ADDITIONAL GUIDANCE – March 18, 2020

Interim Prisma Health Guidance Document on Human Subjects-Related Research Visits at Prisma Health Facilities during COVID-19 Outbreak

In the context of recent municipal and institutional statements on COVID-19 and the rapidly evolving outbreak, Prisma Health has revised its guidance related to human subjects-related research visits. This Guidance Document is being implemented to protect research participants, researchers, and the larger Prisma Health community from risk of infection with COVID-19 as well as to ensure ongoing access to research, which may provide essential support, and care to participants. This Guidance Document will be revised as needed based on new information and circulated to the Prisma Health research community.

Key points are:

- Contact with research participants should be limited to physicians, APPs, nurses, medical assistants and critical research staff with appropriate screening training.
- Participant interactions (e.g., research visit, care coordination) should be performed remotely (e.g., by phone, text, and web-based as appropriate) whenever possible.
- Elective research visits that cannot be performed remotely and are not essential to a participant's health and/or well-being should be postponed until further notice.
- Research visits that cannot be performed remotely and are essential to a participant's health and/or well-being may be performed in person.
- Research subjects should be appropriately screened using the SCREENING GUIDELINES.
- Treatment protocols may require some adjustment to IRB approved processes resulting from transition to virtual visits and alteration of procedures. Any change to a protocol relative to COVID-19 should be documented as a note to the research file as well as to the participants EPIC records.
- See full Guidance Document for additional details.

Principal Investigators or their designees should contact study sponsors to notify them of this guidance and make appropriate arrangements, provide a copy of the attached Open Sponsor Letter.

Please work directly with research team members on plans for research programs and encourage adjustments to processes to ensure appropriate social distancing.

Please continue to review information you are receiving from Prisma Health Hospital Incident Management Team each day.

Most importantly, please visit this Prisma Health webpage which will guide you through decision-making if you have flu-like symptoms or feel you have come in contact with a potential COVID-19 infected person.

For updates on the evolving status of COVID-19 cases within South Carolina please visit SC DHEC.

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