



September 2022

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Autumn is a season of change. In Michigan, we have the glorious color change of the leaves in the fall and the change from hot, sticky days to cool, chilly days. The changing of the seasons always heralds the start of something new and whether that new thing is wonderful or terrible is often up to our own outlook and attitude.

It is also a season of change in one aspect of Ascension Research as we move to a new, regional IRB system. For most of you who do research, the change in IRB structure will be largely transparent to you—we still enter studies into eIRB the same way. But, who reviews the studies and some of the people we interact with may change. These first few months of the new system may be painful as we try to figure out the new path, but if we persevere with an open mind and heart, we will get through this change and be ready for the next. The only constant in life is change.

If you have not received the emails outlining the change to the IRB structure, I have included a copy later in the newsletter.

Congratulations to all of our residents and fellows who have had case reports and research projects accepted to Fall meetings. It is great to be printing posters for inperson meetings again!

Happy Fall! May the bounty of the harvest season fill your heart with joy.

# Dr. Susanna Szpunar

Director, Biomedical Investigations and Research Susan.szpunar@ascension.org



# **Fast Stats**

**Measures of Association** are values that show us the direction and strength of the association between a risk factor and a disease. There are several common measures of association that arise from different study designs.

Odds Ratio (OR): The Odds Ratio can be computed from any study design. It is the ratio of the odds of a case patient being exposed to a factor divided by the odds of a control patient being exposed. The OR is a good estimator of the relative risk when the disease is rare. The null value is 1.

**Relative Risk (RR):** The relative risk is the ratio of the probability of disease in the exposed versus the probability in those unexposed to a risk factor. It can only be computed from prospective studies. This measure shows us the strength of the association between a risk factor and a disease. The null value is 1.

### Risk Difference (RD) or Absolute Risk Reduction (ARR):

This measure is simply the difference in the probability of disease in the exposed and the probability in the unexposed. On a population level, this measure helps us to know how much disease can be prevented if the risk is removed. The null value is 0.

**Number Needed to Treat (NNT):** This value is 100/the ARR when the ARR is expressed as a percentage. This values tells us the number of patients we would need to treat to prevent one case of disease.

Hazards Ratio (HR): The Hazards Ratio is computed from survival data. The probability of events occurring at any point in time is called a Hazard for that group and the weighted RR during the entire study duration is known as the Hazards Ratio. The null value is 1.

Which measure do I use?

- The RR, RD and HR can only be computed from prospective studies.
- The HR comes from studies that have time as a component in the analysis.
- The OR can be computed from any study type, however, it will often overestimate the RR when the disease is rare.



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# <u>Announcements</u>



# **Call for Proposals:**

The Ascension St. John Hospital Medical Staff Committee has generously allocated funds to help support faculty research. These funds are available for physicians and doctoral level researchers only; residents and fellows may apply for funding via the GME Research committee (as usual). A total of \$20,000 per year has been allocated; individual investigators may request up to \$10,000 for a project. An application format and funding policy have been developed.

The deadline for research proposals and the other required documentation (as listed in the policy) for the Fall 2022 cycle is **October 31, 2022.** Review will occur in November.

The application instructions are included in a separate document. Pleas feel free to contact Dr. Susan Szpunar for a copy of the policy or for any questions at <a href="mailto:susan.szpunar@ascension.org">susan.szpunar@ascension.org</a> or 313-343-7838.

# Ascension St. John Advances in Research and Quality Improvement

The GME Research Department is getting ready to launch our own medical journal, "Ascension St. John Advances in Research and Quality Improvement". We are currently finalizing the Instructions for Authors for the various types of articles that can be submitted. The journal will be an on-line journal and we will accept manuscripts from Ascension St. John physicians, researchers, fellows, residents and medical students. With time, we will aim to get our journal indexed in PubMed.

We have convened an outstanding editorial board, with section chiefs for each of the major specialties. More information about the journal will be coming to you soon; we hope to electronically publish the first edition of the journal in the first quarter of 2023. So, if you have a manuscript, case report, review of the literature, meta-analysis, or an expression of medicine in art looking for a journal, dust it off, re-read it and get ready for the day when we will start accepting submissions!

# **Reminders**

- Informed Consent for Case Reports: If you are planning to write a case report on an Ascension St. John patient, please remember that you are required to obtain informed consent. The document and policy can be found in PolicyStat or you can email Dr. Szpunar (susan.szpunar@ascension.org) for the information.
- **Help with Writing:** If you need assistance with writing a manuscript, case report or other document or if you would like someone to proofread and edit your work, please contact the Research Department. Our staff are happy to help with writing and editing, especially if English is not your first language. Please contact Deborah Spampinato at <a href="mailto:Deborah.spampinato@ascension.org">Deborah.spampinato@ascension.org</a>
- Research Travel for Residents and Fellows: Please make sure to get pre-approval for any planned travel from your department and then from the Research Department. Remember that we fund travel only in the continental U.S. and rental cars are not permitted. Residents and fellows may travel twice per calendar year, but only one of those trips can be for a case report. You must be the first author on the research study or case report that you are presenting.







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### **Recent Publications**

Feldpausch B, Giuliano C, Hartner CL, Edwin SB. In-hospital venous thromboembolism: are glucocorticoids a prime suspect? Blood Coagul Fibrinolysis. 2022 Jun 1;33(4):216-219

Hirst CS, Thayer KL, Harwani N, Kapur NK. Post-Closure Technique to Reduce Vascular Complications Related to Impella CP. Cardiovasc Revasc Med. 2022 Jun;39:38-42.

Solomon R, Anne P, Swisher J, Nazeer B, Rosman H, Mehta RH, Maciejko JJ. Evaluating Statin Tolerability in Historically Intolerant Patients After Correcting for Subclinical Hypothyroidism and Vitamin D Insufficiency. High Blood Press Cardiovasc Prev. 2022 Sep 5. Epub ahead of print.

## Ascension Consolidated HRPP/IRB Infrastructure

#### Sent on behalf of Frederick Masoudi, MD, Ascension Chief Science Officer

Ascension Principal Investigators,

We are pleased to announce that the planned transition to a consolidated Ascension Human Research Protection Program (HRPP)/IRB infrastructure will be implemented on October 1, 2022. As of this date, existing Ministry-based IRB panels will begin functioning under the Ascension System Federal wide Assurance (FWA) rather than under your current local Ministry FWA. From a functional standpoint, this consolidation will have very little visible impact on how your studies are reviewed and maintained. You will continue to use the Ascension eIRB system just as you do now to create and submit new studies and follow-on submissions (e.g. continuing reviews, modifications) for either review by an Ascension IRB or by an External IRB.

The primary changes that may impact you and your study teams are:

- 1. IRB policies and procedures are now standardized across the Ascension system. Those consolidated policies and procedures will be available for your review in the eIRB Library on October 1<sup>st</sup>.
- 2. Your local IRB Office will be integrated into the new infrastructure, and you will have new IRB Office contacts (more details below)
- 3. When you submit a new initial study that requires review by an internal Ascension convened IRB, you will be expected to attend the virtual meeting of that IRB panel when your study is being reviewed. The purpose of your attendance is both to present a short (5-10 minute) overview of your study and to answer any questions the Board members may have. You will receive prior notification/invitation for each such presentation. [Note: this requirement has been in effect at many of our Ministries, so for those sites, this will not be an operational change.]

The Ascension HRPP/IRB infrastructure is based on a Regional IRB Office model that is roughly configured geographically. Under this model, your IRB needs will be served by the Ascension North Central Regional IRB Office. Each Regional IRB Office will be staffed by an IRB Leader who will be supported by an IRB Coordinator.

Although the formal appointments into these roles will occur later this calendar year, the following Ascension associates will be performing the duties of these roles, on at least an interim basis, effective October  $1^{st}$ .

Ascension North Central Regional IRB Leader: Lee Bowen, MPA, CIP, CHRC

Ascension North Central Regional IRB Coordinator: Natalie Smith, BA







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# **Just for Fun**





Where Statisticians go to get their P-values.

# **SEMCME Update**

### **Upcoming SEMCME Programs**

Pediatric Lunch & Learn Series, Session Two:
 How the COVID 19 pandemic affects Adverse Childhood
 Experiences (ACEs)

September 21, 2022 - click here to register

- Humor, Healing & Feeling: Becoming a Health Provider
   September 28 Click here to register
- Faculty Development Series 1: An Introduction to the Transformative Reflective Process (TRP)
   October 7, 14, 21 - Click here to register
- Preparing for Practice
   October 12 & 19 Click here to register
- Internal Medicine Board Review Course
   Summer 2022 Click here to register
- ♦ Research Workshop Series July 2022 - Click here to register
- Surgery Basic Science

August 2022 - Click here to register

For more information: <a href="https://semcme.org/">https://semcme.org/</a>

# **CME Update**

- ♦ No upcoming seminars are currently scheduled.
- ◆ Contact Nancy DeRita for more information: Nancy.derita@ascension.org

#### Research Staff

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