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

Welcome to the new Clinical Research Department staff!

- Antonella Fonceva, Oncology Research Coordinator--Reiman
- Nidhi Sheth, Oncology Research Nurse--All Saints

Featured Research Project: Evaluation of Implantable Tibial Neuromodulation Device for OAB

Researcher: Dennis P. Miller, MD- Urology, Gynecology
Protocol: TITAN 1 (MDT20033): Evaluation of Implantable Tibial Neuromodulation (TITAN 1) Feasibility Study

This is a prospective, multicenter, feasibility study to characterize the procedure for the implantable Tibial Neuromodulation device in subjects with overactive bladder. The benefit of this type of implantable device is less frequent office visits and greater adherence.

The study is being conducted at the Ascension SE Wisconsin - Wauwatosa Campus. General eligibility includes adults diagnosed with OAB for at least 6 months and currently experiencing symptoms.

For more information contact Tracy Mente, Clinical Research Nurse, at: 414-585-1679 or tracy.mente@ascension.org

Sponsored Programs- *no updates*

Clinical Research Department- *no updates*

Research Integrity and Protections

In the News:

Study Coordinator Charged in Scheme to Falsify Clinical Trial Data

A federal grand jury in Miami, Florida, returned an indictment today charging a Florida woman with conspiring to falsify clinical trial data regarding an asthma medication. Read more.

In a First, FDA Cites Violation of Clinical Trials Reporting Law

For the first ever, this April the FDA informed a clinical trial sponsor, Acceleron, that it had violated the law requiring that results from human studies of medical treatments and devices be posted to the federal repository ClinicalTrials.gov.

The sponsor (including Sponsor-Investigators) must report data within 1 year of a trial's end, but Acceleron's results are nearly 3 years past due.

The FDA can collect more than $10,000 per day in penalties when the responsible party breaks the law; until now, they had relied on voluntary compliance. Read more.

Annual Research Financial Conflict of Interest (fCOI) Reporting

The annual fCOI disclosure surveys were sent in May. Disclosures are due by July 1st.

If you haven't completed your annual fCOI disclosure, click the link in the email or go to the Research Integrity and Protection **fCOI page** and click the "Complete an fCOI Disclosure" button.

IRB

Announcements

IRB Office Summer Hours

From 6/14-9/17, IRB staff will be available during normal business hours as follows:

- Jackie: Tuesday- Friday
- Becky: Monday- Thursday

This availability, as well as other time off, will be reflected on staff calendars and out of office messages.

July 4th: The IRB Office will have the following limited staffing over the July 4th holiday:

- IRB Office closed: 7/2, 7/5
- Limited Staffing: 7/1, 7/6-7

We will attend to all messages and submissions as soon as possible. If you need to report an emergency use of an investigational product/device contact Jackie Kirchen at 414-915-3229 (text or call), you can also review information on how to begin the process on the IRB website.

"Key Information" in the Informed Consent Document

When the HHS Federal Policy for the Protection of Human Subjects (45 CFR 46 Subpart A) known as the Common Rule was revised, one of the new requirements for the consent document was to include the "Key Information" in the beginning of the consent form. While the FDA regulations have not been revised, they released guidance supporting the changes to the requirements of informed consent. AWRI incorporated these requirements into the consent SOP and template in 2017.

Main topics to present as "Key Information" in the first few pages of the consent form include:

- Consent is being sought for research
- Participation is voluntary
- Purposes of the research
- Expected duration of the prospective subject's participation
- General procedures to be followed
- Most important risks, due to frequency or magnitude
- Benefits to prospective subject or others that can be reasonably expected (or say if none)
- Alternative procedures or treatments, if any

The consent must begin with a concise, focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the ICF must be organized and presented in a way that facilitates comprehension.

HHS has not issued guidance on what constitutes "key information" but it is discussed in the preamble of the revised common rule and there are recommendations from the Secretary's Advisory Committee on Human Research Protections (SACHRP).

Additional Reading and References:
2018 Common Rule, HHS FAQs, SACHRP Recommendations, Revised Common Rule Preamble, FDA Guidance: Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations

Researcher Survey: IRB Consent Template

The IRB is gathering information from researchers and study staff on the use of consent form templates.

Complete this short, anonymous survey by 7/9 to provide your feedback. Click here to complete the survey.

Research Education & Quality Management

Ascension WI Research Education Presentation and Q&A: Informed Consent in Special Populations and Circumstances

Wednesday, June 30 · 1:00 – 2:00pm
Google Meet Click here to join (or dial: (US) +1 478-412-6936 PIN: 413 953 690# or More phone numbers)

Join RI&P staff to discuss ethical, regulatory and operational considerations researchers can encounter when obtaining consent for research from vulnerable populations, as well as other unique and challenging circumstances that they may encounter.

This session will include a presentation, discussion examples and attendee questions and answers.

ALCOA Observations from REQM Reviews

A source document is the first place research data is recorded. Whether this is paper or electronic format, it's important that all research documentation follows the principles outlined by ALCOA:

- **Attributable**: Documentation and entries must include the creator and date of creation/completion
- **Legible:** Entries in the source document must be legible and not obscured
- **Contemporaneous:** All data was recorded at the time it occurred, flows logically and makes sense
- **Original:** Research records must contain the original, first documentation and track all changes
- **Accurate:** Ensuring the data collected is consistent and error free

	REQM Observations	Tips to Avoid Observations
A	• Entries on scales, tools or checklists are not initialed/signed or dated • Delegation logs not created, maintained • Entries appear to have multiple creators/times without additional signature/initials or date	• Include the date and time on each entry and sign/initial at the time of the record creation. Consider adding fields to prompt completers. • Maintain an up to date delegation log to document: who was assigned to complete tasks, the beginning and end dates they were assigned, initials/signature.
L	• Errors scribbled out or written over • White out used on consent and source documents • Can't recognise signature	• Staff should not vary signature/initials from those recorded in the signature log. • Correct errors by striking through the error, add the correction, and initial and date.
C	• Entries on questionnaires, scales, or checklists not dated • Source documents are not available for review • Late notes or entries completed with no explanation of the delay	• Ensure source documents supporting research data are filed in the research file in realtime. • Create a visit note documenting the completion of activities, including questionnaires. • Explain discrepancies by noting late entries or generating a Note to File.
O	• Photocopies, not original, of signed consent documents in research file • Pencil used to make entry, or pencil used initially then written over in ink	• Research file must contain original consent and source documents. • All documentation should be done using a permanent medium, such as ink.
A	• Incorrect rating scales completed • Date subject signed the informed consent differs from date recorded on the consent note	• Review items for completeness and accuracy, and correct any errors, at time of completion. • Generate a Note to File to explain discrepancies or to provide additional clarification.

Want more ALCOA???
See the new TIP SHEET: Clinical Research Good Documentation Practices

References: CR-SOP-605; CR-SOP-215; ICH GCP E6(R2) 4.9; ICH GCP E6(R2) 4.1.5; FDA: "Guidance Investigator Responsibilities- Protecting the Rights, Safety and Welfare of Study Subjects"

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