

Research Guidance for the ChristianaCare Community

Updated March 25, 2020

On behalf of those that support your research at ChristianaCare, we are pleased to share with you some essential research guidance. The COVID 19 pandemic is an evolving situation and requires we work very differently. The safety of those in our care, and of you as our caregivers, is of utmost importance. The Infection Prevention website on the portal is your source of truth regarding institutional guidance.

We have put together this information as per guidance from our institution, the NIH & FDA, and reviewing the responses of our partner organizations.

Clinical research may continue with virtual visits during this period of social distancing due to the pandemic. We will work with you to follow the FDA guidance and maintain your studies as outlined below.

In person visits are only to be conducted with the approval of your Community of Practice Physician Leader or Department Chair. If for any reason you feel your study should continue, AND it involves patient contact with any part of ChristianaCare, please contact them immediately.

All patient visits in CCHS clinical sites should follow The Medical Group guidelines, regarding on-site vs. virtual visits. We strongly urge you to conduct assessments remotely. This may include, where appropriate, self-assessments by the research participant of data such as temperature, blood pressure, etc. which may be performed by them in their home.

If you deviate from the sponsor protocol (e.g., due to altered number/type of visits), please notify the OSP and the IRB. **This includes if you have halted a study.**

If you are in the process of submitting a proposal or renewal: it is likely the study sponsor has extended the deadline. Please consult them for clarification and notify OSP.

Please review the Infection Prevention webpage guidelines for outpatient lab testing and radiologic testing, should this apply to your study patients.

All research administration support services— Office of Sponsored Programs (OSP), Research Finance, IRB—are available remotely, within the bounds of our new working realities. The Legal Department will continue their important role in this process and will be consulted as appropriate. **Key contacts:**

- For pre-award/OSP questions: OSP@christianacare.org [Director: Deborah Harmon, MBA, CPA]
- For post-award /research finance questions: BMaloney@christianacare.org [Director: Brianna Maloney, MBA]
- For IRB questions: IRBOffice@christianacare.org [Director: Jerry Castellano, PharmD, CIP]
- Our main webpage: <https://research.christianacare.org/> www.christianacare.org/irb/

If you are involved with an NIH or FDA study, please review the following, and other links that may be of interest to you:

Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>

FDA Guidance On Conduct of Clinical Trials March 2020: <https://www.fda.gov/media/136238/download>

NIH COVID-19 webpage: <https://www.nih.gov/health-information/coronavirus>

FDA COVID-19 webpage: <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19>

University of Delaware Guidance for Research Community: <https://research.udel.edu/coronavirus/>

We continue to closely monitor the COVID-19 coronavirus and to follow the guidance of public health officials. Visit the Infection Prevention website frequently for updated information for the entire ChristianaCare community.

On behalf of the Research Administration team, we thank you for serving together with Excellence and Love as we improve the lives of our patients and community.

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