COVID-19: Resumption of Human Subjects Research and Operations [May 29, 2020]

We know that everyone is anxiously waiting to resume human subjects research activities. As the state and HHC system begin to implement pivot plans, we feel it is time to allow the resumption of research activities. We realize that there will be no "one-size-fits-all" approach.

Therefore, research activities such as screening, enrollment, and conduct of follow-up visits may now occur in compliance with and as allowed by the physical location where the research takes place. All institutional requirements for screening, testing, PPE, masking, visitation, etc., must be followed.

Given the acute impact on in-person research during the pandemic and the unknown potential for future influence, we are collaborating with Virtual Health and Clinical Informatics to establish a solution to allow remote consenting and visit-based data collection, as appropriate, for research. An additional communication and guidance will be provided in the near future as we fine-tune information for our research community.

We value everyone's patience as we hope to make the most informed decisions that keep our research teams and participants safe. We are available to personally answer any questions and provide ongoing guidance. As always, please reach out to the IRB/HRPP office at 860.972.2893 or irb@hhchealth.org for your research-related inquiries.

Best Regards,

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COVID-19 Related Guidance Documents and Helpful Resources:

- **FDA COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders -** https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders
- **FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
- **Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding -** https://grants.nih.gov/policy/natural-disasters/corona-virus.htm
- **CITI Program -** https://about.citiprogram.org/en/coronavirus-covid-19-resources/
- **WCG (WIRB-Copernicus Group) - Resource Center: COVID-19 and Clinical Trial (including on-demand webinar series) -** https://www.wcgclinical.com/covid-19/#insights
- **WCG (WIRB-Copernicus Group) – Patient Resources: COVID-19 and Participation in Clinical Trials –** https://www.wcgclinical.com/covid-19/covid-19-patient-resources/

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