Ascension

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

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Subject: Research COVID-19 Information for Investigators

In the context of recent municipal and institutional statements on COVID-19 and the rapidly evolving outbreak, the Ascension Wisconsin Research Institute has established guidance related to human subjects-related research. This is being implemented to protect research participants, researchers, and the larger Ascension Wisconsin 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 will be revised as appropriate based on new information and circulated to the Ascension Wisconsin research community. I**f 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.**

Ascension Wisconsin Research Institute

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

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More information and FAQs about Research will be posted on the Ascension Wisconsin Research website.

Research Visits

Face-to-face human subject research that is not essential to the health and/or well-being of the subjects must be paused, effective immediately. See below for guidance on whether your study provides direct benefit, if you have questions you can contact IRB@Ascension.org.

In-person study interactions **may only occur if the research is essential for the health and well-being of the research participant**. All other non-essential in-person research interactions should

be postponed or conducted remotely when possible. If the patient is present in the clinical setting for active treatment, this should be considered an essential visit.
As a reminder, all modifications to study procedures require IRB approval prior to implementation.

Remote Visits
Research visits should be performed remotely (e.g., by phone, Google Hangouts) whenever possible.

Non-Essential Research Visits
Research visits that are not essential to a participant's health and/or well-being should be completed remotely, as described above. If they are not able to be completed remotely, they should be postponed until further notice. This will be re-evaluated regularly and updates provided as needed.

Currently, the determination of whether a research visit is "essential to the health and/or well-being" of a participant is determined by the principal investigator of the research study, the participant, and the participant's care provider, and should be informed by current public health guidance regarding the COVID-19 outbreak.

Examples of non-essential visits might include subject surveys, toxicity checks, etc.

Essential Research Visits
Research visits that cannot be performed remotely and *are* essential to a participant's health and/or well-being may be performed in person, with the following additional guidance:

- Participants should be provided with information regarding the current COVID-19 epidemic and how best to reduce their risk of infection. If possible, this information should be shared before the research visit. See the following CDC COVID-19 link for reference and materials: https://www.cdc.gov/coronavirus/2019-ncov/about/
- All clinical patients, including research participants, will be screened for fever, cough and flu-like symptoms by clinical staff prior to research staff seeing the for the research visit if they present to the clinic area. For COVID-19 positive patients, check with the provider to determine if treatment will be delayed and reschedule research visit to that time interval. This may indicate a protocol violation, but a valid one in light of the clinical condition of the patient.

Examples of essential visits might include subjects active on chemotherapy or other treatments.

Enrollment of new research participants
Enrollment of new participants on a clinical trial or other human subject-related research should be allowed only if:

1. Participation in the trial is essential to a participant's health and/or well-being, as determined as above; or
2. The enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 outbreak.

Study Sponsors

AWRI Directors and Principal investigators or their designees will be asked to contact study sponsors to notify them of this guidance and make appropriate arrangements. All sponsor visits for clinical trials or

other human subject-related research, whether for site qualification, site initiation, or monitoring visits, should be postponed whenever feasible. Consideration for remote monitoring should be based on study need and resource availability.

New Research Studies
No new sponsored trials or NCORP studies will be opened for 30 days minimum and will re-evaluated on an on-going basis.

FAQs

Can I continue to conduct study interactions with research participants?

Updated 3/16/2020
Face-to-face human subject research that does not provide a direct benefit to the subjects must be paused, effective immediately. If you have questions regarding whether your study provides direct benefit, contact IRB@Ascension.org.
Where possible, transition in-person interactions for all studies, regardless of benefit, to remote interactions to limit potential exposure.

Considerations for Face-to-Face Interactions
Those studies providing direct benefit requiring face-to-face interactions, consider measures that can be undertaken to minimize exposure during face-to-face visits. Some specific considerations include:

- Implement participant screening to minimize exposure risk. Refer to Institutional guidance for possible screening questions. Such screenings do not require IRB approval as long as the information will not be added to the research data set.
- Ensure that hand sanitizer and hand washing facilities are readily available and encouraged.
- Establish rigorous disinfecting protocols for any equipment, manipulatives, or other study equipment that will be used with multiple participants.
- Implement extra precautions or postpone study visits especially for participants falling into a high-risk category.

Studies Not Providing Direct Benefit
For studies not providing direct benefit, consider whether some study interactions can be conducted remotely. Some specific considerations include:

- Study interactions such as interviews or simple study follow-up visits may be able to be done by phone or video.
- Reach out to study sponsors to inquire about procedures for modifying protocol schedules.
- If your study requires signed informed consent, consider whether you can modify study procedures by requesting a waiver of documentation of consent so that consent may be obtained without requiring a signature. To be approved to waive documentation of consent, the study must present no more than minimal risk of harm to participants and involve no procedures for which written consent is normally required outside the research context.

Are the Human Subjects Office and Institutional Review Board (IRB) operating as usual?

Updated 3/16/2020

Yes, the staff in the Research Integrity and Protection office and IRBs are conducting business as normal. The Research Integrity and Protection office and IRBs are fully capable of conducting reviews via the online system (Mentor) from any location.

If I change my human subjects research activities, do I have to submit a modification to the IRB?

Updated 3/16/2020

Yes, all human subjects research regulations still apply. If a change to research related activities does occur, a modification is required. All modifications to research related activities require IRB for review and approval prior to implementation. This includes modification to procedures to replace in-person study visits with virtual or phone options for administering questionnaires, surveys, check-ins, screening, and consenting remember that these changes must be approved in advance by the IRB as a modification to

the study, unless they are necessary to eliminate immediate apparent hazards to participants.

If the Ascension Wisconsin IRB is the IRB of record, researchers should use Mentor to submit an amendment as usual. If you do choose to submit a modification select the “COVID-19 Specific Changes” amendment type in Mentor (beginning 3/18/2020). The IRB will prioritize these modifications. See the Mentor User Manual for submission instructions, or contact IRB staff for assistance.

If another IRB is the IRB of record for the study, follow their guidance for updates.

Do I need to modify my consent document to address the risk of COVID-19 if my study involves in-person interactions?

Updated 3/16/2020

At the present time, the IRB does not believe it is necessary to require risks related to COVID-19 be added to the consent document.

What do I do if I have a single patient emergency use case?

Updated 3/16/2020

The procedures for a single patient emergency use of an investigational drug or device remains unchanged during this time. You can find the information, formand SOP on the IRB website. Contact the IRB office in the event an emergency use scenario arises. (FDA Guidelines: https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use)

Should I implement COVID-19 screening?

Updated 3/16/2020

COVID-19 screening should occur for all in person study visits following the institutional guidelines.

What if my subject does not want to come in for their research related visit because of COVID-19?

Updated 3/16/2020

This should be handled in the same manner as it has in the past. Subjects may miss study visits for a variety of reasons. If this occurs, identify if missing a study visit would put the subject at additional risk. If applicable, notify the study sponsor. If necessary, reschedule the visit as soon as possible. Consider whether the study visit can be safely conducted in an alternate location or whether or not the schedule of study related events can be altered. If the missed visit has an impact on the risks or safety of the subject, it should be reported to the IRB as a reportable event (noncompliance).

If a participant elects to withdraw from a clinical research study, it is important to ensure that the participant understands (a) the decision will not impact any other clinical care and (b) what possible alternatives may be available for treating or managing the underlying condition.

Should I modify in-person safety monitoring visits that are essential for the conduct of a clinical trial?

Updated 3/16/2020

Some ongoing clinical studies require in-person follow-up visits to monitor participant safety. For example, a treatment and intervention trial may require physical examinations, laboratory tests, or interviews.

You should plan for the possibility that in-person visits may not be possible or practical. Consider some of the following as possibilities that may or may not work for your study:

- If your study is sponsored, contact the sponsor for recommendations and/or changes in procedures that are being implemented study-wide.
- Conduct interviews by phone, video, or email questionnaires.
- Consider conducting physical examinations at participants' homes or other alternative locations.
- Attempt to combine follow-up visit procedures with other clinical visits participants' may already be doing (i.e., visit with another physician specialist).

Any changes to study procedures made to eliminate apparent immediate hazards to research participants, including those to reduce potential exposure to SARS-CoV-2, or to continue to provide medically necessary study care to participants who have been placed in isolation do not need prior approval by the IRB. All such changes should be reported to the IRB as an unanticipated problem involving risk to subjects or others within 5 days.