COVID-19 & MCW Research:

Site-Specific Research Committees for COVID-19+ Inpatient Investigation

Investigators interested in conducting research/enrolling COVID-19 positive patients should work with the appropriate site to submit a request. These reviews **do not** take the place of IRB approval or OCRICC approval. In addition to these committees, the <u>MCW Tissue Bank is functioning as an institutional</u> <u>biobank</u> to which biospecimen requests can be made. As a reminder, discard samples such as discarded stool or sputum, may be available to investigators using an <u>IRB-granted waiver of consent</u>, which may also reduce the need to approach patients regarding study participation for some studies.

Medical Intensive Care Unit

The MICU has an interdisciplinary group comprised of physicians, nurses, respiratory therapists, research coordinators and other MICU staff that review all studies. Given the extent of studies, demands on nurses, and limited number of patients, the goal is to prioritize studies. At this point, the group has prioritized interventional studies that are mechanistically sound.

Study teams requesting conduct of studies in the MICU space will be required to submit an <u>application</u> (DOCX), along with a copy of their final protocol, to <u>lung@mcw.edu</u>, copying Jeanette Graf and Jennifer Peterson (jgraf@mcw.edu; jenpeterson@mcw.edu).

Contact: lung@mcw.edu

Emergency Department

The Emergency Department Research Review Committee reviews research initiated by any MCW department that will occur in our clinical space. This group monitors for any study overlap, works to ensure that patients are not approached for two different studies by two different teams, and confirms that research does not affect patient flow. Investigators submit an <u>application</u> (DOCX) along with their research proposal to <u>EMReseachReview@mcw.edu</u>. The Committee reviews the submission and responds to the Committee Chair within the week. The Committee Chair then communicates any questions or concerns back to the investigator OR drafts and sends an approval letter to the investigator communicating the Committee's approval. The ED Research & Scholarship Program Manager tracks all approved studies.

In summary, the role of the EM Research Review Committee is to ask the following questions:

- 1. Will this impact care of our patients in our clinical space (ie impede or hinder care)?
- 2. Is there an ethical reason that we should not allow this study to be performed in our clinical space?

If the answer is "NO" to both, study is approved. If the answer is "YES" to one of these questions, it is fair to vote that the study not be approved. If there is uncertainty, it is reasonable to ask questions to clarify so one is able to vote comfortably.

Contact: EMReseachReview@mcw.edu

Inpatient Units (General Internal Medicine)

The Inpatient Research Review Committee reviews research with planned activities that will impact patients on the inpatient general floors, staff or faculty treating patients on the inpatient general floors, or research that will occur in the inpatient general floor clinical space. The group aims to promote and facilitate research while minimizing staff and patient burden. Investigators submit <u>an application</u> (DOCX) along with their research proposal explaining how three primary areas have been addressed:

- 1) impact to inpatient resources or staff,
- 2) impact to inpatient flow or standard treatment activities, and
- 3) impact to discharge process.

The Committee reviews submissions and requests clarification if needed. Committee Co-Chairs then send an approval letter to the investigator to allow further IRB and OCRICC review. Please e-mail <u>application</u> and protocol to Lara Brajkovic at <u>lbrajkovic@mcw.edu</u> with 'COVID-19 Inpatient Research Review' in the subject heading of the email.

Direct any questions regarding the process or concerns to Committee Co-Chairs Dr. Julie Kolinski (jkolinski@mcw.edu) and Dr. Rebekah Walker (rebwalker@mcw.edu).

Contact: jkolinski@mcw.edu; rebwalker@mcw.edu