Corporate Compliance is requesting signed attestation that **all** of the following have occurred with regard to CCAP# 19-75-012-01
Of note:

- The submitted CCAP Management Action Plans have been implemented in their entirety.
- The risk associated with the CCAPs has been sufficiently mitigated.
- Procedures are in place to reasonably assure the related control environment will be sustained over time, including ongoing managerial monitoring for compliance.
- Documentation will be maintained to provide evidence of the assertions made.

IU Health Ambulatory Surgery Center Research Acceptance Process

A. The Researcher or Primary Investigator will submit a completed IU Health ASC Clinical Research Request Form to the Office of Clinical Research (OCR) after the completion of the following requirements:
    1. Ensuring appropriate coordination of the patient's care between the Research team and patient care providers.
    2. Ensuring that all Research is posted to ClinicalTrials.gov as required in Indiana University Policy, RP-11-008: ClinicalTrials.gov Compliance.
    3. Registering protocol and subject information in OnCore Clinical Research Management System as required by the Office of Clinical Research.
    4. Registering protocol and subject information in Cerner PowerTrials (a component of Cerner Millennium, Indiana University Health's electronic medical record system) as required by the Office of Clinical Research.
    5. If protocol includes IU Health billable procedures, ensuring a Medicare coverage analysis is completed and following all applicable policies and procedures regarding clinical research billing.
    6. Receiving required approvals before beginning any Indiana University Health Research. Investigators may be requested to show evidence of approvals. Required approvals can be found in the IU Health Research policy.
    7. Establish where and how will documentation in the Medical Record identify that any surgical procedure(s) is related to Research or Study (H&P, Procedural Note, etc.):
B. OCR will review Clinical Research billing requirements and when applicable, set up OnCore consent notifications to be received by the Surgical Care Affiliates (SCA).
C. The OCR will complete their section and return to the Clinical Director indicating that appropriate financial arrangements have been identified and arranged.
D. The Clinical Director of the ASC will review the internal ASC Research Approval Form to ensure all criteria has been met. Criteria for approval includes:
    1. Any research activities carried out within the organization are appropriate to the expertise of team members and the resources in the organization.
    2. Individuals engaged in research are provided with adequate facilities.
    3. All professional team members are informed of the organization's research policies.
    4. Confirmation of needed supplies are identified, and financial arrangements are finalized.
    5. Confirmation of billing procedures with the Office of Clinical Research.
    6. Confirmation that documentation in the Medical Record exists identifying that any applicable surgical procedure(s) is/are related to Research or Study (H&P, Procedural Note, etc).
E. The Clinical Director will communicate the approved research project criteria to the Medical Director(s) and Clinical Manager(s).
F. SCA will mine OnCore information regarding the coding modification and/or research billing processes contained within the study.

IU HEALTH AMBULATORY SURGERY CENTER (ASC) CLINICAL RESEARCH REQUEST FORM

Requester Section: **This form is to be completed by the Researcher/PI and the OCR before it is submitted to ASC Clinical Director for approval. All fields require a response.**

Title of Research/Study Project:

Study OnCore Protocol ID:

Name of Researcher: Date Contacted:

Name of Principal Investigator or Faculty Member:

Proposed Start Date: Proposed End Date:

Name of IUH ASC(s) where research will be conducted:

Will the ASC be responsible for collecting, storing, and/or reporting out data? Yes ☐ No ☐

Will surgical team members be required to assist with protocol-required procedures? Yes ☐ No ☐
If yes to either question, a one-page study summary is required to provide details

Are there protocol specific supplies required for the study? Yes ☐ No ☐
If yes, who will provide additional supplies?

Is an investigational device being studied (i.e. Is there an IDE number associated with the study)? Yes ☐ No ☐
If yes, has charge help (chargehelp@iuhealth.org) provided you with a research charge code? Yes ☐ No ☐
Code:

Where and how will documentation in the Medical Record identify that any surgical procedure(s) is related to Research or Study? H&P ☐ Intraop Note ☐ Procedural Note ☐ Enrollment note in Research/Clinical Trials ☐
Other:

PRIMARY INVESTIGATOR OR DESIGNEE: SUBMIT THIS DOCUMENT TO THE OCR AT ocrfin@iu.edu

Office of Clinical Research Review: **This section will be completed by the OCR ☐ or their delegates IUSCCC-CTO ☐.**

1. Project Signed Off by the IU Health Office of Research (OCR)? Yes ☐ No ☐** Sign-Off Date:

** **The ASC is unable to participate in any Research not vetted & approved by the OCR.**

2. Did the Coverage Analysis note any specific billing requirements? Yes ☐ No ☐ If yes, check all that apply:

☐ Some items or services require special coding on claims

☐ Some items or services should be billed to the Research Study Team

Ambulatory Surgery Review and Approval Section: **All fields require a response.**

The ASC will be able to support all participation requests as noted above: Yes ☐ No ☐
If no, identify limitations of participation:

Medical Record Process documentation that will identify Research or Study confirmed with physician? Yes ☐

Approved By: _____ Date: _____
ASC Clinical Director