**HALF-PINT Study Management FAQ**

**Screening**

**Q: A patient was admitted in the evening but I didn’t screen until the following morning. The first two glucose results meet randomization criteria but the patient has not yet consented. The next morning he is consented and enrolled, but glucoses are consistently less than 150 mg/dL. Do we consider the first two results, prior to consent, to qualify the subject for randomization, or track only the glucose results since he was consented?**

A: Patients are first determined to be eligible for HALF-PINT based upon the Inclusion and Exclusion criteria and are then consented if appropriate. Tracking of glucose levels for hyperglycemia (study defined as > 150 mg/dL, with a consecutive, confirmatory value also > 150 mg/dL, within 24 hours or less) begins only *after* consent has been obtained. Therefore, the subject *would not* be randomized based upon the glucose values obtained prior to consent.

**Q: What if a patient is admitted during the night and started on insulin prior to being screened? If she is eligible, should we still consent and then track this patient for hyperglycemia?**

A: Yes, if eligible (meets all inclusion criteria and no exclusion criteria) you would initiate the consent process and then track this subject as you would all others.

**Q: Yesterday I screened a neonate who met clinical eligibility except that he was 23 days old. He had been born prematurely and was one day short of 42 weeks (adjusted) gestational age. The patient is now 24 days old (meeting the required > 2 weeks and > 42 weeks corrected gestational age) and still meets other eligibility criteria. Should we try and consent this patient or is it too late?**

A: Even if the patient was intubated or put on IV vasopressors/inotropes prior to meeting study defined age eligibility (because they are less than 2 weeks/42 weeks corrected gestational age), they can be screened upon aging into the age (meeting the minimum) eligibility criteria. If the patient meets all inclusion and no exclusion criteria, consent process should be initiated.

**Tracking**

**Q: If a consented subject is randomized, do we stop tracking on the Consented Subject Tracking Sheet?**

A: YES! Consented subjects are only tracked on the Consented Subject Tracking Sheet until:

1. They meet the study definition of hyperglycemia and are randomized (future glucose values are then entered into CHECKS algorithm, discontinue documenting on Tracking sheet ) or
2. They reach study day C-28 (28 days of tracking with no hyperglycemia; then study discharged) or
3. They become ineligible for a reason other than off vasopressors/inotropes or extubated (e.g., discharged from ICU, family/team have decided to limit/redirect care from aggressive ICU technological support, subject had new cardiac surgery; then study discharged).

**Q: A subject had two glucose results documented within 10 minutes of each other that were over 150 mg/dL which appeared to be run at different times and therefore from different blood draws. Would we consider these to be the initial and confirmatory values and therefore randomize?**

A: As long as it could be definitively determined that the two results were from *different blood draws* the subject would then be randomized. Two results from a single blood draw, even if run on a bedside glucometer and the central lab, do not constitute initial and confirmatory measurements.

**Post-Randomization**

**Q: Is the 28 days of tracking consented subjects the same 28 days that they will be studied? If so, and the subject is randomized on Day 27, wouldn’t their blood glucose (BG) be managed for only one day?**

A: No, these are separate parameters.

* Subject is consented on Study Day C-1 and followed on the Consented Subject Tracking From for hyperglycemia for up to 28 days. If they do not developed study-defined hyperglycemia within this timeframe, they are study discharged at Day C-28.
* If a consented subject develops hyperglycemia within the 28 days following consent and is randomized, the BG is then managed (via the CHECKS algorithm) for up to 28 days (or ICU discharge, whichever occurs first); day 1 of BG management starts on the day of randomization (marking a new 28 day timeframe).

**Q: I have a HALF-PINT subject that was not on ventilator support prior to this ICU admission. She was hospitalized following a trauma, though, and will now be ventilator dependent. Since she is now going to be chronically ventilated, does she become ineligible and is therefore study discharged?**

A: No. Although her respiratory status has changed, she was eligible at the time of enrollment as she had no prior history of chronic ventilator dependence. Upon her study discharge it will be documented that she was still intubated at study discharge.

**Q: Can you enter more than one Adverse Event (AE) per study day?**

A: Yes - there is no limit to the number of AEs that can be entered per subject per study day.