SOP Updates Pre-Test
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A. No, she can’t become pregnant.
B. No, if she agrees to use barrier contraception.
C. Yes, baseline pregnancy test is needed.
Q2. New Research Orders include new pregnancy test language in the lab section of the order. For OLD (existing) MD orders Pregnancy Test should be verified by:

A. Writing the results on the order and initialing
B. Using preprinted Red Pregnancy Labels
C. Attaching Lab Report to the orders
D. Do nothing, provider can check pregnancy test in PowerChart
Q3. Per Winship policy, when are CRCs/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.
Q4. Dr. B is the study PI located at John’s Creek, and a deviation occurred on his study at the Clifton Road site. The CRN/CRC sent an email notification to the regulatory staff, other applicable staff, and to Dr. B. Was she compliant with Winship SOP 4.3?

A. Yes

B. No
A study subject has developed nausea after taking drug X. The subject asks the CRC if this drug can cause nausea, and would like additional information. Can the CRC provide education to the subject regarding this drug?

A. Yes, the CRC can provide education regarding study drug.
B. Yes, but CRC has to check with physician-investigator first.
C. No, per SOP 6.2, only licensed healthcare professionals can provide the subject with education regarding study drug.
Pregnancy Test Policy

Tatiana Kurilo, MPH, CCRC
Quality Management and Education
Pregnancy Test Internal QM audit

**Results from Feb 2015 audit:**
- 48 female FCBP active study subjects from all Working Groups were selected
- Baseline/screening pregnancy test missed on 4 subjects. Required per protocol subsequent test were missed 6 subjects.

**Results from July 2015 audit** after implementation of CTO CAPA:
- 33 female FCBP active study subjects from all Working Groups were selected
- 0 cases of missed baseline/screening pregnancy test required per protocol subsequent test were missed 1 subject

**Results from October 2015 audit:**
- 25 female FCBP active study subjects from all Working Groups were selected
- 3 cases of missed baseline/screening pregnancy test required per protocol subsequent test were missed 1 subject
- Birth Control Form was missed in five (5) cases
- 10 cases non-compliance with new Lab procedure implemented in June 2015

**Results from January 2016**
- 16 female FCBP active study subjects from all Working Groups were selected
- 1 case of missed baseline/screening pregnancy test required per protocol
- Birth Control Form was missed in one (1) case
- One case of non-compliance with Winship Lab procedure implemented in June 2015
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

• Sometimes there are more than one baseline pregnancy tests

• Ensure that baseline pregnancy test done BEFORE patient received his/her first study drug if required per Protocol
Pregnancy Test verification for Research Orders

- Only **Licensed** medical professionals are allowed to sign off the pregnancy test verification
  - Medical Doctor (MD)
  - 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 MD/RN/APP Initial ___________ Date_________
When we **do NOT** order Pregnancy Test for the baseline assessment?

- Subject is MALE
- 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 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 when required per Protocol if:

- Subject is FCBP
- Tubal Ligation and Spouse’s successful vasectomy do not waive pregnancy test requirement
For Existing Orders – Please Use Labels
Questions
Consenting Errors

Found During Central Subject Registration
Common Consenting Errors

• Time Inconsistency
  • AM/PM vs. Military

• Consenting Professional not listed on DOA or OnCore staff list

• Incorrect version of consent form used

• HIPPA Consent missing at the time of consent

• Correction errors
  • Put a single line through the error, initial and date

• Incomplete
  • Missing initials or check marks in optional tissue and/or blood draw section

• Delayed submission to CSR

• Missing Items
  • AM/PM missing
  • PI signature or date missing
Most Common Consenting Errors

June 2015 – December 2015

- Time Inconsistency: 21
- Incorrect Version of Consent: 10
- Incomplete Consents: 41
- Late Registrations: 17
- DOA/Staff List: 19
- ERMS Registration: 21
- Corrections: 8
Errors Found on ERMS Registration Forms

- Incorrect
  - DOB
  - MRN Number
- Missing
  - DOB
  - MRN Number
  - Race
  - Ethnicity
  - Disease Site
  - Histology
  - Consenting Physician
  - Consenting CRC/CRN
Requirements

• Team leads should train new hires and current staff on consenting SOPs and ERMS registration forms completion
• Physicians and CRC/CRNs should work together ensuring times are consistent
• Use only AM/PM time when signing consents
• Consenting professional will print only from OnCore the day of consent
• Submit consents to Winship Central Registration no later than 24 hours after signing consent
• Regulatory staff will keep most current versions of DOA logs, staff lists, and consent forms in OnCore
Thank You
for your dedication to high quality cancer research at Winship!
SOP Updates

Carolina Lecours, BA
Quality Management and Education
SOP Updates

• Revised SOPs

  ➢ 4.1 Managing Research Records
  ➢ 4.3 Protocol Deviations
  ➢ 5.1 Site Initiation
  ➢ 5.3 Preparation, Conduct, and Follow-up of Sponsor Monitor Visits
  ➢ 6.2 Study Drug Orders for IDS study drugs
  ➢ 6.3 Drug Accountability for non-IDS study drugs
4.1 Managing Research Records

Must include:

- Source documentation and prompt reporting for all aspects of treatment
- Enrollment
- Randomization
- AE reporting in a format that is easily verified by sponsors, auditors, and monitors

An official research chart will be created for each study subject after eligibility status is confirmed, including:

- Subjects who sign an informed consent document but do not meet eligibility requirements (screen failures)
- The record must include source documentation of the subject’s trial participation
4.1 Managing Research Records

The Green Chart

Consent Eligibility Enrollment
Treatment phase
Response documents
Labs
Adverse Events
Others
4.3 Protocol Deviations

**Definition:** Unplanned excursion from the protocol that is not implemented or intended as a systematic change.

Protocol deviations include but are not limited to these situations:

- Non-compliance
- Missing labs
- Missing visits
- Missing assessments, or outside of window
- Any other procedure or omission of a procedure, which is required by the IRB approved protocol
4.3 Protocol Deviations Cont.

• Determine the root cause of deviation and the involved departments and/or individuals

• Document the deviation on the protocol-specific deviation form/log, or Emory University, VA, or CHOA protocol deviation log and review in the working group team meeting

• Develop a corrective and preventive action plan (CAPA) as applicable and place in the research record

• Send an email notification to the regulatory specialist, PI, and all applicable study staff
5.1 Site Initiation

- May be scheduled when a trial has IRB approval and a signed contract, and before enrollment of the first patient
- Availability of pivotal staff members and space must be determined prior to scheduling visit
- Includes the following:
  - CRN /CRC (and at least one other CRN/CRC for back up staff)
  - PI or other care providers as available
  - Regulatory staff
  - IDS
  - Representatives from infusion center, clinic or hospital
  - Clinical Pharmacist
  - Assistant Director of Clinical Research Staff
  - CTO lab staff
  - Other staff deemed necessary to complete study
5.1 Site Initiation Cont.

In addition, must include:

- Documentation of the visit and any training provided will be kept in regulatory binder.
- Additional training for involved sites, i.e. infusion center, inpatient clinic, or clinic staff will be provided before the study subjects are treated.
SOP 5.3 Preparation, Conduct, and Follow-up of Sponsor Monitor Visits

Scheduling the monitor visit:

- Identify which research team members are responsible
- Work with sponsor’s monitor to schedule a mutually convenient date and time
- Confirm availability of space
- Request that monitors schedule their visit with regulatory, IDS, and PI

Preparing for the monitor visit:

- Regulatory documents
- Source documents
- CRFs
- Queries
Managing the monitor visit:

• Ensure monitor has documents required
• Provide updates
• Ensure access to only study-specific records in PowerChart
• Work with monitor during visit i.e. address issues, etc.
• Ensure monitor has opportunity to meet with all required personnel
• Ensure understanding of any issues that require follow-up
• Ensure monitor signs monitor visit log
• Schedule an end of monitor visit meeting
• Follow-up after the conclusion of the monitor visit
6.2 Study Drug Orders for IDS study drugs

Change:

• Any drug given to a subject will be administered by a licensed healthcare professional, such as Pharmacist (Pharm. D.), Physician-Investigator, Clinical Research Nurse (CRN), Registered Nurse (RN), and Advanced Practice Providers (APP), and documented in the subject's medical record.

• **Licensed healthcare professionals**, such as Pharmacist (Pharm. D.), Physician-Investigator, Clinical Research Nurse (CRN), Registered Nurse (RN), and Advanced Practice Providers (APP), are the only ones who can provide the subject education regarding the study drug.
6.3 Drug Accountability for Non-IDS study drugs

Change

- Licensed healthcare professionals, such as, Pharmacist (Pharm. D.), physician-investigator, Clinical Research Nurse (CRN), Registered Nurse (RN), and Advanced Practice Providers (APP), are the only ones who can provide the subject education regarding the study drug
Important Reminders

• All SOPs are available:
  ➢ SOP binder in the CTO QM Office
  ➢ SOP binders at each Winship site
  ➢ Electronically on the Winship intranet under Clinical Trials:
    ➢ https://apps.winship.emory.edu/intranet/clinicaltrials/index.php

• The Monthly Protocol Card is now available on the Winship intranet under Clinical Trials
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