



As we begin a new academic year at Ascension St. John Hospital, I want to warmly welcome all of the new medical students, residents and fellows who are now part of the Ascension St. John community.

Whether you are new to Ascension or have worked here for many years, a lot has changed in the business of doing research at Ascension over the past year.

Notably, we have moved to a single Ascension IRB, changed to new IRB software (eIRB) and moved to a national process for research finance and accounting. Whenever things change, there is a sense of loss when we change something familiar and a sense of apprehension when we move into a new environment.

The Ascension St. John Research community has done an excellent job in adopting the new ways of doing business. There are always questions, though, about new processes and how to get things done. Never fear...there are many resources and individuals who are willing to help you navigate the new research landscape.

I encourage you to reach out to me with any questions about our new ways of doing business. If I cannot help you, I will direct you to someone who can.

On behalf of GME Research, we are eager to work with the new students, residents and fellows and to continue to work with our existing trainees and faculty members. There are exciting days ahead of us in research—I hope you can be part of the innovation. Let’s kick off a great year!

Best wishes,

Dr. Susanna Szpunar



Director, Biomedical Investigations and Research

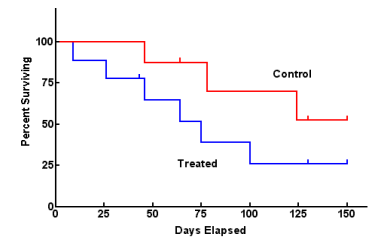
Susan.szpunar@ascension.org

Fast Stats

Survival Analysis

Survival, or “time-to-event” analysis, is a useful tool for looking at differences in when an event occurs, as opposed to whether an event occurs at all. Survival analysis is frequently used in oncology and transplant medicine to compare the effectiveness of different treatment regimens on progression free and overall survival of a patient or an organ.

There are three commonly used methods of survival analysis, which differ in important ways.



Life Table Analysis:

- ◆ In this form of survival analysis, the follow-up period of observation is divided into equally spaced smaller time intervals.
- ◆ For each interval, all people who have been observed at least that long are used to calculate the probability of a terminal event occurring in that interval. The probabilities estimated from each of the intervals are then used to estimate the overall probability of the event occurring at different time points.
- ◆ For this method, each individual can only be included if they have not become censored (i.e. lost to follow-up) for any reason other than the event occurring. This method is best used when the number of events is small.

Kaplan Meier Analysis:

- ◆ The Kaplan-Meier procedure is a method of estimating time-to-event models in the presence of censored cases.
- ◆ The Kaplan-Meier model is based on estimating conditional probabilities at each time point when an event occurs and taking the product limit of those probabilities to estimate the survival rate at each point in time.
- ◆ In Kaplan Meier analysis, you don’t set time intervals. The probability of an event is determined at each time an event occurs. You can count each person for as much time as they contribute to follow-up.

Cox Proportional Hazards:

- ◆ Cox Regression builds a predictive model for time-to-event data. The model produces a survival function that predicts the probability that the event of interest has occurred at a given time t for given values of the predictor variables.



Ascension IRB

- ◆ Ascension now operates under a single IRB structure, with one Federal Wide Assurance Number (FWA00015877).
- ◆ All studies that qualify for expedited review are routed to the Ascension Minimal Risk Board. For projects that require full board review in Michigan, the projects go to the North Central IRB. The North Central IRB is composed primarily of the IRB members of the former Ascension St. John IRB.
- ◆ Studies that will eventually go to a central IRB, such as WCG or Advarra, are first submitted to the Reliance Board of the Ascension IRB.
- ◆ Instead of IRBNet, we now use a program called eIRB. All investigators should register in eIRB at <https://eirb.ascension.org>. Make sure to register with your @ascension email address.
- ◆ Investigators also need to complete an Investigator Agreement form (found on the eIRB website) and send that form, along with a CV, to the mailbox researchintegrity@ascension.org
- ◆ CITI training (the basic course in human subjects protections for investigators and financial conflict of interest) is also required. If the training is done under an Ascension affiliation, the IRB staff can look up the training certificate (it no longer has to be submitted, unless done under a different affiliation). www.citiprogram.org
- ◆ The staff members of each of the IRB boards are happy to answer questions and provide assistance. You can find their names and contact information on the eIRB website.

Guidelines for Authorship on a Scientific Publication

The following statements summarize the Guidelines succinctly:¹

- ◆ Each author should have participated sufficiently in the work *to take public responsibility for it*
- ◆ Authorship credit should be based only on **substantial contributions** to:
 - ◆ *conception and design, or analysis and interpretation of data; and*
 - ◆ *drafting the article or revising it critically for important intellectual content; and*
 - ◆ *final approval of the version to be published.*

¹From Uniform Requirements for Manuscripts Submitted to Biomedical Journals. New Engl J Med 1991; 324:424-428.



Substantial contribution includes a combination of: reviewing and summarizing background information; hypothesis development and study design for at least one critical component of the study; data collection; data analysis; data interpretation; drafting the article and revising it; final approval of version to be published (usually indicated by signature on copyright assignment form).

Non critical contribution includes: chart review and abstraction **only**; advising the patient about an ongoing study; providing case data that could be obtained regardless of the study; literature searches; or technical assistance.

The first author has the responsibility of providing copies of the drafts to ALL CO-AUTHORS for review and comment PRIOR to submission. The first author must take into account co-authors' remarks, comments and changes. All co-authors should agree on and be able to take public responsibility for the work.





Case Reports

1. Consent is required for case reports. The Ascension St. John case report consent can be found in PolicyStat or you can request a copy from Dr. Szpunar.
2. The consent is a written consent; a verbal consent is NOT sufficient.
3. If the patient is unable to give consent, you may request consent from the patient’s legally authorized representative.
4. It is best practice to try to obtain consent while the patient is in the hospital or in the office—it may be difficult to contact the patient later.
5. If the patient dies, you should still attempt to obtain consent from the patient’s next of kin.
6. Know the 18 elements of PHI—these should not be included in your case report (see page 4).

It is important to obtain consent for case reports because, with current technology, social media, GPS and numerous other factors, it can be very easy to identify a patient based on very little information. In one instance, a patient was identified based on a newspaper story indicating that someone celebrated a milestone birthday and lived within a certain zip code!

Recent Publications

Aref A, Abdalla A, Drelichman ER. The role of local excision after neoadjuvant therapy for locally advanced rectal cancer: a different perspective. *Clin Colon Rectal Surg.* 2022 Nov 29;36(4):290-4.

Baracy MG Jr, Afzal F, Szpunar SM, Tremp M, Grace C, Liovas M et al. Coronavirus disease 2019 (COVID-19) and the risk of hypertensive disorders of pregnancy: a retrospective cohort study. *Hypertension in Pregnancy* 2021 Aug; 40 (3):226-35.

Bhargava A, Sharma M, Riederer K, Fukushima EA, Szpunar SM, Saravolatz L. Risk factors for in-hospital mortality from coronavirus disease 2019 infection among black patients—an urban center experience. *Clin Infect Dis* 2021 Dec;73(11):e4005-11.

Dhar JP, Walline H, Mor G, Fathallah L, Szpunar S, Saravolatz L, Carey T. Cervical health in systemic lupus erythematosus. *Womens Health Rep (New Rochelle).* 2023 Jul 12;4(1):328-37.

Eisenschink J, Leveille D, Leveille R, Mollica A, Rhodenizer J. Postoperative opioid consumption following hallux valgus and rigidus surgery: a guide to postoperative prescription writing. *J Foot Ankle Surg.* 2023 Jun 12:S1067-2516 (23)00136-9.

Kanitra JJ, Bjorklund RL, Clausen DJ, Hayward RD, Paxton RA, Haouilou JC. Protamine use in transcarotid arterial revascularization. *Vascular.* 2023 Apr;31(2):312-16.

Rustia GM, Baracy MG Jr, Khair E, Hagglund KH, Aslam MF. Pain with differing insufflation pressures during robotic sacrocolpopexy: a randomized controlled trial. *Obstet Gynecol.* 2023 Jul 1;142(1):151-9.





18 Elements of PHI

1. Patient names
2. Geographical elements
3. Dates related to the health or identity of individuals
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health insurance beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers
13. Device attributes or serial numbers
14. Digital identifiers, such as website URLs
15. IP addresses
16. Biometric elements, including finger, retinal, and voiceprints
17. Photographs of a patient's face
18. Other identifying numbers or codes

Upcoming SEMCME Programs

SEMCME Ob/Gyn: Fetal Assessment Course

August 4th, 2023, 8:00-12:30 via Zoom

[Click here for information and registration](#)

SEMCME Faculty Development: Holistic Review in Resident Recruitment and Selection

August 24, 2023, 1:00-3:00pm via Zoom

[Click here for information and registration](#)

SEMCME Presents: 2023 Fall Chief Resident Workshop

Keynote by: Saroj Misra, DO, FAAFP, FACFP

September 8, 2023 I 12:00-4:00pm

Beaumont Services Center

26901 Beaumont Blvd., Southfield, MI 48033

2023-2024 Research Workshop Series

Workshop series to help residents learn the fundamentals of research methodology through comprehensive discussion coupled with relevant research study examples. All recordings and materials are available.

[Click here for information and registration](#)

CME Update

- ◆ No upcoming seminars are currently scheduled.
- ◆ Contact Nancy DeRita for more information:

Research/AV/Simulation Staff

Susanna Szpunar, PhD	Director, Biomedical Inv. & Research	Susan.szpunar@ascension.org
Deborah Spampinato	Administrative Asst. II	Deborah.spampinato@ascension.org
Karen Hagglund, MS	Clinical Scholar	Karen.hagglund@ascension.org
Alice Mar, BA	Clinical Scholar	Alice.mar@ascension.org
Shelby Miller, MPH	Clinical Scholar	Shelby.miller@ascension.org
Mary (Chase) Trost, MA	Research Assistant	Mary.chase@ascension.org
Jeremy Drohan	Audio/Video Specialist	Jeremy.drohan@ascension.org
Steven Sherrard, CCEMT-P, EMSIC	Simulation Specialist	Steven.sherrard@ascension.org

