



With this last issue of Research Vitals for 2019, we welcome the holiday season. While Diwali has already occurred, a host of winter holidays and holydays are yet approaching. Here are just a few of the special days occurring before the end of 2019:

- ✧ 11/28/19 Thanksgiving
- ✧ 12/23/19 Chanukah/Hanukkah (first day)
- ✧ 12/24/19 Christmas eve
- ✧ 12/25/19 Christmas day
- ✧ 12/26/19 Kwanzaa (first day)
- ✧ 12/30/19 Chanukah/Hanukkah (last day)
- ✧ 12/31/19 New Year's eve
- ✧ 1/1/20 New Year's day
- ✧ 1/7/20 Orthodox Christmas



Please join us for a "lunch and learn" session on 11/14/19. Ashley Sosnoski, Compliance Director for Ascension Southeast Michigan will be speaking on HIPAA, data security and research compliance. The event will be held in the auditorium, but there will also be a Zoom number for people who wish to join remotely. Please email Debbie LaBuda to register for the event:
Deborah.spampinato@ascension.org.

On behalf of the Research and IRB staff, we wish you and your families, a happy, healthy holiday season!

Dr. Susanna Szpunar

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Research vs. QA/QI

Quality Improvement is defined as:

- ✧ "...systematic, data-guided activities designed to bring about immediate improvements in health delivery in particular settings"—*working group, the Hastings Center. org*
- ✧ "The combined efforts to make changes that will potentially lead to better patient outcomes, better system performance and better professional development." (Lo et al, 2009).

Research is defined as:

- ✧ "A systematic investigation involving human subjects, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (Common Rule (45 CFR 46.102(d)) and
- ✧ An "experiment that involves a test article on one or more human subjects." (FDA, 21 CFR 50.3(c))

Thus, QI in health care, unlike research, focuses on translating existing knowledge from research into clinical practice to improve the quality of health care for individuals and populations.

According to the Institute of Medicine, the key difference between these two concepts is that "research studies are intended to create new knowledge that can be generalizable to other populations and settings, while QI in health care uses existing knowledge to improve health care outcomes within a local care institution or setting." (IOM, 2001; National Strategy for Improvement in Health Care, 2012).

Some key differences between research and QI are:

- ✧ Research seeks to test an hypothesis
- ✧ QI seeks to improve a process or performance

Both involve systematic collection of data. While research may place subjects at risk, typically the only risk in QI is the risk of loss of confidentiality.

Because of the fine line between Research and QI, all projects should be submitted to the IRB for the proper determination.

Ascension St. John Kudos!

American College of Physicians Michigan Chapter Fall Meeting, Grand Rapids, Oct. 2019

First Place Poster—Research:

Dr. Safa Maki: Code Status Documentation at Ascension St. John Hospital



First Place Oral—Research:

Dr. Photios Vassilyadi: Analyzing Trends in Patients without a Medical Home

Second Place Oral—Research:

Dr. Bishop Abraham: Use of Torsemide versus Furosemide in Patients with Heart Failure: A Systematic Review and Meta-Analysis

Second Place Clinical Vignette, Medical Student:

Sajithaa Varadarasa (St. George University): Modeling the Diagnosis: A Case of Allergic Bronchopulmonary Aspergillosis



American College of Gastroenterology Annual Scientific Meeting, October, 2019

Presidential Poster and Outstanding Poster Presentation Award:

Dr. Katherine Bill: NAC of All Trades: Use of N-acetylcysteine in Cocaine-Induced Liver Failure



Congratulations to all of our winners!

Recent Publications

Crisher M, Giuliano C, Hartner C. Insulin detemir versus insulin glargine in the hospital: do hypoglycemia rates differ? Clin Diabetes 2019 Apr;37(2):167-171. PMID 31057223.

Hamza A, Khan U, Khurram M, Abraham R, Mazzara P, Hadid T, et al. Prognostic utility of tumor-infiltrating lymphocytes in noncolorectal gastrointestinal malignancies. Int J Surg Pathol 2019 May;27(3):263-267. PMID 30426804.

Patel V, Vendittelli P, Garg R, Szpunar S, LaLonde T, Lee J, et al. Neutrophil-lymphocyte ratio: a prognostic tool in patients with in-hospital cardiac arrest. World J Crit Care Med 2019 Feb;8(2):9-17. PMID 30815378.

Rock K, Hayward R, Edhayan E. Obesity and hospital outcomes following traumatic injury: associations in 9 years of patient data from a single metropolitan area. Clin Obes 2019 Apr;9(2):e12293. PMID 30657640.

Sharma M, Braekevelt K, Kale-Pradhan P, Szpunar S, Khatib R. Are blacks at higher risk for vancomycin-related acute kidney injury? J Pharm Pract 2019 Jan; epub ahead of print. PMID 30669919.

Pearson C, Kim D, Mika V, Imran Ayaz S, Millis S, Dunne R, et al. Emergency department visits in patients with low acuity conditions: factors associated with resource utilization. Am J Emerg Med 2018 Aug;36(8):1327-1331. PMID 29277493.

Please inform the Research Department of any publications, including abstracts.

We will enter them into our database. Send information to Susan Szpunar or Alice Mar.



Institutional Review Board Updates

Payment and Reimbursement to Research Subjects

During the review of studies that include compensation for participation, the IRB will ensure that:

- compensation is not considered a benefit that would be part of the weighing of benefits or risks;
- it is a recruitment incentive;
- all payments are described in the protocol and informed consent;
- payment is not contingent upon completing the study;
- payment is void of all coercion or undue influence.

Please see worksheet #1301 uploaded in IRBNet or contact the IRB office for further information.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

Changes in Research

Federal regulations (21 CFR 56.108(a)(3) and 45 CFR 46.103(b)(4)) and hospital policies require “prompt reporting to the IRB of changes in research activity.” The completion of a study and changes in research personnel are examples of changes in research activity. Research activities limited to changes in study team members (PI changes for more than minimal risk studies are reviewed at a convened meeting) will be reviewed within 1 business week. To facilitate processing these changes, ensure that all study team members have current CITI training.

Did you know?

Research Misconduct is defined as “fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” (Office of Research Integrity).

“Fabrication is making up data or results and recording or reporting them.”

“Falsification is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.”

“Plagiarism is the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.”

Upcoming CME Events

- ◆ December 4, 2019 Hematology & Oncology Seminar
- ◆ March 26, 2020 Radiology Seminar
- ◆ April 29, 2020 Pediatric Seminar

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

SEMCME Events

- ◆ December 4, 2019—Research Workshop Series III Written and Oral Presentation of Scientific Research St. Mary Mercy Hospital, Noon—4:00 pm
- ◆ December 6, 2019—Clinical Reasoning: Minding the GAP from UME to GME Holiday Inn Detroit Northwest, Livonia, Noon—4:30 pm

To register: <https://semcme.org/>

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.

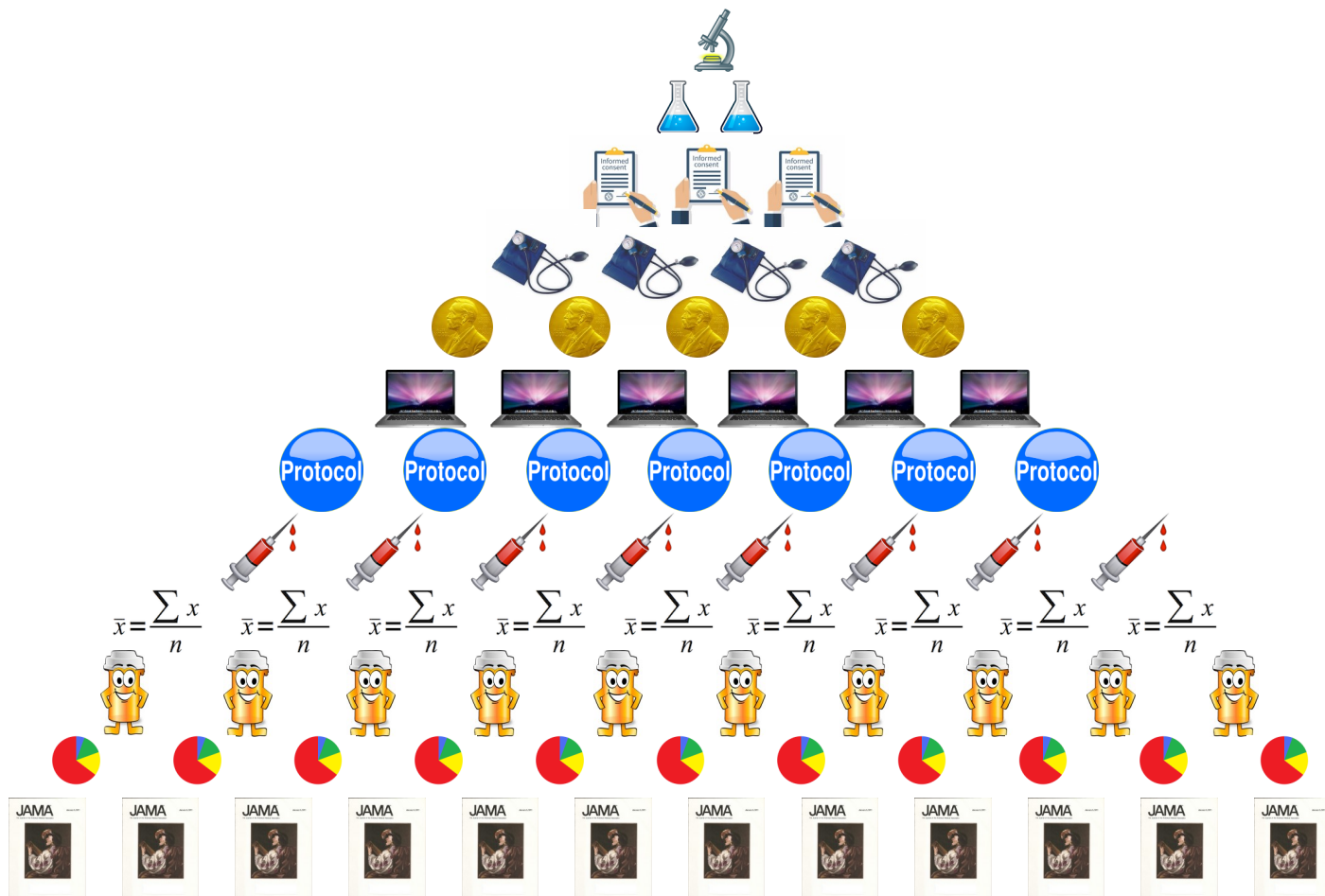
The policy and forms can be found on PolicyStat at <https://ascensionsemichigan.policystat.com/>.

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.



A Researcher's Twelve Days of Christmas



Research and IRB Staff

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