TIC-TOC Trial: Staff Training Checklist SITE ID: _____

Instructions: *Each site staff member completing study activities on this trial (listed on the DOA) should complete this checklist prior to beginning any work on the study.*

Once a site is aware of a new staff person joining the TIC-TOC Study, they will need to provide the DCC with a completed New People in PECARN signup. This will initiate an Active Directory (AD) account to be created. Please do this first as the AD account is the key to many of the trainings on this checklist. The form can be found in the TIC-TOC eRoom.
After the DCC receives the above document, an AD account will be set up and the staff member can proceed with the necessary trainings. (Skip this step if this staff member is already established in PECARN.)

The following training checklist is based off the Joint Task Force for Clinical Trial Competency (www.clinicaltrialcompentency.org)
"The Joint Task Force for Clinical Trial Competency has identified the skills required for safe, ethical, and high-quality clinical research."

TRAINING

❑ **Read Protocol** - All parts of the clinical protocol are important. Specifically you should be able to identify/explain the:

- Study Design
- Inclusion/Exclusion Criteria
- Informed Consent and EFIC Process
- Specific Aims and Outcome Measures
- Randomization Plan
- Methods/Study Procedures
- Process for identifying and reporting AE/SAEs

❑ **Read Manual of Operations (MOO)** - The purpose of the MOO is to review and describe the specific activities necessary to carry out the study protocol. Here you will find detailed descriptions of each step of the workflow. In addition, there are several tools created to guide you. You should be able to:

- Review incl/excl criteria and determine eligibility - Eligibility Cheat Sheet
- Review procedures for enrolling with EFIC vs obtaining consent - EFIC Enrollment Tips
- Determine what blood samples need collected, timing of collection, priority, processing procedures, storage, and shipping - Blood Draw Priority List
- Review Randomization - Use Next Box, What if the box you need is not available?
- Determine the appropriate dose of study drug to give to the participant. Use the weight based-dosing cards and other instructions to determine the study drug dose. Be familiar with pump programing instructions to assist the clinical staff. Weight-based Dosing Card
  - » As a drug study, what clinical trial phase does this study fall under?
- Understand how to identify and report AE/SAEs and other participant safety issues.

❑ **Good Clinical Practice (GCP)** - All clinical research staff must have current GCP training documentation on file. This includes the most recent ICH GCP R2 regulations.

❑ **Written Informed Consent and Exception From Informed Consent (EFIC)** - Learn and know procedures for when to obtain written informed consent versus enrolling with EFIC. Be sure to understand the requirements for EFIC enrollments.

- Review location for obtaining consent and/or offering opportunity to object to EFIC
- Read site specific informed consent document
- Review how written informed consent is obtained - Informed Consent Checklist
- Review process for enrolling with EFIC - EFIC Enrollment Checklist

❑ **Protection of Human Subjects** - All clinical research staff must have current Protection of Human Subjects training documentation on file. This may involve CITI Training documentation or other site specific systems.

❑ **Read, Know, Learn Your Site Specific Workflow Document** - Each site has completed a workflow document based on site specific parameters in order to describe how the study will be carried out at your institution. This is based off a standard template of study activities provided by the DCC. Review the Site specific workflow created by your study team in preparation for the competency check-off/simulation activity.

❑ **Complete all training modules and documentation related to the Electronic Data Capture (EDC) Systems required for this trial:**

- Complete the online Moodle course & take a short quiz for OpenClinica and Query Manager
- Complete the online Moodle course & take the short quiz for REDCap
- Review the procedures for imaging up-loads in XNAT (as applicable)

❑ **Communication is an important component to success in clinical trials. Orient yourself to the TIC-TOC Trials eRoom (if applicable) by identifying the location of the following:**

- Protocol, MOO, Study Updates, Contact List, EDB tools, Study Worksheets, Training Information, IRB Materials, Pharmacy Manual

❑ **Know site personnel involved in the study** (ED Clinicians, nurses, pharmacist). Know how you will communicate with clinical research staff regarding study participants. Be familiar with your Delegation of Authority Log to know who is responsible for what tasks.

Once you have completed this checklist,
you may proceed to the Competency Check-off.

There may be others tasks and documents necessary to review in order to carry out this trial.
The PI at your institution is responsible for all study tasks and may delegate them to research staff per ICH GCP.
Remember to review all site specific policies and guidelines for clinical research.

X **Form Completed By (Signature):**_____ **Date:**_____

Print Name: _____