TIC-TOC Trial: Competency Check-Off

Instructions: *Each site staff member working on this trial should complete this competency check-off activity prior to beginning any work on the study. This activity is open-book and interactive. Use this form for jotting down notes, answers to each section must be verbalized to test administrator. You have 3 attempts to pass the competency.*

1 Screening - Review 3 patient scenarios and determine eligibility for each.

Instructions: *The competency check-off administrator will provide you with three patient scenarios. Review the injury information and verbalize whether the patient is eligible or not AND if the patient should be approached for consent.*

Tools to use: *Ring of Knowledge, Eligibility worksheet, MOO.* ***RC's may confirm answer with PI.***

- ☐ First Patient - Review scenario and indicate whether patient is eligible or not eligible. ***(Patient Scenario # _____)***
- ☐ Second Patient - Review scenario and indicate whether patient is eligible or not eligible. ***(Patient Scenario # _____)***
- ☐ Third Patient - Review scenario and indicate whether patient is eligible or not eligible. ***(Patient Scenario # _____)***

2 Enrollment - Obtain informed consent

Instructions: *From the 3 patient scenarios used in part one, choose ONE that is an eligible patient who should be approached for consent. Notify the test administrator which patient scenario you'll be using.* ***INFORMATION FROM THIS SCENARIO WILL BE USED FOR THE REMAINDER OF THE CHECK-OFF.***

Using the provided parent/LAR name and patient name, conduct a mock consent. Be sure to verbalize where consent will be obtained.

Tools to use: *Parental Permission form, Informed Consent Checklist, MOO.*

Patient Scenario # _____

3 Study Drug Administration / Randomization

Instructions: *Using the information from your patient scenario, verbalize the answers to the following questions.*

Tools to use: *Ring of Knowledge, Use Next Box dosing cards, GFR calculator, MOO.*

- ☐ Which Use Next Box (injury strata) should you pull for this patient?
- ☐ What is the bolus dose and rate for this patient?
- ☐ What type of pump should be used to administer study drug to this patient?
- ☐ What is the patient's GFR and renal impairment status?
- ☐ What is the maintenance dose and rate for this patient?

4 Baseline Activities / Sample Collection

Instructions: *Verbalize your understanding of sample collection and processing by responding to the questions below.*

Tools to use: *Ring of Knowledge, Blood Draw Priority List, Site Specific Workflow, MOO.*

- ☐ When should blood draw number #1 be collected? How much blood should be drawn? Which tube(s) are needed for this draw? How are samples processed after collection? If the full amount of blood is not drawn, what do you do?
- ☐ When should blood draw number #2 be collected? How much blood should be drawn? Which tube(s) are needed for this draw? How are samples processed after collection?
- ☐ When should blood draw number #5 be collected? How much blood should be drawn? Which tube(s) are needed for this draw? How are samples processed after collection? If the full amount of blood is not drawn, what do you do?
- ☐ When should blood draws #3, #4 and #6 be collected? Which tube(s) are needed for these draws? What does 'convenience sample' mean?

5 Follow-up / AE/SAE Tracking - Review follow-up to occur after initial study activities in the ED including adverse event reporting.

Instructions: *Verbalize answers to the below questions. The check-off administrator will assign you 2 AE/SAE Scenarios which will be used to answer the last question.*

Tools to use: *Site Specific Workflow, MOO.*

- ☐ Discuss floor communication plan - explain study procedures to floor nurse/clinical team including study drug instructions, sample collection, 24hr CT (if applicable), and research team contact info.
- ☐ Verbalize plan for getting drug vial back to IDS Pharmacy
- ☐ Review 2 AE/SAEs - correctly identify if event qualifies as an AE or SAE and appropriate reporting

Returned used forms to test administrator. Please do not share this information with study staff members who have not completed the competency!

TIC-TOC Trial: Competency Check-Off Score Form

SITE ID: _____

Attempt #: _____

Instructions: *Use this scoring form to grade each site staff member completing the competency check-off activity prior to beginning work on the study. Research staff must contact the DCC after 3 failed attempts for additional guidance.*

P / F **Screening -** Using the Eligibility Cheat Sheet and the Eligibility Form, review 3 patient scenarios and determine eligibility for each.

- ☐ First Patient - Correct assessment of eligibility
- ☐ Second Patient - Correct assessment of eligibility
- ☐ Third Patient - Correct assessment of eligibility

P /F **Enrollment -** Obtain Informed Consent - walk through the conversation around consent.

- ☐ Verbalized where consent will be obtained (quiet space)
- ☐ Introduced the study - provided 2-3 sentence description about the trial
- ☐ Explained the details - Reviewed in "bullet point fashion" the main components of the trials (drug, sample collection, CT, follow-up surveys, chart review)
- ☐ Reviewed the consent document - went through section by section and allowed time to read and ask questions
- ☐ All 8 required elements reviewed: (description, risks, benefits, alternatives, confidentiality, compensation, contacts, voluntary)

P / F **Study Drug Administration / Randomization -** Initiate study drug by pulling the correct Use Next Box and walk through all administration steps.

- ☐ Indicated the correct 'Use Next Box' to pull
- ☐ Determined correct bolus dosing and what type of pump to use
- ☐ Calculated GFR, renal impairment status, and determined maintenance dosing

P / F **Baseline Activities / Sample Collection -** Identify the correct time points and pull the correct tubes for each sample collection time point.

- ☐ Sample Collection #1 - correct time point, blood draw amount, tubes, priority
- ☐ Sample Collection #2 - correct time point, blood draw amount, tubes
- ☐ Sample Collection #5 - correct time point, blood draw amount, tubes, priority
- ☐ Convenience Samples - correct time points, tubes, what a convenience sample is
- ☐ Demonstrated proper collection and processing procedures

P / F **Follow-up / AE/SAE Tracking - Review follow-up to occur after initial study activities in the ED including adverse event reporting.**

- ☐ Discuss floor communication plan - explain study procedures to floor nurse/clinical team including study drug instructions, sample collection, 24hr CT (if applicable), and research team contact info.
- ☐ Verbalize getting drug vial back to IDS Pharmacy
- ☐ Review 2 AE/SAEs - correctly identify if event qualifies as an AE or SAE and appropriate reporting

Participants must pass all sections to pass the competency check-off	**Pass / Fail**

Research Staff (print):_____ **Date:**_____

Competency Administrator(print): _____ **Date:**_____

Competency Administrator(Signature): _____

*****Email all completed score forms to deveree.partridge@hsc.utah.edu***