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**To:** Ascension Wisconsin Investigators  
**From:** Douglas Reding, MD MPH FACP and Jane Neu, Director  
**Date:** **Updated June 25th, 2020**  
June 12, 2020  
**Subject:** **Amendment to Enrollment Suspension in Non-COVID-19 Clinical Trials**

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Dear Investigators,

**Ascension Wisconsin will be decreasing support for recruitment and enrollment resources in non-COVID-19 clinical trials that are FDA regulated and/or managed through the Clinical Research Department for a 6-8-week period beginning at the activation of the COVID vaccine study**

Ascension Wisconsin has been pre-site selected as a clinical trial site for a COVID vaccine study sponsored by Inovio Pharmaceuticals. It is a double blinded study to evaluate the effectiveness of the vaccine vs a placebo. The enrollment for this trial is competitive, with a goal of at least a minimum of 60 subjects enrolled per month during July, and maybe August. Patients will receive the vaccine at baseline and again in 28 days.

All clinical research department staff are needed to support this short term, high volume enrollment period to ensure the safe and compliant conduct of research. We are working to make enrollment available at 3 Ascension Wisconsin clinic sites. We will have a team of trials associates at those clinic sites to complete recruitment, consent signing and providing the vaccine. Due to the tight time frame, while we considered bringing in temporary staff, the hiring and on-boarding process would not make this option helpful.

During this time recruitment and enrollment resources on other studies will be decreased but not suspended. Research coordinators will continue to follow currently active study subjects. If a special clinical circumstance develops, please call Jane or Dr. Reding.

If you work on research that is not FDA regulated and/or supported through the Clinical Research Department, you can continue all research activities per the previous AWRI guidance and Policy on research during the COVID-19 outbreak.

Please contact me and/or Jane Neu with any questions or concerns. We recognize the inconvenience of this clinical research support re-assignment. However, COVID vaccine trials are an Ascension national research priority. 3 other Ascension markets are facing the same challenges to meet aggressive COVID vaccine recruitment goals. We are meeting with those markets to trouble shot solutions. Many are focusing research efforts to the vaccine effort as has been proposed in Wisconsin. Thanks you for your support with this change. Hopefully the disruption will be temporary as we have proposed. We will keep you updated with further changes and timelines for transition to a more usual support for all clinical studies.