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 includes: Executive Leadership, Sponsored Programs, Clinical Research Department, and Research Integrity and Protections.

The AWRI Newsletter is a combination of news and updates from within 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!*

Recognition

We would like to recognize Clinical Research Department associates who were invited to present or participate at events.

Emily Lindman, BS, CCRC, Clinical Research Coordinator, was invited to present on recruitment strategies at the Ra Pharma RA101495-02.301 RAISE European Investigators' Meeting ~ 19-22 February 2020 ~ Lisbon, Portugal

Jerry Kounga, PhD, PharmD, MSc, RPh, CDSPV, Investigational Drug Pharmacist, was invited to a round table discussion at the *World Drug Safety Congress USA 2020* - 23-25 March 2020 - Boston, Massachusetts

Staff Updates

Since our last newsletter, Becky Snyder assumed the role of the Ascension Wisconsin IRB Coordinator. Becky was previously a Regulatory Specialist in the Clinical Research Department and also has over eight years of experience as an IACUC coordinator. Becky will support all IRB submissions and can be reached at 414-465-3059 or rebecka.snyder@ascension.org.

Research Integrity and Protections

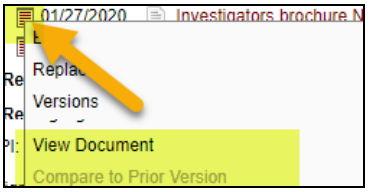
Annual fCOI Disclosure Surveys Due July 21st

The annual financial conflict of interest (fCOI) disclosure survey was sent to all active researchers on 7/6/2020 and responses are due by 7/21/2020. See the RI&P website for more information on AWRI fCOI policy and review.

IRB

Mentor Updates

View, Comment and Compare Documents within Mentor
You can now view documents, enter comments and compare the document to prior versions within a document viewer in Mentor. Just left click the red page icon (context menu) to the left of the document title and select the desired option.



All submissions and PI signatures completed electronically in Mentor
All submission types have now been transitioned to being completed in Mentor and signed by the PI electronically. We appreciate your patience through this transition. If you have any ongoing questions or concerns about this process, please contact the IRB staff.

IRB SOP and Guidance Updates

- SOP-904 Informed Consent Process for Research: Legally Authorized Representative (LAR): Updated to allow the "next of kin" to provide consent for adults with decisional impairment in certain circumstances
- IRB Guide- Relying on NCI CIRB: Updates include the process for submitting notifications and staff updates to the AWRI IRB and boilerplate consent language.
- CITI Program Training Instruction Guide: The guide has updated instructions for account registration and completing required training.

Research Education & Quality Management

Research Education and Quality Management (REQM) Corner

Best Practice Recommendation: Opt in/out choice on a research study Informed Consent Document
Although not required, it is becoming more common for industry study monitors to request that the opt in/opt out boxes marked on an informed consent document are also initiated and dated by the subject. This provides additional confirmation that the box was marked by the subject at the time initial consent was obtained. Ascension Wisconsin consent templates do not currently include an allocated line for the subject to initial and date; however the study team can add it to the consent template.

Research Education & Research News

OHRP e-Consent Information Video
OHRP announced a new informative video on e-Consent titled "Use of e-Consent in Human Subjects Research", which was a presentation given by Megan Doerr, MS, LGC, principal scientist at Sage Bionetworks, during a lunch-and-learn webcast for OHRP in January 2020. Ms. Doerr described various forms of e-consent, the importance of accessibility and readability, the use of apps for research purposes, and shared case studies to explore ways of approaching e-consent to satisfy regulatory requirements and ethical standards.

Best Practice Recommendation: Research Document Version Control (i.e.protocol, questionnaire, source docs)

What is Version Control? Version Control is the management of multiple versions of the same document. Version control enables us to tell one version of a document from another which is important in research to ensure that the current IRB reviewed and approved document is being used.

Why is Version Control Important? Version control helps us to track changes easily when documents are being reviewed by a number of different users. It allows study team members, IRB Coordinators and REQM Coordinators to easily determine which version of a document was implemented at what time frame.

Do I need to maintain previous versions? All versions put into practice beginning with IRB submission until the closing of the study must be maintained in the Regulatory File. It is important to develop a mechanism to ensure that when retiring one version, it is clear to study team members that there is an updated version. This can be done in several ways such as writing "obsolete" at the top of the old version template or generating a Note to File.

Sponsored Programs Office

Clinical Trial Management System (CTMS) Update

Ascension Wisconsin recently transitioned to Clinical Conductor for our new Clinical Trial Management System (CTMS). A CTMS is used by the Clinical Research Department to manage study conduct and by the Sponsored Programs Office to manage finance and billing compliance. If you do not work in the Clinical Research Department or on funded projects, your research will not be impacted.

The use of Clinical Conductor is an Ascension-wide initiative, with some ministry markets already using the product. AWRI has been working with the Ascension Seton project team since November to plan the transition. Currently, Clinical Conductor will be used to track finances and patient activity; however, a regulatory feature may be added in the future.

Review of the migrated data and user training are continuing and we appreciate everyone's work and patience during this implementation.

Clinical Research Department

Ascension Wisconsin as part of the CROWN Consortium Receives $5M from National Cancer Institute to Advance Cancer Research across 48 Counties in Wisconsin and Northern Michigan

The National Cancer Institute (NCI), part of the National Institutes of Health (NHI), has awarded the Cancer Research of Wisconsin and Northern Michigan (CROWN) Consortium a $5 million grant to provide patients in Wisconsin and Northern Michigan access to more leading-edge clinical trials over the next six years. This grant is funded through the NCI Community Oncology Research Program (NCORP).

Established in 2018, the CROWN Consortium is a collaboration of three of Wisconsin's largest cancer treatment organizations: HSHS St. Vincent Hospital Cancer Centers, Ascension Wisconsin and Aspirus, Inc. Together, these organizations offer an experienced research infrastructure with a team of highly-skilled investigators across many areas of clinical research, including hematology, medical and radiation oncology, palliative care and pediatric oncology.

The CROWN Consortium serves nearly five million residents in 48 counties in Wisconsin and Northern Michigan, including many rural and medically-underserved populations. The NCORP grant will allow the CROWN Consortium to offer patients in these regions an expanded menu of leading-edge clinical trials that will focus on new cancer treatments; controlling cancer symptoms; cancer screenings; preventing and monitoring cancer; and evaluating how cancer care is delivered. In the past five years, the CROWN Consortium has enrolled a combined total of more than 2,000 patients in NCI-sponsored clinical trials. The CROWN Consortium is one of only 46 community cancer treatment programs across the U.S. to be awarded an NCORP grant in 2019.

Although academic medical centers play a crucial role in cancer clinical research, the majority of cancer care takes place in the community setting. Expanding clinical research beyond the academic environment allows access to a larger and more diverse patient population treated in a variety of healthcare delivery settings, which can accelerate accrual to cancer clinical trials and other human subjects research and increase the generalizability and relevance of study findings. Research in community settings reflects the complexity of cancer care delivery and engages community oncologists in research to develop care delivery approaches that can be implemented within usual clinical workflow. (https://ncorp.cancer.gov/about/)

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.