Mastering Clinical Research

December 7, 2016
7:30 am
Mastering Clinical Research

Pre-Test Questions
New Question and Answer Response System Log In Directions

Use the following link to access pre and post test questions:
http://www.socrative.com/

Click three bars in top right corner and Select Student Log In
Enter Room Name: PRESLEY4685
Enter your name:
Wait for quiz to begin
Answer questions and click submit

After the pre-test, you will need to re-enter your name for the post-test.
Investigator Initiated Study Implementation Team

Amanda Hutchison-Rzepka
Lymphoma Team Lead
Investigator Initiated Implementation Team Lead
What is Our Purpose?

The Investigator Initiated Study Implementation Team was created to better facilitate Winship Investigator Initiated trials and submission process improvement.

We are an advisory team that reviews 4 core IIT elements:

(1) protocol clarity (not science),
(2) ONCORE CRF reflection of protocol,
(3) Laboratory procedures, and
(4) Emory and Winship policy and procedures.
### Who Is Part of The Team?

We have an Established, Experienced Team

Currently 20 members from within the CTO:
CRCs, Team Leads, CTRC, Internal Monitors, Regulatory & Oncore

<table>
<thead>
<tr>
<th>Amanda Rzepka</th>
<th>Neera Jagirdar</th>
<th>Lisa Hwang</th>
<th>Lydia Cox</th>
<th>Nikki Hirsch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tivona Jones</td>
<td>Vanessa Phelan</td>
<td>Tatiana Kurilo</td>
<td>Lisa Floyd</td>
<td>Pam Bourbo</td>
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<tr>
<td>Ki-Ling Suen</td>
<td>Stephanie McMillan</td>
<td>Monique Guyinn</td>
<td>Hayley Von Hollen</td>
<td>Shannon Gleason</td>
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<tr>
<td>Latrisha Moore</td>
<td>Alicia Escobar</td>
<td>Rachael Maynard</td>
<td>Leslie Wendt</td>
<td>Ireana Mackey</td>
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How Does the Review Work?

We Have an Established Collaborative Review Process That Works

A New IIT is Submitted to the CTRC

The CTRC (Lisa Hwang) Notifies the IIT Team Lead

The IIT Team Lead Assigns 4 Reviewers (1 is a Lead Reviewer)

Lead Reviewers send Review Summary to IIT Team Lead

IIT Team Lead gives De-identified Feedback to the PI
How Can We Help?

We have Tools:
• Protocol Template
• Protocol Checklist
• Key Contact List
Future Goals

• Always Recruiting more Experienced Members
• Building a Lab Manual template
• Developing a Non-Therapeutic Protocol template
• Build Standard CRFs
• More Outreach
What Do We Hope to Improve?

• More CTRC Approvals
• Faster IRB Approvals
• Less Amendments
• Less Queries
• Less Deviations
Thank you !!!

Any Questions?

Contacts:

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ahutch7@emory.edu

Lisa Hwang
404-778-5714
m.lisa.hwang@emory.edu
External Adverse Event Review

8.5

Kim Nguyen, BS
Assistant Director, Regulatory Affairs
**Purpose:** To describe the procedures for documentation of review by the Principal Investigator (PI) or designated Subinvestigator of all External Safety Reports (ESRs) received for approved clinical studies.

**Scope:** All Winship investigators and staff involved in the management of subjects who participate in cancer-related clinical research.
Procedures:

Regulatory Specialists and/or designee will retrieve the individual ESRs weekly and save in the study specific folder on the shared drive.

• If the ESR includes instructions to report to the IRB: the regulatory specialist will promptly prepare submission to the IRB of record without awaiting PI concurrence.

• If the ESR includes instruction to follow local policy:
  • the regulatory specialist and/or designee will on a weekly basis send an email with the ESR(s) attached or have them available paper-copied to the PI or designated Subinvestigator, using the Email/Paper Template for External Safety Review, requesting that the PI or designated Subinvestigator review and respond within 5 business days. A back-up Regulatory Specialist will be copied on the email.
  • The PI or designated Subinvestigator will review the ESRs and respond via email within the requested timeframe. If PI or designated Subinvestigator assesses and documents that the ESR is not reportable to the IRB, then their email response will be filed with the ESR in the study regulatory documents as documentation of review.
• If the regulatory specialist and/or designee does not receive a response within 5 business days, the regulatory specialist and/or designee will send a follow-up email.
• If PI or designated Subinvestigator deems an ESR to be an unanticipated problem (UP), the regulatory specialist will submit the report to the IRB of record per the policy of the IRB, and retain the ESR in the study regulatory documents.

Additional Considerations:
Winship Cancer Institute manages and reports ESRs once a study has IRB Initial Approval. Any reports received after the IRB final closure will not be acknowledged or retained by the Winship Cancer Institute.

In instances where the Winship Cancer Institute Principal Investigator serves as the sponsor and holds the IND, the PI will be responsible for reviewing the ESRs to determine which events need to be reported to the FDA and for notifying the site investigators of multi-center studies. This includes any required changes to the investigational brochure, informed consent form, protocol and or inclusion/exclusion criteria. The Emory sponsor will maintain a file for the ESRs at Winship Cancer Institute and provide documentation of review, assessment and required reporting.

Attachments: Email/Paper Template for External Safety Review
From: Nguyen, Kim
Sent: Tuesday, November 15, 2016 0:25 PM
To: E-Rayes, Basuel
Subject: [EXTERNAL SAFETY REPORT REVIEW] - ML28412

Importance: High
Tracking: 
Read: 
Read 11/16/2016 8:51 AM

Hello Dr. E-Rayes,

Please review the attached external safety reports (listed below) and provide your response within 5 days. Your email response will be filed in the study records as documentation of review.

SUSAR_15O_20-AUG-2016_RO4075646_BEVACIZUMAB_AER1870825_ACUTE_KIDNEY_INJURY_ES
SUSAR_15O_22-JAN-2013_RO4075646_BEVACIZUMAB_AER1177509_EPILPSYCH_H
SUSAR_15O_02-NOV-2013_RO4075646_BEVACIZUMAB_AER1178341_MULTIPLE_EVENTS_CA_SU
SUSAR_15O_06-OCT-2016_RO4075666_BEVACIZUMAB_AER1785431_MULTIPLE_EVENTS_CA_SU
SUSAR_15O_09-NOV-2016_RO4075646_BEVACIZUMAB_AER1879315566_FNCIETATITUJ_IP_FU
SUSAR_15O_13-OCT-2016_RO4075646_BEVACIZUMAB_AER1723666_FU
SUSAR_15O_15-SEP-2016_RO4075665_BEVACIZUMAB_AER1700425_ACUTE_KIDNEY_INJURY_ES

1. Do any of the events need to be submitted PROMPTLY to the IRB? Yes [ ] No [ ]

If YES, please list the report number(s) below.

If NO, then the events are NOT reportable to the IRB.

Please confirm that you have reviewed the events listed above and determined IRB reporting requirements by checking this box. [ ]

Kim Nguyen
EXTERNAL SAFETY REPORT REVIEW FORM

IRB Study #: IR8000
PI: Dr.
Title: Unique identifier for this event: Please see below

Please review the attached external safety reports and provide your response within 5 days. Your response below will be filed in the study records as documentation of review.

1.
2.
3.

1. Do any of the events need to be submitted PROMPTLY to the IRB? Yes ☐ No ☐
   If YES, please list the report number(s) below.
   
   __________________________
   __________________________
   __________________________

   If NO, then the events are NOT reportable to the IRB.
   Please confirm that you have reviewed the events listed above and determined IRB reporting requirements by checking this box: ☐

   ________________ ________________
   Principal Investigator Signature Date
Winship CTO SOPs and Forms can be found on Winship Intranet:

https://apps.winship.emory.edu/intranet/clinical_trials
Questions?
Mastering Clinical Research

Post-Test Questions
Thank You

Happy Holidays