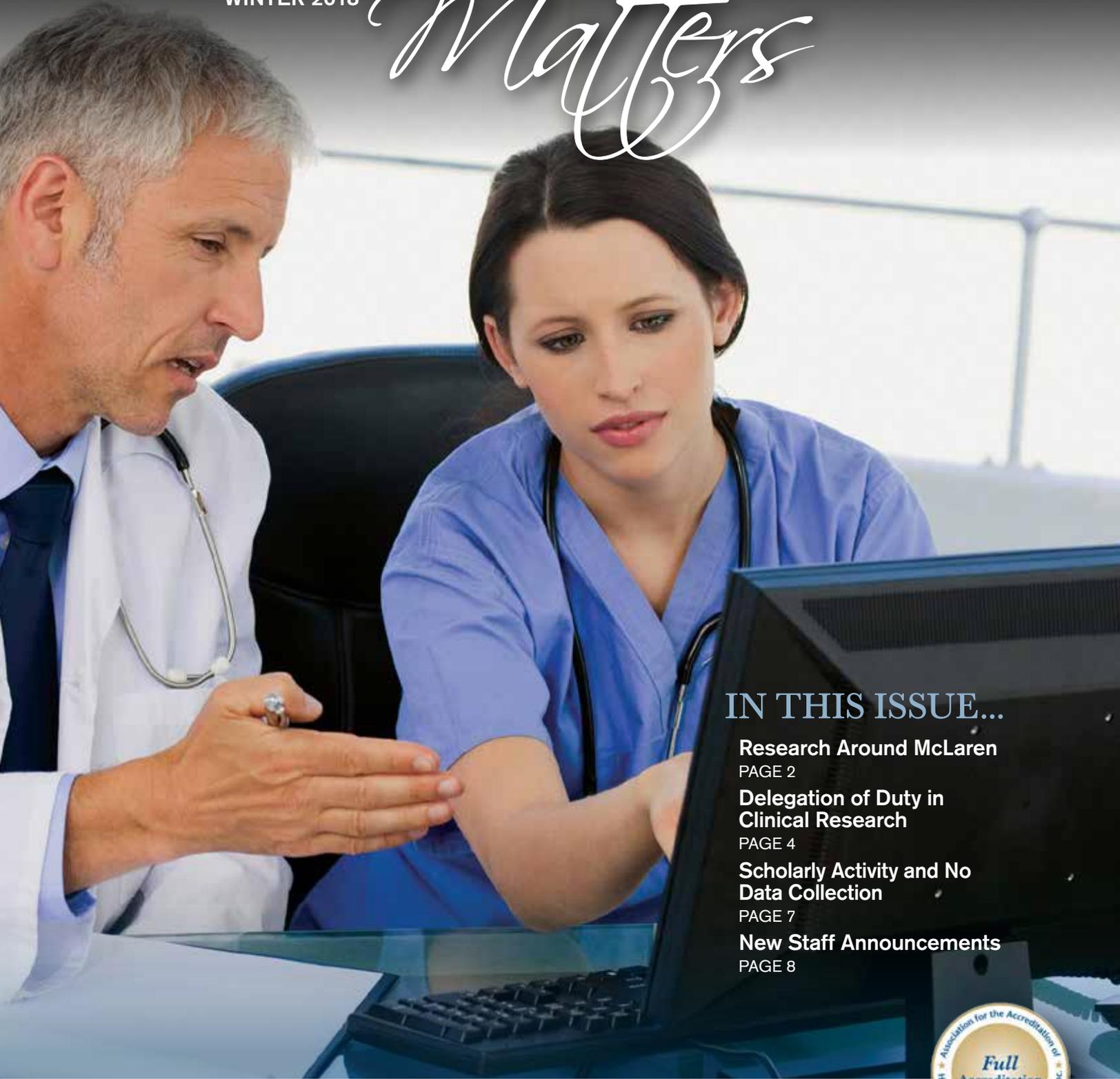


# RESEARCH

WINTER 2018

# Matters



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**Richard Keirn, MD**  
Director, McLaren Oakland  
Baybrooke Internal Medicine  
Residents Clinic



**Felicity Harper, PhD**

If you have any research accolades or research projects or stories you would like featured in this newsletter, contact Patricia Ivery at [patricia.ivery@mcclaren.org](mailto:patricia.ivery@mcclaren.org)

## RESEARCH AROUND McLAREN

### RESEARCH PLAYS IMPORTANT ROLE IN HONING CLINICAL SKILLS

By Richard Keirn, MD

Resident research matters for multiple reasons. The need to prepare the next generation of physicians to search out and develop new treatments is obvious. Their need to translate the data from clinical trials into new office protocols and patient teaching points is also important.

But to me, it's that research helps hone skills that are important in clinical medicine. Teaching resident researchers how to define a problem, examine it from multiple angles, and develop the specific questions necessary to reveal the answer, is also a process central to clinical encounters.

The importance of academic medicine has been long realized by the Accreditation Council for Graduate Medical Education. They are strongly committed to research as a tool for the education of our physicians in training. So much so, that they made the completion of a scholarly activity project a requirement for graduation.

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### USING MUSIC AS A TOOL FOR DISTRESS REDUCTION DURING CANCER TREATMENT

By Felicity Harper, PhD

Music is the soundtrack of our everyday lives. Music helps to wake us up in the morning, entertains us on the way to work, and keeps us company while shopping and waiting for the doctor. Music therapy is the use of music interventions to reduce pain and anxiety and aid in stress management and emotional expression. For patients with cancer, listening to music may provide a vital coping mechanism to help with both the physical and emotional side effects of cancer treatment.

Many patients are accompanied by caregivers who research shows can be as distressed as patients, and in fact, patient and caregiver distress are often correlated. Our study, "Using Music as a Tool for Distress Reduction During Cancer Treatment," builds on a project by Ally Heath, a long-term volunteer at Karmanos Cancer Institute and a Bloomfield Hills High School student. "Ally had been giving iPods to patients in the infusion suite and came to us with the idea that maybe music would help both patients and their caregivers," said Dr. Felicity Harper, Principal Investigator of the study.

In the current study, patients and caregivers who consent to participate are given an iPod that is pre-loaded with music across a variety of genres and decades, including Motown, the 60s, 70s, 80s, classical, and country. Participants are asked about their pain (patients only), mood, and distress before and after a 60-minute listening period. We will compare pre-listening to post-listening levels to determine the effect of listening to music. With better understanding of how music might benefit patients and caregivers, and specifically through the use of a low-cost and readily accessible technology, we can develop clinical guidelines for the use of music in our infusion clinics, thus having a significant impact on clinical care practices and improvement in patient and caregiver outcomes.

The interest from Karmanos Cancer Institute patients and caregivers has exceeded expectations, which has allowed us to quickly accrue a lot of participants and help us get closer to determining the benefit of a music intervention.

Dr. Harper is an Associate Professor of Oncology at Wayne State School of Medicine and a licensed clinical psychologist at Karmanos Cancer Institute. She is also the Co-Program Leader of the Population Studies and Disparities Research Program at Karmanos.

If you have questions regarding the article, please contact Dr. Felicity Harper directly at [harperf@karmanos.org](mailto:harperf@karmanos.org).



Left to right: **Laura Hilty** (vice president, Forte), **Barb Rauschendorfer** (director, post-award extramural fund, Karmanos), **Kasha Krul** (manager, CTO regulatory, Karmanos), **Mary Jo O'Loughlin** (director, pre-award contracting, Karmanos), **Shree Kalluri** (CEO, Forte).

### **KARMANOS NAMED WINNER OF TOP PERFORMANCE AWARD FOR EXCELLENCE IN CLINICAL RESEARCH OPERATIONS**

The Karmanos Cancer Institute Clinical Trials Office (teams of regulatory, pre-award and post-award) has been selected as the fall 2018 winner of the Top Performance Award for the OnCore Organization, receiving the highest overall score, as part of the biannual Awards for Excellence in Clinical Research Operations.

Twice a year, the Awards for Excellence in Clinical Research Operations are presented by Forte to recognize the top performing sites within Site Benchmarks. The awards recognize research sites for their efforts to improve clinical research operations by contributing and comparing their metrics to an anonymized aggregate of peer organizations in Site Benchmarks. The recipients were announced at the Onsemble Conference on September 19, 2018.

### **McLAREN SITED AS A TOP ENROLLING SITE**

**McLaren Macomb** and **McLaren Flint** research team continues to be recognized as one of the top 4 enrolling sites across the United States in the **TARGET New Nano Registry**. The purpose of this prospective registry is to collect real world, post-marketing data on the use of Stryker Target® 360, Target® 2D, Target® Helical and 2nd generation Target® Nano coils for the embolization of ruptured or unruptured intracranial saccular aneurysms.

Congratulations to the TARGET research team, Primary Investigator Aniel Majjhoo, MD, Co-Investigator Bharath Naravetla, MD and Clinical Research Associates Valentyna Onishchuk, Bernice Edwin and Melissa Szemites!

## **ARE YOU INTERESTED IN PARTICIPATING IN A RESEARCH STUDY?**

For information on enrolling in a clinical trial please visit our website at <https://www.mclaren.org/main/research-trials1.aspx>. Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

We have enrolling studies for the following conditions (not a complete list):

- Diabetes
- High Blood Pressure (Hypertension)
- Stroke
- Heart Attacks / Heart Failure / Heart Disease
- Kidney Diseases
- Lung Diseases
- Peripheral Artery Disease
- Carotid Artery Disease
- Mastectomy
- Various Cancers
  - Breast
  - Lung
  - Prostate
  - Multiple Myeloma
- Patients who underwent intracranial aneurysm coiling
- Drug study for patients with recent acute coronary syndrome

For a complete list of conditions, please visit our website listed above.

# EQUIP CORNER



## DELEGATION OF DUTY IN CLINICAL RESEARCH

By Patricia Ivery, RN, MSN

Although the primary investigator (PI) assumes full responsibility and oversight of conducting a research trial to ensure protection of human subjects and integrity of the research data collected, it is common to delegate some tasks to other members of the clinical research team. Generally, the research team is composed of individuals with varying degrees of research experience and education. This may include sub-investigators, research coordinators, research nurses, physicians, nurse practitioners, pharmacists, biostatisticians, lab personnel, etc.

Although delegation of duties is acceptable, overall responsibility remains with the PI. When delegating activities, the PI must carefully evaluate each team member's capability of carrying out the task. The PI must ensure that all persons participating in the study, regardless of title (i.e. fellow physician associates, employees), are informed about their obligations in meeting the requirements of the protocol. Each team member should also be reminded that they must follow institutional Human Research Protections Program (HRPP) policies and applicable federal regulations [Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS)].

### **Regulations and HRPP Policy**

The PI must continually supervise all aspects of research throughout the entire lifecycle of the study. It is important to remember that failure to supervise individual team members is considered a federal violation. According to the federal guidance on investigator responsibilities, the FDA focuses on four major areas regarding delegation of duty <sup>2</sup>:

1. Whether individuals who were delegated tasks were qualified to perform such tasks.
2. Whether study staff received adequate training on how to conduct the delegated tasks and was provided with an adequate understanding of the study.
3. Whether there was adequate supervision and involvement in the ongoing conduct of the study.

4. Whether there was adequate, supervision or oversight of any third parties involved in the conduct of a study to the extent such supervision or oversight was reasonably possible.

Furthermore, during a HRPP quality assurance review or audit there will be an assessment of appropriate delegation by the PI, including the following questions<sup>3</sup>:

1. Have all research personnel received training on the protection of human subjects?
2. If applicable, have the research personnel received conflict of interest training?
3. Have all individual research personnel been given IRB approval to participate in the research project?
4. Are research personnel abiding by applicable regulations, guidance and policies relevant to the research study?
5. Are all research personnel trained to perform the necessary protocol procedures to which they are delegated?
6. Are the qualifications of each individual sufficient for the delegated task?

#### Appropriate Delegation of Study-Related Tasks

All delegated duties or tasks must be documented correctly on the “Delegation of Duty” or “Authority” log. Although not a federal requirement, written delegation can serve to validate proper delegation of duty. The log should list appropriately qualified team members who have been delegated to carry out specific research duties. Many industry sponsors provide delegation of duty or authority logs for study sites to complete. Although form itself may vary slightly from sponsor to sponsor, they generally require the same basic information including printed full name, signature and initials of each team member, start date, end date, assigned duties and the PI’s signature. If you are using a sponsor form, make sure you follow their guidelines on completion. If the sponsor does not provide a delegation log, or you are the sponsor-investigator, the HRPP office can supply a delegation of duty log for you.

It is the PI’s responsibility to check the delegation of duty log form prior to the commencement of the study. Sponsor monitors and the HRPP will not only look to see that this form is completed, they will also verify that it accurately reflects the team member’s capability and scope of practice. When assigning a task, the PI should ask questions such as:

- Are all team members aware of, and agree to carry out the assigned task?
- Does this task require medical training?
- Does this task require a medical license?
- Does this individual have experience in research trials?
- Does this individual have in-depth understanding of the protocol and are they capable of consenting a subject?
- Has this person been adequately trained?

The PI must delegate tasks to team members who are appropriately educated, qualified, trained, experienced, and licensed (if applicable). An example of poor delegation decision-making is delegating the duty to conduct a medical physical examination to a research nurse. This is inappropriate for two reasons. 1) In most states, including Michigan, conducting medical physical examination is not within the scope of practice of a registered nurse who is not a nurse practitioner and 2)

## BROWN BAG SERIES

**How to Survive an FDA Audit**  
December 18, 2018 12:00-12:45  
LIVE WEBINAR

**Statistics in Clinical Research:  
Understanding Protocols and  
Statistical References**  
Guest Dr. Carlos Rios, Corporate  
Director of Scholarly Inquiry  
March 12, 2019 12-12:45  
LIVE WEBINAR

To register contact Marybeth  
McCarthy at 248-484-4987 or  
marybeth.mccarthy@mclaren.org

## UPCOMING EDUCATION AND CONFERENCES

**MAGI Clinical Research  
Conference**  
March 3-6, 2019, Orlando FL

**ACRP Annual Conference**  
April 12-15, 2019, Nashville, TN

# EQUIP CORNER



## DELEGATION OF DUTY IN CLINICAL RESEARCH

CONTINUED FROM PAGE 5

In some studies findings, from a physical examination will determine a subject's eligibility. This is not the responsibility of the study coordinator or registered nurse.

### PI Oversight and Ongoing Involvement

Research studies must be conducted according to FDA and DHHS regulations, which safeguard the protections of research subjects. Prior to initiating a study, the PI should establish that they have adequate time, resources, and appropriately trained personnel to conduct the research study.

The PI should regularly update the delegation of duty log as new personnel are added or removed, and/or study roles and responsibilities change. In order to maintain a trail of study conduct, expired versions should be retained.

Federal authorities recommend having an oversight plan. To ensure an appropriate oversight process is in place, the PI should ask themselves the following questions:

- Is there a procedure in place for regular communication with the PI or unencumbered access to the PI?
- Is there a procedure or policy in place for handling and communicating to the PI any protocol deviations, subject safety issues, study queries, adverse event assessment, etc.?
- Are there routine research team meetings with accompanying meeting minutes?
- What is the method for evaluating adherence to delegated duties?
- Do you regularly monitor staff adherence to the protocol or accuracy of data collection?
- Do you keep training/education records?

### Summary

There are consequences for lack of delegation and oversight; consequences that can affect the safety of research subjects and the integrity of research data. The severity of these consequences can range from reporting a deviation to the IRB, to termination of an investigator's privileges to do research. The PI is the one and only team member ultimately responsible for the conduct of the study. Are you in compliance with delegation and oversight of your study?

### References

1. *Investigator Responsibility in conducting investigations of drugs or biologics [21 CFR 312.3(b) and 21 CFR 812.3(i)]*
2. *Guidance for Industry Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects*
3. *HRPP Policy MHC\_RP0125 – Investigator Responsibilities*
4. *International Conference on Harmonization Good Clinical Practice Guideline - 8.3.24*

# SCHOLARLY ACTIVITY AND NO DATA COLLECTION

By Carlos F. Rios-Bedoya, MPH, ScD

The usual process for a scholarly project involves a data collection stage. This stage is one of the most time consuming and resource intensive in the scholarly activity enterprise. It used to be that this was one stage impossible to skip or ignore when engaging in scholarly activity. However, advances in computing software and changes in data sharing policy have made data collection not an essential stage for all scholarly activity projects. There are at least two types of scholarly projects where data collection is not needed. These scholarly projects are meta-analysis and secondary data analysis.

Meta-analysis is defined as “a quantitative statistical analysis of several separate but similar experiments or studies in order to test the pooled data for statistical significance”. This type of statistical analysis is based on using results from past studies (i.e., no data collection) but requires complicated statistics and advanced statistical knowledge that previously was out of reach for many clinicians and most researchers. Fortunately, that is no longer the case today. Modern statistical meta-analysis software has become very user friendly both in its implementation and interpretation of the findings. Therefore, meta-analysis has become accessible and available to clinicians and researchers as a way to increase their scholarly activity productivity without having to collect any data and thus shortening the time between research hypothesis and manuscript publication. As with any type of research project, a meta-analysis project should follow a rigorous design process from idea conceptualization to data analysis. A well-recognized guideline for meta-analysis can be found at the Cochrane Database of Systematic Reviews (<https://training.cochrane.org/handbook>). In the Division of Scholarly Inquiry, we have the personnel and the software needed to assist residents/fellows/faculty interested in knowing more about meta-analysis and how to use do it as part of their scholarly activity requirement.

Secondary data analysis is the other type of study where data collection is not needed. This type of study has gained a lot of popularity after federal regulations required that researchers funded by the federal government should make their federally funded research data available for public use after proper deidentification has been performed. Thereafter, thousands of databases from dozens of fields have been made available for researchers to download, analyze, and publish the results of those analyses. This is another scholarly activity where residents/fellows/faculty do not need to do any data collection. One of the main single repositories of these publicly available datasets is the Inter-university Consortium for Political and Social Research (ICPSR; <https://www.icpsr.umich.edu/icpsrweb/>) based in Ann Arbor at the University of Michigan. McLaren is a member of this consortium and has access to all the databases housed at the ICPSR. Also, in the Division of Scholarly Inquiry, we have the personnel and the software needed to assist residents/fellows/faculty interested in knowing more about how to access, download, and analyze any of these databases as part of their scholarly activity requirement.

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## FACULTY, FELLOWS & RESIDENT SCHOLARLY ACTIVITY NEWS

### GREAT NEWS FROM THE FAMILY MEDICINE RESIDENCY

The Family Medicine Residency at McLaren Flint had five residents (Dr. Adriane Marchese, Dr. Lauren Marchese, Dr. Vrikshajanani Chakravarthy, Dr. Raathathulaksi Krishnamohan, and Dr. Syed Zaidi) attend the FMX (Family Medicine Experience) Conference this year, which is the largest annual meeting by the American Academy of Family Physicians. Each of them presented posters of their scholarly activity. And one resident, Dr. Syed Zaidi, won First Place for resident research for his and his team's original research study entitled “None Should be Afraid of the Water: Somatic Symptom Disorder and Illness Anxiety Disorder in the Aftermath of the Flint Water Crisis”. This is the second year in a row that one of our Family Medicine Residents won First Place at this large national conference.



# NEW STAFF ANNOUNCEMENTS



Stephanie Edwards

## STEPHANIE EDWARDS

Stephanie Edwards joins the Research Administration department as the new Clinical Research Contract & Budget Specialist. Stephanie is an experienced attorney and compliance specialist well-versed in regulatory interpretation and contract negotiation. She is an active member of the Michigan Bar Association and

is a Certified IRB Professional. Most recently, Stephanie worked in Oakland University's Research Office as a Regulatory Compliance Specialist. Prior to working at Oakland, Stephanie practiced law at Lewis Roca Rothgerber LLP and Miller, Canfield, Paddock & Stone, P.L.C. where she became familiar various areas of health care law.



Markeda Richards

## MARKEDA RICHARDS

McLaren Corporate Research is pleased to announce the promotion of research team member Markeda Richards to the position of IRB Analyst. Markeda has been a dedicated employee of McLaren since August 2015. She previously served in the role as Coordinator for both HRPP and Research Administration. Her IRB Analyst responsibilities will include working closely with the IRB members as well as the researchers at McLaren.



MaKayla Connelly

## MAKALYA CONNELLY, BS

Karmanos Cancer Institute (KCI) is pleased to announce the promotion of Makalya Connelly to the position of Clinical Research Coordinator II. Ms. Connelly works at KCI at McLaren Northern Michigan.



Amanda Snyder

## AMANDA SNYDER, RN

Amanda Snyder, RN, has joined the Karmanos Cancer Institute Clinical Trials Office. Amanda is providing clinical trial Research Nurse support at Karmanos Cancer Institute at McLaren Bay Region in the areas of medical, radiation, surgical and gynecological oncology.

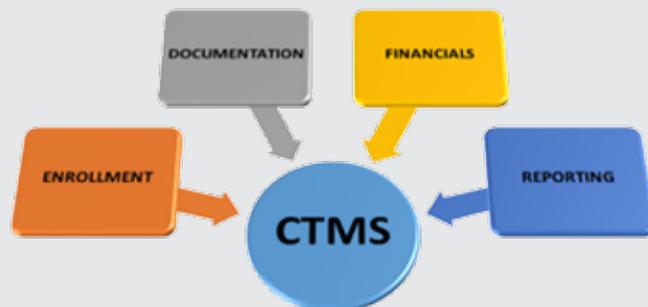
Amanda received her Associates

Degree in Nursing from Delta College and has been a Registered Nurse for 6 years working as a Radiation Oncology Nurse at Karmanos Cancer Institute at McLaren Bay Region. Welcome Amanda!

## CTMS UPDATE

McLaren Center for Research and Innovation continues the process of implementing a Clinical Trials Management System (CTMS) to support research operations across the system. Our system IBM CTMS for Sites system allows clinical research administration to streamline current workflows, manage study progress and finances.

IBM CTMS for Sites is up and running at McLaren Lansing and McLaren Bay. The next two sites slated to go live with CTMS is McLaren Macomb and McLaren Flint in November 2018.



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