# Ascension Wisconsin Research Institute (AWRI) Newsletter

AWRI supports and advances research across all Ascension Wisconsin ministries, fulfilling the Ascension promise to those we serve through innovation, development and delivery of Healthcare That Works, Healthcare That Is Safe and Healthcare That Leaves No One Behind.

The AWRI Newsletter is a combination of news and updates from within AWRI.
The AWRI includes: Executive Leadership, Sponsored Programs, Clinical Research Department, and Research Integrity and Protections. Learn more about AWRI.

## AWRI Updates and Announcements

### Research During COVID-19

**AWRI leadership is continually assessing and updating the guidance for the conduct of research during the COVID-19 response. The most current information is posted online.** *Bookmark this page for quick access!*

### Staff Updates

- Crystal Sirny, Oncology Research Coordinator--All Saints
- Jessica Dunham, Temporary Research Coordinator-CSM
- Victoria North, Temporary Research Coordinator-CSM
- Ankit Dube, Temporary Research coordinator-CSM

### Featured Research Project: Fight COVID MKE

**Researcher:** Patty Golden, D.O.- Regional Medical Director AMG, Medical Director of Community Clinics Ascension WI
**Protocol:** FightCOVIDMKE: Randomized COVID-19 Testing in Vulnerable Communities and Risk Tool Creation

The Ascension All Saints Family Health Center and Ascension Columbia St. Mary's Milwaukee Family Health Center are participating in a multisite study led by Dr. John Meuer and the Medical College of Wisconsin CTSI. The purpose of this project is to better understand risk for and protections form COVID-19 infection, illness, hospitalization and death. The goal is to measure COVID antibody levels from a blood test of up to 20,000 adults in Milwaukee County and to assess risks for severe illness from surveys and health records of diagnoses and hospital stays. The information will be used to create a web-based individual risk assessment tool. Visit the Fight COVID MKE website to learn more.

## Sponsored Programs

*No Updates*

# Research Integrity and Protections

## QI Self-Certification Tool  UPDATED for Projects Not Considered Human Subject Research

In 2018, the Ascension WI IRB developed an online survey tool for users to confirm projects that qualified as Quality Improvement (QI). The QI Self-Certification tool has been expanded to include the following determinations:

- QI/Program Evaluation
- Case Report or Case Series
- Decedent Research
- Research that doesn't involve human subjects

**Access the tool HERE**

*This  link is also on the IRB website*

This tool is intended to assist users in determining when a project falls outside of the IRB's purview because it does not constitute human subject research. It is also now available to all ministries across Ascension.

Using an automated decision-making tool allows the study teams to obtain the determination more quickly, and frees up the IRB to focus on projects that require IRB review and oversight. Users complete this tool and receive certification that the project does not require IRB review and oversight- in lieu of submitting to the IRB. This documentation can be provided to journals, conferences, funders, and others as needed.

## *Coming Soon-* Annual Financial Conflict of Interest in Research Reporting

**What:** In accordance to the Financial Conflict of Interest in Research policy all active researchers must complete the annual disclosure. Learn more **here**

**Who:** All individuals listed as a study team member on an open study with the IRB.

**How:** An email with a link and instructions  will be sent in the next few weeks.

**When:** Disclosures will be due by May 31st, 2021.

## IRB

### Announcements

- IRB Convened IRB 2021 Meeting Schedule and FAQs
- IRB Rosters for IRB #1 and IRB#2 were updated 3/1/2021 and are also posted on the IRB website.

### IRB SOP and Guidance Updates

- HUD User Guide

### New eIRB System Announced

The IRB will be implementing a new electronic IRB (eIRB) system which will replace Menor, the current eIRB. This eIRB system, part of the Huron Research Suite, will be used by all Ascension ministries. Currently, Ascension Wisocnsin is expected to begin the implementation approximately January 2022. More information will be shared as the date is finalized and implementation planning begins.

## Research Education & Quality Management

### Reminders from REQM Review Findings

- Entries in source documents must be completed in indelible ink; pencil should never be used.
- Only members of the documented, approved study team are allowed to obtain consent or interact with subjects, or their identifiable data, for study purposes.
- Consent forms should be reviewed for completeness at the time of consent and prior to providing a signed copy to the subject. This includes verifying that all signatures, dates, times and designated lines for printed names are completed. A Note to File should be created to explain any discrepancies.

### Best Practice: Opt in/Opt out in Consent Form

It is becoming common for Sponsors to request that opt in/opt out sections on the informed consent form be initiated and dated at the time of completion by the subject. This practice provides additional documentation that this was completed by the subject at the initial time consent was obtained. Study teams may want to consider including space for initials/date in this section of consent forms.

REQM reports will include this as a best practice recommendation; this isn't a deviation and doesn't require a Note to File.

# Clinical Research Department

## Remote Site Monitoring and Consenting Activities

The below information is compiled to help inform research teams on ways to optimize managing research projects and best mitigate the new challenges that we all are facing during the pandemic. These tips are meant to complement existing regulations or policies and address specific issues facing clinical trials or FDA-regulated studies. When remote monitoring processes have not previously been described by the sponsor, these processes and procedures should be established (e.g., in a revised study monitoring plan).

**Video conferencing and screen sharing:** Research staff can complete virtual sessions with monitors, and screen share in order to access the EMR. However, staff must host the meeting using the Ascension's HIPAA-compliant version of Google Workspace.

**Electronic Signatures and Part 11 Compliance:** Ascension has systems available to obtain electronic signatures (AdobeSign, Docusign, DocHub Google add on). However, these electronic platforms are not compliant with FDA regulations governing electronic records and electronic signatures as delineated in 21 CFR Part 11 (referred to as "Part 11"). Ascension is working on a systems solution that will be compliant with 21 CFR Part 11. The FDA has issued guidance specific for research during the COVID 19 Public Health Emergency, which includes options for obtaining signatures when an electronic system that is Part 11 compliant is not available. Question 26 in this guidance, allows handwritten stylus or finger-drawn signatures executed on electronic documents that are then printed (or appropriately witnessed).

All investigators should review and follow the joint FDA/OHRP guidance on obtaining electronic consent signatures in FDA-regulated research, Use of Electronic Informed Consent in Clinical Investigations and the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency.

**Questions, Comments or suggestions for the AWRI Newsletter?** Contact Bridget Psicihulis, RHIA, CCRC, Coordinator of Research Education and Quality Management at bridget.psicihulis@ascension.org or 414-465-3121.