Ascension Wisconsin Research Institute (AWRI) Newsletter

News and updates from AWRI. 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

Join us in welcoming new AWRI associates!

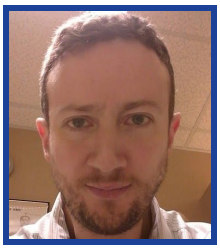
- **Tracy Mente** will be re-joining our Clinical Research team effective 11/2. After spending time as a research manager at DaVita adding skills to her portfolio, she's excited to re-engage with AWRI. Tracy will be supporting Multispecialty research activities, primarily COVID-19 and CSM Stroke research.
- **Letrane Spears** joined Clinical Research in June as a regulatory coordinator overseeing industry studies. Letrane is a Navy veteran, holds a degree in Healthcare Administration Management and has a strong background in research regulatory coordination and non-healthcare ISO/quality/project management.
- **Sheena Talbert** will be joining the Sponsored Programs team as Sr. Revenue Cycle Analyst on November 30th. Sheena comes to us from Sixteenth Street Community Health Center and has a strong background in healthcare revenue cycle operations and financial analysis.

Recognition

Congratulations to AWRI team members celebrating service anniversaries!!!

- **Bridget Psicihulis**, REMQ Coordinator- 10 years. AWRI is lucky and grateful to have Bridget on our team supporting our research community to ensure the safe and ethical conduct of research.
- **Shalonda Porter,** Research Coordinator- 25 years. Shalonda began at Wheaton Franciscan Healthcare as a PAC/HUC and Medical Assistant before joining our research team in 2019. We're glad to have her leading Cancer Care Delivery Research (CCDR) for AWRI and CROWN NCORP.

Featured Research Project: Peri-neural Electrical Dry Needling Migraine Treatment Study



Researcher: Dr. Joe Tepp PT, Cert DN
Protocol: Peri-neural Electrical Dry Needling Migraine Treatment Study

Joe Tepp is a Doctor of Physical Therapy at the Ascension Rehabilitation Services Layton Avenue Clinic in Milwaukee. His experience includes 11 years practicing physical therapy with expertise in chronic pain management, completion of an orthopedic PT residency and certification in dry needling.

The goal of this investigator initiated research project is to determine the effectiveness of a specific treatment protocol using dry needling with perineural electrical stimulation in comparison to standard treatment in physical therapy for patients with migraine headaches.

The study is currently recruiting subjects who are over 18 and have been diagnosed with, or have symptoms of, migraine headaches. You can find more information about the study on ClinicalTrials.gov, or you can contact Dr. Tepp at: 414-389-3023 or joseph.tepp@ascension.org.

Research Integrity and Protections

Protecting Subject PHI During Remote Monitoring

Industry Sponsored clinical trials often have study monitors who visit sites to verify study conduct and records. Restrictions due to COVID-19 may limit the ability of monitors to be on-site. Sponsors may have various remote monitoring processes and while subjects provide authorization for sharing identifiable information with sponsors and monitors (through research consent and HIPAA authorization), it is important for the PI and study staff to ensure the systems used safeguard subject data.

Tips for Protecting PHI

Video Conferencing Initiate Google Meet	For remote monitoring that requires screen sharing of PHI, current guidance is for Ascension Wisconsin staff to initiate the meeting using Google Meet. Other systems are being evaluated. Corporate Compliance recommends not sharing PHI using other video conferencing apps.
Email Encrypt Email with -secure- or -phi- .	PHI should NOT be transmitted via email (either in the body or as an attachment) over the Internet (externally) unless using secure Zix encryption. To enable Zix encryption, insert the word -secure- or -phi- (hyphens MUST be included without any spaces between the hyphen and words) in the subject field of the email.
Paper Documents Transport securely and destroy	Secure paper PHI when transporting to remote worksites using safeguards such as: bag or briefcase that closes, keep out of sight (i.e. trunk), store in your personal remote workspace. If you need to destroy paper containing PHI, they must be incinerated or cross cut shredded.

Related Policies, SOPs & Guidance

AW Polies: Safeguards for Patient Information; AW Policy: Uses and Disclosure of Protected Health Information
IRB SOP: 701 Use/Disclosure of Protected Health Information for Research

Institutional Review Board (IRB)

IRB Updates

IRB Rosters and Fee Schedule Updated
You can find the following updated documents on the IRB website:

- IRB#1 and IRB#2 were updated 9/22/2020, find them under "IRB Rosters".
- IRB fee schedule was updated 10/1/2020, find them under "IRB Memos"

Mentor User Manual Updated
The Mentor User Manual has been updated, the current version is accessible on the main IRB page in Mentor.

Mentor Updates and News

Tips for Updating the Mentor IRB Application Sections at the time of an Amendment
The details about the local site conduct of a research study is documented in Mentor in the Protocol Applications Sections. Anytime you make a protocol change (amendment) that impacts the information in the IRB approved Applications Sections, those sections must be updated as well.

When you create an amendment, you will have the option in the "create amendment" pop-up window to select the one or more Application Section(s) that are being altered as a result of the requested revisions in the amendment. You'll then be taken to the Amendment tab area, you will see red links in the upper left to enter the Amendment Details (amendment submission form) and any of the IRB Application Sections that you selected to update. Click each of those links and complete all answers and/or revisions.

Protocols open before the electronic IRB application sections were implemented

These protocols still have a "paper" IRB application uploaded to the "Approved IRB Application" section on the protocol page. When you select the Application Section(s) to revise, and click the red link to enter the new information, the section will be blank since the approved content is in a paper form. While the paper and electronic forms are very similar, there are some differences. Refer to the current approved paper form, insert the information in the appropriate question and incorporate any additional information or updates. You do not need to complete all application sections electronically, only those sections that need to be updated due to the amendment.

Protocols that have existing electronic IRB application section(s) entered in Mentor

These protocols have existing content in the electronic IRB Application Section(s). Be sure to use the track changes feature to document what is being changed and integrate any new information seamlessly.Texts boxes in the application sections have activity buttons in the gray bar immediately above the text area. Click the "Track Changes" activity button to turn it on. The text you delete from the approved version will then be strikethrough font and the text you add will appear with a highlighted background. After the IRB approves the amendment, the content changes will be integrated into the approved IRB Application for the study.

Want to see it in Action?

Join the IRB Office for a training session!

You'll learn more about how to update the electronic application section(s) when submitting a protocol amendment.

Join one of the following online sessions:

Tues. Nov 10th 10am
add event to your calendar

Fri. Nov 13th 12pm
add event to your calendar

As always, please reach out to the IRB office with any questions on how to populate the electronic IRB Application Section(s) with amendments.

Research Education & Quality Management (REQM)

Review of Common FDA Inspection Deficiencies and Warning Letters to Research Sites

FDA inspections of clinical investigators are conducted under FDA's Bioresearch Monitoring (BIMO) Program. FDA Information Sheet Guidance: FDA Inspections of Clinical Investigators describes when and how BIMO inspections are completed, and offers some common findings.

Common deficiencies observed by FDA inspectors include:

- failure to follow the investigational plan
- protocol deviations
- inadequate recordkeeping
- inadequate investigational product accountability
- inadequate subject protection, including informed consent issues

The FDA observations are similar to the most common findings identified during routine post-approval study monitoring by Ascension Wisconsin REQM, which include the following:

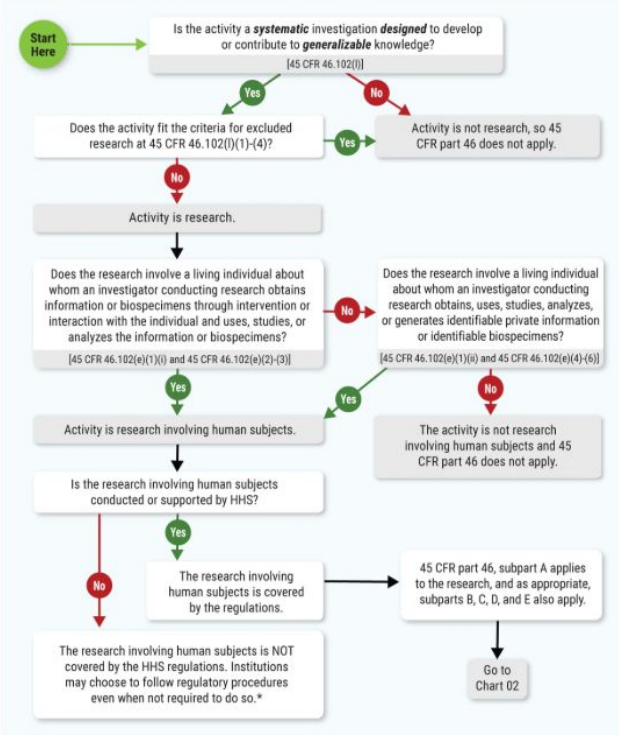
- inadequate recordkeeping, documentation, organization, source
- deficiencies in informed consent process, documentation
- inadequate investigational product accountability, documentation

All warning letters issued by the FDA are also publicly available. REQM compiled a summary of the deficiencies noted in the 2019-2020 warning letters here.

OHRP Updates Decision Charts

OHRP updated its Decision Charts to reflect the revised Common Rule requirements. These graphic charts are designed to help you decide if an activity is research involving human subjects that must be reviewed by an institutional review board (IRB) and whether informed consent, or documentation of informed consent, can be waived.

Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?



Check out all the updated decision charts.

The Sponsored Programs Office and Clinical Research Department have no updates this newsletter

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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.

Oct 2020 AWRI Newsletter- Supplemental

FDA Warning Letter Summary

Below is a summary of the FDA warning letters issued by the FDA in 2019 and 2020. All FDA warning letters are available publically online. The summaries include the findings from three sites; two sites where the Investigator was also the Sponsor (Sponsor-Investigator) and one from a Clinical Investigator.

Failure to ensure proper monitoring and Institutional Review Board (IRB) review and approval [21 CFR 812.40].

- No documentation indicating that monitoring was done ensuring that the safety, rights, and well-being of the subjects are protected, and that the data are complete and accurate. Monitoring should be performed with the frequency necessary to ensure that the investigation is conducted according to the investigational plan, FDA regulations, and any conditions of approval required by the FDA or the reviewing IRB. **(Sponsor-Investigator of an IDE)**
- No documentation indicating that any continuing review by an IRB was conducted from 2002 to 2019. Records show that the study remained open to enrollment and study data collection without IRB approval. **(Sponsor-Investigator of an IDE)**

Failure to submit complete and accurate progress reports [21 CFR 812.150(b)(5)].

- No correspondence occurred with an IRB from 2009 to 2019. Within this timeframe, subject data was collected and recorded. FDA records show no progress reports for the years 2010- 2012, 2014-2018 were submitted to the FDA. **(Sponsor-Investigator of an IDE)**

Failure to maintain accurate, complete, and current records of shipment, receipt, use, or disposition of a device and failure to maintain the records during the investigation and for a period of 2 years after the date on which the investigation is terminated or completed [21 CFR 812.140(a)(2)(i) and (iii), 21 CFR 812.140(b)(2), and 21 CFR 812.140(d)].

- Subject records do not include documentation of the type, quantity, batch number, or code mark of the implanted device. This includes information relating to the device that was retrieved from a subject, as well as for the implanted electronics replacement. (**Sponsor-Investigator of an IDE)**
- Review of the study documentation revealed that source records (e.g., informed consent documents, data record books, hospital records, and/or medical records) for subjects which were reviewed in a previous inspection were no longer in the subjects' records for review. (**Sponsor-Investigator of an IDE)**

Failure to maintain an effective IND with respect to the investigations (21 CFR 312.50).

- FDA terminated IND because annual reports were not submitted for at least 2 years.The site continued to enroll subjects and administer study drug to 18 subjects, compromising subject safety and rights for a period of more than 3 years. (**Sponsor-investigator)**

Failure to promptly report all changes in research activity to the Institutional Review Board (IRB) [21 CFR 312.66].

- Site did not promptly report to the IRB the FDA's Pre-termination Letter or Termination Letter. (**Sponsor-investigator)**

Failure to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].

- Protocol requires that subjects with cardiac atrioventricular conduction abnormalities are excluded. One subject was enrolled with first-degree atrioventricular block. (**Sponsor-investigator)**
- Two subjects were randomized who had dose increases during Study Period 2 above the therapeutic level established for each subject at the end of Study Period 1 and should have been discontinued per protocol. (**Investigator)**
- Subjects experienced elevated UFC levels during the randomized withdrawal period, but were not discontinued per protocol. **(Investigator)**