

Date: July 1st, 2019

To: Froedtert Health Leaders, MCW Administrators, MCW Principal Investigators, and MCW Research Staff

From: Nancy Schallert, CHC, Executive Director, Corporate Compliance and Risk Management
Roberta Navarro, BSN RN, Manager, Froedtert Health OCRICC

Re: OCRICC FY20 Revised Workflows for Requests of Froedtert Health Services for Clinical Research

The Froedtert Health Office of Clinical Research and Innovative Care (OCRICC) is responsible for approving clinical research that is conducted in one or more of our institutions or is requesting the use of our Froedtert Health resources (i.e., space, staff, equipment).

To demonstrate our continued commitment to clinical research and to improve our turn-around time (TAT) for providing administrative approval, OCRICC is making the following changes to our operational and pricing workflows effective July 1, 2019:

- OCRICC has always required the submission of an application when conducting research in one of our Froedtert Health institutions/hospitals or requesting the use of our Froedtert Health resources. OCRICC has revised and shortened our application for administrative approval. The updated Request for Froedtert Health OCRICC Administrative Approval Application will allow for researchers to save their work & come back to **complete** the submission at a later date if needed. Access the Froedtert Health OCRICC Administrative Approval Application here: <https://www.froedtert.com/research/ocricc>
- Historically, OCRICC has informed research teams to submit their OCRICC application early, so Froedtert Health is aware of the upcoming research project. However, we have found that because research teams are submitting before they have all the information that we need to complete our review, it is causing OCRICC to rework the study multiple times, delaying approval. As a result, we are making the following changes to the process:
 - A project cannot be submitted for OCRICC review without ALL required documents. The list of required documents can be found here: <https://www.froedtert.com/research/ocricc>
 - OCRICC will complete their review and provide approval without waiting for Froedtert Health/MCW IRB Approval.
 - OCRICC will expect that research teams follow the instructions provided within the OCRICC Administrative Approval Letter, instead of us delaying approval until documents can be reconciled and validation of the operational plan has been done.
- A new Froedtert Health Operational Feasibility Tool will be required to be submitted with the Request for Froedtert Health OCRICC Administrative Approval Application. In order to expedite OCRICC review and approval, the research teams need to prepare the preliminary planning tool & explanation of how they propose the research will be conducted at our institution. This will need to be documented on the Froedtert Health Operational Feasibility Tool and submitted with the application for OCRICC to review and validate.

- Froedtert Health has created an institutional Research Chargemaster reflective of the most requested pricing from FY18/FY19. This tool is to be used by researchers & their teams to obtain pricing requests for time-sensitive preliminary/estimate budgets, grant applications and study financial feasibility reviews.
- If the service needed is not listed on the Research Chargemaster, OCRICC has developed a Request for Froedtert Health Research Pricing Application. This should be used when you are not ready to submit for administrative approval and are just determining feasibility, developing a study budget, or submitting a grant application and need preliminary pricing.
 - To facilitate the best TAT, we are asking research teams to include the Common Procedural Terminology (CPT) code on the Request for Froedtert Health Research Pricing Application so we know what specific service you need.
 - For services that don't have a CPT Code (no Medicare reimbursement rate), we will request the research team provide a comparable service and CPT code in order to determine the price. This will improve the TAT compared to what we have historically done, which was to develop a cost-based price.

The Request for Froedtert Health Research Pricing Application includes some instruction on resources available to help research staff determine the correct CPT code.

The Froedtert Health Research Chargemaster & Froedtert Health Research Pricing Application can be found here: <https://www.froedtert.com/research/ocricc>

OCRICC has developed documents and FAQs with more information and guidance on these changes. We encourage all research teams to review the documents, so they understand the new workflows and requirements, as well as, resources that can help you implement these changes. All these tools can be located at <https://www.froedtert.com/research/ocricc>.

We hope these changes will help OCRICC to be more efficient while continuing to allow MCW researchers to remain competitive in pursuing clinical research opportunities. It will be important that any concerns about Froedtert Health pricing or inability to meet a sponsor's budget are communicated and escalated to OCRICC leadership.

For information not addressed within this Memo or the FAQs and guidance documents, please contact either of us or contact OCRICC at ocricc@froedtert.com.