**HALF-PINT Study: Request for Approval to Approach Patient/Family**

Dear Attending Physician or Delegate,

Your patient \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(first and last name)* is eligible for enrollment in the Heart and Lung Failure – Pediatric Insulin Titration Trial (HALF-PINT) study being conducted in the ICU at [Insert Name of Hospital]. This trial randomly assigns participants to blood glucose target ranges 80–110 mg/dL vs. 150–180 mg/dL. It includes the use of a subcutaneous continuous glucose sensor, an in-line blood conservation system, IV insulin infusion, and a computerized insulin dosing spreadsheet. We would like to approach this patient and his/her parent(s) or legal guardian(s) to discuss the details of the study and offer them the opportunity to consent for participation in this study.

**Documentation of Pregnancy Status**

Only non-pregnant females may be included in the study due to the potential harm of iatrogenic hypoglycemia to the developing fetus. Please certify below whether this patient is pregnant, and the information upon which this determination is based. Please note that a pregnancy test should not be ordered for the exclusive purpose of determining eligibility for the study.

I assert that this patient IS NOT pregnant and can participate in HALF-PINT because:

\_\_ Patient is male

\_\_ A previous pregnancy test performed for clinical reasons is *negative*

\_\_ Patient is prepubertal

\_\_ Patient is female but lacks the required reproductive anatomy (uterus, vagina, ovaries)

\_\_ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(please explain)*

I assert that this patient IS pregnant and cannot participate in HALF-PINT because:

\_\_ A previous pregnancy test performed for clinical reasons is *positive*

\_\_ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(please explain)*

\_\_ I assert that this patient cannot participate in HALF-PINT because pregnancy status is *unknown.*

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**Approval to Approach for Informed Consent**

Will you allow study staff to approach this family and obtain informed consent if they wish to participate?

\_\_ Yes

\_\_ No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(please explain)*

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*Name of Attending Physician or Delegate* *Role in ICU*

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*Signature of Attending Physician or Delegate Date*