



When the previous issue of this newsletter was published and shared, we lived in an entirely different world. Little did we know how our lives and our work would change because of COVID-19.

This pandemic has truly demonstrated the depth of commitment to patient care and research among our physicians, nurses and other staff. The super-human efforts that went into combatting this disease are remarkable, and will be remembered for the rest of our lives.

Just as clinical care changed and expanded in response to the pandemic, so did research. At Ascension St. John, a wealth of research studies aimed at understanding and treating COVID-19 are underway. Even more studies are under review and will soon be active.

Already, Dr. Ashish Bhargava (Infectious Disease) has a research paper published in Clinical Infectious Disease <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa674/5848851> Many more publications from Ascension St. John researchers are to come.

The research department offers you support and assistance as you carry out this important and potentially life-saving research. Thank you for all you are and all you do.

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Guidelines for Authorship

With all the COVID-19 research as well as final papers from our graduating residents, there are always questions about how to determine who qualifies as an “author” of a study. There are some simple, straight-forward guidelines to follow. The Uniform Requirements for Manuscripts Submitted to Biomedical Journals states:

1. Each author should have participated sufficiently in the work *to take public responsibility for it*.
2. 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.*

Further details:

1. Participation would normally have these main components:
 - a) reviewing and summarizing background information;
 - b) hypothesis development and study design for at least one critical component of the study;
 - c) data collection;
 - d) data analysis;
 - e) data interpretation;
 - f) drafting the article and revising it;
 - g) final approval of version to be published.
2. Non-critical contributions (examples below) can be noted in the acknowledgement section, or within the body of the paper. Examples:
 - a) chart review and abstraction;
 - b) advising the patient of an ongoing study in which she/he may participate and/or referring a patient to the study;
 - c) providing case data that would have been obtained regardless of the study; and
 - d) literature searches.



2020 Resident Research Competition



Because of the COVID-19 pandemic, we were unable to hold our annual “Resident Research Day”. Nevertheless, we still had a research competition. Judges received de-identified abstracts and PowerPoint presentations from the residents who were selected to represent their departments. Here is the list of winners:

First Place (tie):

Dr. Sunetris Fluellen, Obstetrics & Gynecology: A Randomized Clinical Trial Comparing Skin Closure with Tissue Adhesives vs. Subcuticular Suture after Robotic Urogynecologic Procedures

Dr. Mina Joseph, Pediatrics: Educational Sessions at ADA Camp Midicha Improve Carbohydrate Counting and Insulin Calculation Ability in Children with Type I Diabetes Mellitus

Second Place (tie):

Dr. Duygu Uzun, Pediatrics: Differences in Lipoprotein (a) Levels Among Children Diagnosed with a Primary Hypercholesterolemia Being Treated at a Pediatric Lipid Clinic

Dr. Karim Saleb, Internal Medicine: Comparative Outcomes of Ultrasound-Assisted Catheter Directed Thrombolysis in Low versus Normal Cardiac Index Submassive Pulmonary Embolism

Third Place (tie):

Dr. Ali Bazzi, Obstetrics & Gynecology: When to Remove the Indwelling Catheter after Minimally Invasive Sacrocolpopexy? CARESS (Catheter Removal after Sacrocolpopexy Surgery): A Randomized Control Trial

Dr. Hasan Rana, Internal Medicine: Aspirin Therapy Among Patients with Diabetes at an Urban Community Teaching Hospital

Honorable Mention (tie):

Dr. Mika Hirano, Podiatric Surgery & Medicine: Factors that Determine Success for Limb Salvage in Patients Who Underwent Partial Calcaneotomy Resulting from Osteomyelitis of the Calcaneus

Dr. Eugene Uh, Internal Medicine: Effectiveness of Low-Dose CT Scans for Lung Cancer Screening in the Community Setting: A Retrospective Study

Dr. Mina Joseph also won 4th place at the SEMCME research forum, another virtual event.

Congratulations to our winners and to all of the residents who completed their research projects!

A special thank you to this year’s judges:

Mohammad Kousha, MD (Pulmonary and Critical Care Medicine)

Melphine Harriott, PhD (Clinical Microbiology)

Danielle Bell, MD (Pediatrics)

Muhammad Aslam, MD (OB/GYN)

Lamia Fathallah, MD (Pathology)

Sarah Hagle, MD (Family Medicine)

Elizabeth Bankstahl, MD (Internal Medicine)

Margarita Pena, MD (Emergency Medicine)

Laura Lamar, DPM (Podiatric Medicine and Surgery)

Institutional Review Board Reminders

Sponsored Research:

During the COVID-19 pandemic, many study sponsors have issued guidance to study teams for conducting clinical trials. If you have not received guidance from your study sponsor, principal investigators or their designees are being asked to contact study sponsors to inform them of local site changes during this pandemic. Please note that the Ascension St. John IRB will consider the current environment and will use available flexibility in decision making that will assist our institution and investigators protect human participants in research and public health.

The U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) has provided guidance that the Ascension St. John Hospital IRB uses to provide flexibility during this time.

FDA

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>

OHRP

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>

Information from OHRP on Public Health Research:

- **Public Health and Clinical Activities:** Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require institutional review board (IRB) approval before being implemented. For example, if a hospital implements mandatory clinical screening procedures related to COVID-19 for all people who come to that institution, including research subjects, these screening procedures do not need to be reviewed by an IRB before they may be implemented. Further, as these activities are not research procedures, the hospital does not need IRB review in order to share the screening results with a public health authority or the research subjects, although other permissions or notice may be necessary under applicable law or policy.

Excluded Public Health Surveillance Activities:

- Some types of public health surveillance activities, including collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority [2], are explicitly excluded from the Revised Common Rule (2018 Requirements) (45 CFR 46.102(l)(2)). However, note that FDA regulations may apply if this involves use of an investigational in vitro diagnostic device. The following is an example of an activity that could be conducted under 45 CFR 46.102(l)(2) as a public health surveillance activity.
- *Example:* If a public health authority authorizes general screening for COVID-19 for public health surveillance purposes, and requests that test results be shared as necessary with a public health authority to allow the public health authority to identify, monitor, assess or investigate the COVID-19 outbreak, an investigator may incorporate these activities into an existing research study visit without prior IRB review and approval.

Consent for Case Reports

Many journals now require that patients or their legally authorized representatives provide consent for a case report. This is a relatively new trend, resulting primarily from evolving information technology and social media that make it easier to identify people with very little information.

At Ascension St. John Hospital, we have published guidelines for obtaining informed consent for a case report, as well as a standard case report consent form, and a consent for photography or videos, if needed.

The policy and forms can be found on PolicyStat at <https://ascensionsemichigan.policystat.com/>.

Once you access PolicyStat, search for “informed consent for case reports.” The policy and forms are also available on the research page on the intranet

<https://medicaleducationsjp.com/medical-education> .

Because it is often difficult to contact patients or their families after they leave the hospital, if you are caring for a patient and think there is a possibility that you will write a case report, please obtain the consent while you are with the patient. If you don't use it, that's okay. But, if you decide to write a case report, you have saved yourself the hassle of trying to track down the patient later.





Congratulations Graduates!

From all of the Research and IRB Staff

**Best Wishes as You Graduate
and Embark on Your Next Venture!**

We will miss you!

Upcoming CME Events

- ◆ September 9, 2020 Obstetrics & Gynecology Seminar
- ◆ November 4, 2020 Family Medicine Seminar
- ◆ December 9, 2020 Cardiology Seminar

CME conferences may be held virtually. Further information will be posted soon.

Physicians wishing to complete their mandatory requirements for CME: www.cmu.edu to access the courses.

SEMCME Events

Surgical Ultrasound: Basic Knowledge and Scanning Skills for Surgical Residents

November 20, 2020 & December 4, 2020
8:00 am - Noon and 1:00 pm - 5:00 pm

Four highly "hands-on" competency-based courses for SEMCME surgical residents (PGY 1 & 2) with an experience in basic ultrasound concepts and techniques, employing a variety of teaching methods including didactic sessions, demonstrations, and hands-on learning.

There is no online registration for these courses. Please see your residency coordinator to sign up.

COVID-19 Webinar Series

Click here for links to recorded webinars:

[COVID-19 WEBINARS flyer](#)

For more information, visit: <https://semcme.org/>



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