



To: Ascension Wisconsin Research Investigators

cc: Lisa Benson, MD, Dr. Culling, Greg Brusko, MD, Elizabeth Pace, Elizabeth Lemons, Jackie Kirchen, Brian Scharfenberger, Jane Neu, Michelle Hartness

From: Douglas Reding, MD; VP Research/Academic Affairs

Date: June 8, 2020

Subject: UPDATED Research COVID-19 Information for Investigators

Dear Colleagues,

Normal clinical research practices had been suspended on March 17th in light of the COVID-19 Coronavirus pandemic. As you are now aware, the rates of infection and mortality are continuing to fall in some areas and hospitals within our system. Ascension Wisconsin facilities are now conducting elective procedures and opening up their general practices to be 100% open July 1, 2020. Furthermore, Gov. Evers has relaxed travel restrictions and social distancing mandates and many businesses are now open. With this in mind, I would like to provide the following guidance regarding the resumption of normal clinical research activities:

Beginning on Monday July 1, we will resume our normal clinical research activities. This will include the following:

1. Reactivating all clinical studies that had been halted.
2. Allowing study sponsors and monitors to come on-site as needed after September 8th.
3. Scheduling on site procedures and tests for study participants.
4. Appropriate PPE should still be worn in accordance with the requirements of your local hospital or clinics.
5. Remote visits (e.g., by phone, Zoom, Webex, etc.), are still acceptable when appropriate.
6. For in person visits, all research participants should be screened for fever, cough and flu-like symptoms by work site or hospital staff prior to the research visit, with repeat screening by research staff at the time of any additional in-person visits. Subjects who appear to be infected should be tested for either the presence of antibody or virus and referred accordingly.

Research staff who are working from home should adhere to the Institutional Guidance and continue to work from home until September 8th, unless required to be onsite to directly support the conduct of research as specified above.

If you have any questions or concerns regarding clinical research or comments on these guidelines, please contact me.

Douglas Reding, MD, MPH, FACP

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***UPDATE* Ascension Wisconsin Temporary Policy: Human Subjects Research at Ascension Wisconsin during the COVID-19 Outbreak**

Updated June 8, 2020

Beginning on Monday July 1st, normal clinical research activities may resume. The temporary policies and procedures put into effect March 17th should remain in effect until that time.

Review the Update Memo from Dr. Reding for more details.

This guidance will be revised as appropriate based on new information and circulated to the Ascension Wisconsin research community. If you have questions or concerns regarding information related to content in this memo or below guidance, contact Dr. Douglas Reding at Douglas.Reding@ascension.org or 414-465-3709.