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SUBJECT: New Process for Submitting Clinical Trials Forms to the Office of Quality

Dear Emory Investigators, Research Nurses and Clinical Research Coordinators,

A collaborative effort between the Office for Clinical Research (OCR), Institutional Review Board (IRB), Office of Quality (OoQ), and Emory Healthcare (EHC) Nursing has streamlined the approval process for clinical trials requesting EHC Nursing staff assistance. As of **October 4, 2016**, the following set of changes will take place:

* Study teams will complete the **newly, revised Clinical Research Key Points (CRKP) in eIRB.**

The CRKP consolidates three previously separate forms: o the Clinical Research Key Points

o the OoQ Clinical Research Readiness Checklist, and o the EHC Nursing Clinical Research Preparedness Checklist.

Study teams **will now submit the CRKP electronically via eIRB for all clinical trials**, **including studies reviewed by WIRB**. WIRB studies will now use eIRB for Emory IRB signoff instead of “Form B” (Form A still required).

* Clinical Research Coordinators (CRC) will continue to submit the EML and Radiology

Checklists, if applicable, **directly to the OoQ**. CRCs **no longer have to obtain signatures from EML or Radiology** prior to submission. EML and Radiology will sign approvals electronically.

Improved processes resulting from these changes include:

* EHC Nursing will review and approve all protocols within 7 days. EHC Unit Directors, Specialty Directors, and Clinical Nurse Specialists from all non-Winship inpatient units and outpatient clinics now have the capability to sign approvals electronically.

* CRCs no longer have to obtain signatures from EHC Nursing or submit them to the OoQ.

* Winship clinical trials are covered under a separate policy and verification process, and will not require EHC Nursing approval or EHC Nursing signatures.

**NOTE:** the requirement that study teams **must complete training of EHC Nursing staff before EHC Nursing will perform any research activities** has not changed**.**

If you have any questions, please contact ocr@emory.edu.

Sincerely,



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Associate Dean for Clinical Research

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