention

• CRC/CRN will:
  – Coordinate scheduling of testing
  – Update subject status in Oncore® in a timely matter
  – Use ERMS to track subject visits
  – Record Conmeds and AEs on Winship Con med log and the Winship AE log and on sponsor supplied forms or electronic data capture system. Conmeds and AEs will be recorded as they occur or change
  – Enter data on CRFs within 30 days or as required by protocol or negotiated contract, whichever is shorter
SOP 3.9 Procedure- Follow Up

• Subjects must be followed for the period of time specified by the protocol

• CRC/CRN will:
  – Coordinate scheduling/ordering of testing and evaluations according to protocol for subjects who are no longer receiving study intervention
  – Enter changes in subject study status into Oncore® and ERMS
SOP 3.9 Procedure- Death

• CRC/CRN will:
  – Notify sponsor as required by protocol
  – Update Oncore® to reflect the death and the date of death

• Regulatory Specialist will:
  – Notify IRB according to IRB policies. Unexpected deaths which may be related to participation in a clinical trial must be reported promptly
Questions..