



AT THE FOREFRONT  
**UChicago**  
**Medicine**

Office of  
Clinical  
Research

To: Clinical Research Faculty and Staff

From: Bethany Martell, Executive Director- OCR

CC: Millie Maleckar, Director BSD IRB, Pamela Gonzalez, Director ROC, and Walter Stadler, Dean Clinical Research

Re: New Study Submission Requirements due to the Removal of Requirement for Concurrent Routing

Date: February 1, 2021

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During Fall 2020, the BSD Operational Excellence Office in collaboration with the OCR and clinical research leaders in the Dept of Medicine Clinical Research Support Office (CRSO) and Clinical Trials Financial Group (CTFG), Section of Hematology-Oncology and the Cancer Center Clinical Trials Office (CCTO), participated in a virtual Kaizen event focused on the Dept. of Medicine Pre-Submission activities for new clinical trials. There are a number of action items from this event and one is related to the Concurrent Routing Requirements that have been in place since 2009.

Effective February 1, 2021 the existing standard for concurrent routing of the budget/contract documents at the time of IRB submission will no longer be required. The current nature of study initiation activities, need for agility, challenges in coordination between various stakeholders and desire to start the budget/contract earlier in the process and move on a more parallel pathway, mean concurrent routing may not be meeting our collective needs.

The need to ensure the IRB submission and associated documentation are aligned with the billing/budget/contract documents remains as does the need to ensure billing plans harmonize with the informed consent. To that end, there are changes to the IRB new study submission requirements as well as to the ROC submission and final approval requirements.

### **IRB New Study Submission Requirements**

In addition to the existing IRB new study [submission](#) requirements (see New Protocol checklists), when a study meets any of the following criteria, the Medicare Coverage Analysis (MCA)/ completed schema review memo and signed schema are required to be in ARTEMIS. For IRB purposes, a record should be created in ARTEMIS at the time of IRB submission, to allow the record to be linked in AURA-IRB. The ARTEMIS record can remain in "DRAFT" state with the documents uploaded. The record does not need to have been submitted, for the documents to be reviewed during the IRB review process. IRB Protocols that do not include this documentation in ARTEMIS will be returned to the submitter in AURA-IRB.

Submissions requiring MCA/Schema in ARTEMIS at time of IRB submission include:

- Protocols including drugs, medical devices or biologics with or without an IND/IDE
- Protocols with any clinical activities and a written informed consent document



## ROC New Study Submission Requirements

New submissions that meet any of the following criteria are required to be submitted in ARTEMIS to begin the divisional and institutional billing/budget/contract review processes.

- Protocols including drugs, medical devices or biologics with or without an IND/IDE
- Protocols with any clinical activities and a written informed consent document
- External agreements that are not otherwise required to be routed to URA through AURA-Grants
  - This includes clinical trial agreements, work orders to master agreements, subcontracts with per subject/per occurrence reimbursement models, and the like

For a submission to be accepted, and when applicable be routed to URA for contract negotiation, at minimum the record must:

- Be associated with an IRB record from AURA-IRB
- List department and URA contact people as well as other required ARTEMIS fields
- Include name and contact information for any external entities, if applicable
- Include the Medical Coverage Analysis/schema and memo
- Include the draft agreement, if applicable

Submissions that meet the protocol acceptance criteria will be routed to URA, as applicable. Protocols that do not include this documentation in ARTEMIS or AURA-IRB will be returned to the submitter.

## Protocols with IRB Reliance Agreements

Studies that meet the above criteria (either IRB submission or billing/budget/contract submission), are required to fulfill the submissions requirements regardless of the reviewing IRB. If there is an associated IRB Reliance Agreement, meaning that our institution is relying upon a different IRB, these documents are still required. This information is required both for the institutional determination to allow reliance as well as for the billing/budget/contract review and approval processes which are unchanged by reliance.

For questions about these requirements, please contact the Office of Clinical Research  
[clinicresearch@bsd.uchicago.edu](mailto:clinicresearch@bsd.uchicago.edu)