

Research News



Dr. Bruce Graham

Getting to the Heart of Cardiac Research

Dr. Bruce Graham is the father of Cardiac Research at IU Health Ball Memorial Hospital. He graduated from Yorktown High School in 1974. After graduating from Purdue with a degree in Engineering, he went on to Medical School at IU School of Medicine. His internship and residency were completed at University of Texas, Galveston. This was followed by a Fellowship in Cardiology at Loma Linda University Medical Center. After joining the staff as an Assistant Professor of Medicine at Loma Linda University School of Medicine for three years, he became an Assistant Professor of Medicine at University of Missouri School of Medicine. Finally, he joined the Medical Consultants practice and became affiliated with IU Health Ball Memorial Hospital in 1991.

Soon thereafter, Dr. Graham approached the hospital research department about helping him pursue cardiac research. He had participated in several studies in both Loma Linda, California and University of Missouri; he felt this was a very beneficial service to offer patients in East Central Indiana. At the time, standard of care for heart attacks included diagnostic cardiac catheterizations with staged angioplasty the following day. Standard of care for devices consisted of surgeons putting in pacemakers. Defibrillator patients were sent to Indianapolis for insertion. Reperfusion therapy was in its infancy and the one cardiac study the hospital was participating in was the Isis Trial. This centered on a thrombolytic named Streptokinase. Dr. William Whitaker was its primary investigator, and it ended shortly after Dr. Graham arrived.

Yet, Dr. Graham was instrumental in continuing Dr. Whitaker's study of thrombolytic therapy in the treatment of an acute myocardial infarction. Once thrombolytics were approved for use by the FDA, he lobbied to add them to our arsenal, effectively improving outcomes from an acute heart attack. He also pioneered intervention for an acute MI on the same day as the cardiac catheterization. When bare metal and drug eluting stents finally became available for use, Dr. Graham became proficient in their insertion. The device manufacturers offered him training to insert defibrillators; he jumped at the chance to learn how to insert them himself, thus eliminating the need for patients to go to Indianapolis and reducing the wait time to receive a device. Later strides in care spurred by Dr. Graham include using the radial artery in the wrist for cardiac catheterization (eliminating the need for the patient to lie flat for an extended period of time) and using an intra-aortic balloon pump as medical management to bridge the patient's before they undergo cardiac bypass surgery.

In conjunction with all these improvements over the last 27 years in our institution, Dr. Graham has participated in over fifty cardiac research studies. He has also initiated several studies on his own. Dr. Graham has a wide range of interests including better treatments for heart attacks, heart failure, lipid control, blood pressure control, reducing cardiac arrhythmias and peripheral vascular disease. The knowledge he has acquired as result of his participation in cardiac research has translated into spearheading new treatments for East-Central Indiana patients. We are very fortunate to have a cardiologist with Dr. Graham's commitment to improvement in cardiac care in our institution.



Sherry K. Adair, BS,
RN, AD Research
Coordinator



Ball Memorial Hospital

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Research News is now available for your viewing online at iuhealth.org/ball-memorial-newsletter

Now Featuring Dr. Bruce Graham, PI



Dr. Bruce Graham

APPRAISE ATP (anti-tachycardia pacing) study is the “Assessment of Primary Prevention Patients Receiving An ICD – Systematic Evaluation of ATP” This study includes subjects with a Boston Scientific ICD (internal cardiac defibrillator) implanted for primary prevention to determine the value of ATP in these patients. The first all-cause shock post-randomization is the primary endpoint. This is a global, multi-center clinical trial to include up to 2600 patients with a trial mean duration of approximately 5.5 years.

“ATP is programmed electrical stimulation delivered by an implantable cardiac defibrillator that is intended to terminate re-entrant ventricular tachycardia.” Subjects will be randomized to one of two treatment arms, including ATP with shock or shock only therapy. By utilizing current programming guidelines with higher detection rates and longer delays, the study hopes to understand the role of ATP better.



Alicia Belangee,
BSN, RN, Research
Coordinator

Key inclusion criteria include:

- Subject with a Boston Scientific transvenous ICD (de novo implant or upgrade from pacemaker to ICD)
- Subject is \geq age 21, willing and capable of providing informed consent and complying with study follow-up visits

Key exclusion criteria include:

- History of spontaneous sustained VT or VF not due to a reversible cause
- NYHA Class IV (CHF symptoms) within prior 90 calendar days
- Subject receiving a CRT-D device, subcutaneous ICD, or existing transvenous ICD implanted for greater than 60 days
- MI, CABG or PCI within the past 90 days
- Active heart transplant list or VAD
- Currently requiring hemodialysis

In follow-up, the majority of our subjects will be followed remotely via their LATITUDE™ system that collects and stores data from their devices every six months. Their monitoring system will alert Boston



Scientific for arrhythmias, shocks, atrial arrhythmia burden and store any triggered events. In addition, a phone visit will occur with the LATITUDE™ device reports to assess for cardiac medication changes, reportable adverse events and device deficiencies. Each subject will also return for annual, in-clinic follow-up visits for device interrogation.

Dr. Graham is also spearheading an investigator driven, 5 year retrospective analysis to determine if a Heparin only strategy for acute coronary syndrome is reasonable for safety and effectiveness during coronary intervention, versus the use of other anti-coagulants such, as Angiomax and Integrelin, which are widely used within our institution. Dr. Graham, with assistance from resident Dr. Aisha Davis, Internal Medicine Clinic and cardiologist Dr. Bhavana Siddegowda Bangalore, is in the beginning phases of finalizing the purpose, literature review/ background information and statistical analyses to be used to help determine pertinent data collection points for the study. This will prove to be an interesting tool to help identify the best strategy to reduce adverse events and drive our institutional standards.

The SMART Registry study that Dr. Graham participates as a sub-investigator (led by Dr. Michael Moran) will evaluate cardiac resynchronization therapy and defibrillator (CRT-D) optimization techniques utilized and their effectiveness. This will include Boston Scientific's quadripolar models, which may utilize LV Vector Guide™, SmartDelay features, Left Ventricular MultiSafe Pacing (LV MSP) and/or Heart Logic™ Index. Subjects included in this study will be newly implanted or upgraded to a specific Boston Scientific CRT-D device within the prior 21 days. Any commercially available lead from any manufacturer can be used. All therapies will be based on local standard of care to capture real world data.

References: Boston Scientific, APPRAISE ATP Clinical Investigation Plan, Version AB, 02AUG2016; Boston Scientific SMART Registry Clinical Investigation Plan, Version B, 06FEB2017.

Submitting Your Article for Publication: Avoiding Pitfalls



J. Matthew Neal, MD,
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FACE, FAAPL
Executive Medical
Director, Academic
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You may be reading this article because you have finished your article and are preparing it for publication. Congratulations! This has been the end product of much hard work on your part (and likely others on your team who have also contributed).

However, the process is not yet over; assuming the ultimate goal is publication, there are still some hurdles to overcome and potential land mines that can “blow up” your manuscript and prevent you from achieving your goal, if you are the designated article submitter. This brief article outlines some tips to maximize your success. While none of this is at all glamorous or even professionally satisfying, you need

to view the process as a means to a successful end (being a published author).

1. Make sure that the content of your article is congruent with that typically published by the periodical. Don't submit a case report to JAMA or New England Journal of Medicine. How do you know what types of articles your prospective journal publishes? Pick up some copies and read them. Know the relevant journals in your specialty; ask a senior colleague if you need advice. Don't set yourself up for failure by submitting material that is not typically accepted.

2. Read the journal's Instructions for Authors (IFA). This can always be found on the journal's Web site. These instructions are there for a reason: journals receive many publications (most of which cannot be published due to space constraints), and there must be “rules” to ensure efficiency in review and publication. The instructions are meant to be followed. Not following them will likely lead to a quick rejection letter from a junior staffer or robot. I have seen several articles rejected simply because the author was not familiar with the layout of the journal's articles and the IFA. Look to the journal itself for examples. A famous and accomplished scholar may be able to get by with breaking some of the rules, but you likely can't.

3. Make sure your document is in the best state possible before submitting. Have a trusted colleague review for style, spelling, and grammatical errors; too many of these will send your manuscript to the rejection pile, even though the content

may be excellent. It's okay not to be an expert at these things, but there are people out there to help you. There is no excuse for sloppiness, as there is too much other competition in peer-reviewed journals.

4. Format your article properly. This usually means double-spaced, 12 point font, with non-justified (“ragged”) right margin. A cover letter and abstract will also be needed. Don't use fancy fonts or colors (the only non-standard fonts should be when you need to show symbols or equations not available in the standard font). Again, the IFA is an important resource.

5. Do not imbed your figures, graphs, etc. in the source document. The person on the other end may not be able to read it, and large imbedded items (e.g., photographs) can bog down their server. These should be references in the main document and uploaded as separate attachments (again, see the IFA).

6. Get help if the quality of your graphs or illustrations leaves something to be desired. Few of us are professional illustrators. Overly complex figures will not be looked upon favorably. Again, refer to examples in the journal and the IFA.

7. Make sure you give them your best contact information. It is frustrating for a journal to try and contact the corresponding author and find that the email address or phone number is no longer valid. (The corresponding author does not have to be the lead author. He/she should be the one who can best be depended on to carry out correspondence).

8. Have an experienced colleague walk you through your submission, as it can be a daunting process for the uninitiated. Frustration with the process may lead to errors, discouragement, and failure.

Following these steps can help you along your road to successful publication. Remember that first manuscripts are rarely accepted in their native form. The only way to improve at something is to continue to enhance your skills. As mentioned, it is important to have a trusted, experienced mentor who can walk you through the process. Would you expect to take a new set of golf clubs out to the course and expect to become successful at the game by yourself? You might achieve some basic level of skill, but you would not avoid typical mistakes that could be corrected by taking lessons from an experienced professional. The same principles apply here; the only way to improve at something is to do it, make mistakes, correct them as best you can, and repeat the process. No one gets there overnight!

IN THE SPOTLIGHT: NURSING RESEARCH

IU Health Ball Memorial Hospital receives AMSN grant for falls prevention study

The Academy of Medical-Surgical Nurses (AMSN) has awarded IU Health Ball Memorial Hospital a ten thousand dollar grant for falls prevention research. The study aims to provide medical-surgical nurses with new knowledge to engage inpatients in risk reduction through an innovative, video-based educational intervention.

Although falls are a common cause of injury among medical-surgical patients, research has not yet verified the effectiveness of specific educational strategies for fall prevention. The nationally funded study allows researchers to test the impact of video education on adult medical-surgical patients aged 45 and older who are at-risk for falls. The three-minute videos, created in partnership with the Ball State University School of Nursing, depict specific educational strategies for fall prevention and are tailored to the age and gender of the medical-surgical inpatients.

The 12-month study, which launched in September 2017, is currently taking place on five medical-surgical units at IU Health Ball Memorial Hospital. So far, the responses from patients have been positive.

“We have six RN research assistants rounding on units to identify qualified patients,” said Renee Twibell, PhD, RN, CNE and nurse researcher. “Patients seem to value the commitment of IU Health to research and willingly share their opinions and perspectives on fall prevention plans.”

This is the first study to evaluate fall-related outcomes of tailored, video-based education in medical-surgical inpatients. If the video education improves fall-related outcomes, specifically frequency of falls and fall-related perceptions among patients, the results will be shared nationally. The study may be replicated on medical-surgical units of other hospitals in the IU Health system. Positive patient outcomes would also lead to the creation of additional video education for a more comprehensive and individualized approach to falls prevention plans.

It’s an honor for our hospital to receive this grant,” said Lori Delaney, clinical nurse specialist. “Dozens of applicants request AMSN funding each year, and only one is selected annually. By testing this innovative, individualized approach to safety education, we hope to gain new knowledge and reduce harm to our patients.”



Mona Geinosky,
MSN, RN, CCRP
Manager - Research

Approved Research Projects

From July 1, 2017 through November 30, 2017, the following research projects and their principal investigators (PI) have been approved:

LUN15-233 Randomized Phase II Trial of Docetaxel plus Nivolumab or Docetaxel alone in patients with advanced non-squamous NSCLC previously treated with single agent Nivolumab

PI: Joseph Spahr, MD

The Effect of a Hospital-wide Safety Intervention on Verbal and Physical Abuse of Nurses

PI: Brittany Dorton, MSN, RN, CMSRND

SMART Registry: Strategic Management to Optimize Response To Cardiac Resynchronization Therapy Registry Study
Reference Number: C1949

PI: Michael Moran, MD

Understanding the Interplay between Innovativeness, Credibility, and Satisfaction in a Medical Residency

PI: Josh Rainey, PhD, HSPP

Identifying a Research subject in Cerner



Rachael Maddox,
Research Assistant

With the vast number of patients treated each day throughout the IU Health system, it is important that staff are able to quickly identify those patients taking part in a research study. The reason for this is mainly two fold. Firstly and most importantly is patient safety. Secondly, staff should be aware what investigational medications the patient could be taking to limit drug interruption. If staff is unaware the patient is on a study, or whom they should contact, the patient runs the risk of not getting the trial drug in a timely fashion.

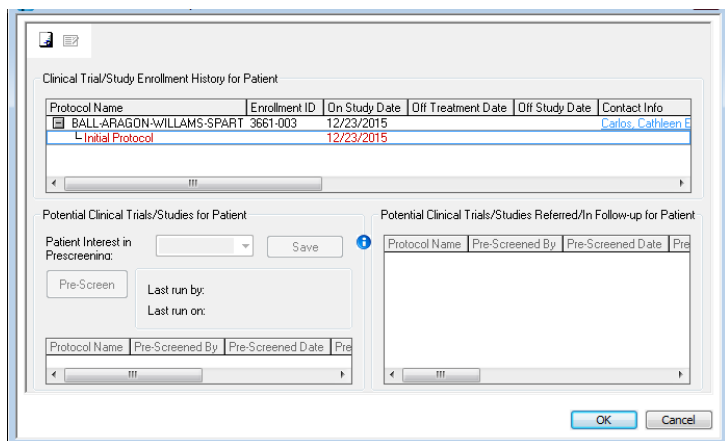
In 2015 a new computer system called OnCore was rolled out to track research studies across the IU Health System. OnCore acts as a data base allowing Research staff to enter information about research studies, as well as link subjects to the study they are taking part in. The OnCore system has the ability to communicate with Cerner. This means once the subject is entered as being on a study in the OnCore system it also identifies the patient as a research subject in their Cerner chart. This identifying tag can be seen across the IU Health System no matter which IU Health facility has enrolled the patient.

This identifying tag means staff will be able to access relevant study related information including pharmaceutical medications or devices that are being utilized. Contained in the tag is also information on how to contact the study team.



Steps to access the study information

1. Locate the tag in the patients chart. It is a hyperlink located under the MRN and FIN number.
2. Click the hyperlink
3. **Under Contact Info-** Click on the name listed and a second window will pop up containing contact information for study staff.
4. **Under Protocol name-** Double click on Initial Protocol. This will open a second window where you can select to see the Contact sheet or the Protocol summary.



If you have any questions please reach out to Rachael Maddox, Research Assistant at 765.751.2708 or rmaddox1@iuhealth.org.



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