Midwest Cardiovascular Research Foundation

Winter 2013

From the MCRF President

Happy Holidays to all of you from the staff of MCRF! We wish all of you a wonderful, healthy and happy New Year.

healing.

Dr. Nicolas W. Shammas, MD

At the Foundation we are excited about the upcoming year. We have several educational programs in the making including the 2 main cardiology conferences, Cardiology at the Bix July 25, 2014 and Cardiovascular Interventions and Practice Guidelines (CIPG) September 26, 2014, both will be co-directed by Dr Shammas and Dr Foreman. Several focused conferences will also be conducted throughout the year for both health care professionals and the community. In addition, we are excited about the several research programs ongoing at MCRF ranging from new device trials to various pharmacologic interventions. The Foundation is at the center of 2 main trials, Endomax (a randomized trial of bivalirudin versus unfractionated heparin in peripheral vascular intervention) and the JET registry (jetstream atherectomy in treating infrainguinal peripheral vascular disease). Dr Shammas serves on the national steering committees of both trials. Recently we have been involved in the Clarity trial, a new project in collaboration with wound

care physicians and evaluating the role of orbital atherectomy in wound

MCRF continues to collaborate with all health care entities in the area. We work closely with both Genesis Medical Center and Trinity Medical Center. Also, several projects are ongoing at Cardiovascular Medicine PC. The Ranexa randomized trial at CVM is nearing its end of enrolment and our hope is to present data at an upcoming major cardiology meeting. Soon, we will find the value of ranolazine in patients with severe, non operable ischemic cardiomyopathy patients, already on maximum therapy with beta blockers, angiotensin blockers and one additional anti-ischemic drug. The primary endpoint of the study is improvement in angina and dyspnea as assessed by standardized questionnaires. Electrophysiologic based research is also ongoing wit Dr Foreman leading the way at the Foundation. A key trial is evaluating the role of biventricular pacing/ICD in symptomatic patients with moderate reduction in left ventricular function and a LBBB on baseline ECG.

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New Clinical Trials

Several new studies are coming to the foundation in the near future:

- Orbit II: is a post market registry. Orbitt II recently started at the foundation and is currently enrolling patients. In this study, new oral anticoagulants are being evaluated for safety in a real world post market registry including how to manage bleeding complications in patients with non valvular atrial fibrillation.
- Clarity: is a randomized study evaluating the role of FFR and IVUS in below the knee peripheral interventions. Clarity recently started at the foundation and is currently enrolling patients. This study also will randomize patients to Orbital atherectomy versus angioplasty and their impact on wound healing in patients with ulcerations.

Obesity Practicum

This summer Dr Shammas and the foundation were

involved in an obesity-based research conducted by Cara Voelliger as part of her master thesis. Dr Shammas functioned as Cara's mentor in her research effort, which translated into a well-written and researched manuscript on the role of



psychological counseling prior to surgery for obesity and the potential conflicts between patient's autonomy versus physician's soft or strict paternalism. Cara presented her abstract at CIPG 2013.

Student Research Program

Three (3) students participated or continued their research at the Foundation. Cara Voelliger, Christina Harb and Tommy Harris continued their work on collecting data related to outcomes of patients over the age of 90 years that were admitted to Genesis Medical Center with an acute coronary syndrome. The project was partially supported by the research office at Genesis Medical Center and the Bechtel Trust. We anticipate the data to be available before the end of December 2013

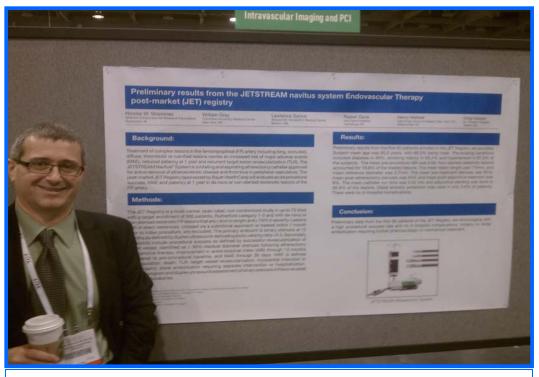
The new projects for the summer of 2014 are now in the planning phase. Interested students will be able to apply for the Jesse Stoakes Research Award provided by the Foundation in January 2014. Check www.mcrfmd.com in mid January for applications. The Foundation is planning on taking 2 or 3 students this upcoming summer (starting end last week of May and end third week of June 2013). Students will be paid a stipend for their work. They typically receive training on how to conduct clinical research, how to write research protocols, basic biostatistical concepts, data collection and data entry, data analysis which all eventually culminate in abstracts and manuscripts that they could potentially co-author. The foundation always welcomes tax exempt support to this vital program to train our future clinical scientists.



Research News

Three abstracts presented at Transcatheter Cardiovascular Therapeutics (TCT) 2013

Dr. Nicolas Shammas presented 2 poster abstracts "Preliminary results from the Jetstream navitus system Endovascular Therapy post-market (JET) registry" and "Differences in Patients' Selection and Outcomes of SilverHawk Atherectomy versus Laser Atherectomy in Treating In-Stent Restenosis of the Femoropopliteal Arteries: A Retrospective Analysis from a Single Center" at TCT 2013 in San Francisco, one of the largest interventional meeting in the world. Also, the foundation collaborated in another abstract presented at the same meeting "Multicenter Registry for Peripheral Arterial Disease Interventions and Outcomes (XLPAD Registry)." The XLPAD registry has been developed and launched by several centers in the United States with Dr. Subhash Banerjee as principal investigator at the VAMC of the University of Texas Southwestern Medical Center at Dallas. Dr Shammas is on the steering committee of XLPAD and MCRF is one of the main sites enrolling in this registry.



Dr. Shammas at his poster at TCT 2013, San Francisco, CA

Cardiology at the Bix 2013 Conference

Cardiology at the Bix 2013 is a multidisciplinary conference for general cardiologists, endovascular specialists, primary care providers, cardiovascular nurses, technicians and nurse practitioners jointly sponsored by Midwest Cardiovascular Research Foundation and Genesis Medical Center. This symposium is designed to give a comprehensive update in various aspects of cardiovascular diseases and focuses on adhering to national guidelines. The invited faculty provided attendees with practical tips useful in daily practice. This year featured a series of short but focused topics in the management of peripheral arterial and coronary artery disease, treatment of congestive heart failure and management of patients with atrial fibrillation and those at risk of sudden cardiac death.

Thanks to our Speakers:

Robert Brewer, MD; Blair Foreman, MD; Michael Gimbel III, MD; Rafat Padaria, MD; Vijay Rajendran, MD; Nicolas W. Shammas, MD

This conference was made possible through the generous contributions from our sponsors: Abbott Vascular, Angioscore, Astellas Pharmaceuticals, AstraZeneca, Bayer Interventional, Boehringer Ingelheim Pharmaceuticals, Boston Scientific, Bristol-Myers Squibb, Cardiovascular Systems, Inc., Cordis Corporation, Daiichi-Sankyo/Lilly, Forest Pharmaceuticals, Gilead Sciences, Inc., Janssen Pharmaceuticals, Inc., The Medicines Company, Medtronic Cardiac Rhythm Disease Management, Spectranetics, St. Jude Medical, Thoratec Corporation, and Zoll Lifevest Corporation.



Audience Comments: "Very good conference—please continue to offer these presentations." "Excellent—case histories are nice! Nice to see the doctors using research based information." "Well organized event...very glad to attend. Thank you!" "This was my first year at the conference and overall I was very satisfied."

Cardiovascular Interventions and Practice Guidelines 2013 Conference

Cardiovascular Interventions and Practice Guidelines (CIPG 2013) is a multidisciplinary conference for general cardiologists, endovascular specialists, primary care providers, cardiovascular nurses, technicians and nurse practitioners jointly sponsored by Midwest Cardiovascular Research Foundation and Genesis Medical Center. This was held on Friday, October 11, 2013, at the Adler Health Education Center Genesis Heart Institute, Davenport, Iowa.

Thanks to our Speakers:

Cornelius Davis III, MD; Blair Foreman, MD; Ziyad Hijazi, MD; Rafat Padaria, MD; Vijay Rajendran, MD; Nicolas W. Shammas, MD; Melham Sharafuddin, MD

This conference was made possible through the generous contributions from our sponsors: Abbott Vascular, Astellas Pharma, AstraZeneca, Bard Pheripheral Vascular, Bayer Healthcare, Boehringer Ingelheim, Boston Scientific Corporation, Bristol-Myers Squibb, Cardiovascular Systems, Inc., Cordis Corporation, Covidien Corporation, Daaichi-Sankyo/Eli Lilly, Gilead Sciences, Inc., Janssen Pharmaceuticals, The Medicines Company, Medtronic, Inc., Spectranetics, St. Jude Medical, Thoratec Corporation, Zoll Lifevest Corporation.

Audience Comments: "Excellent presentations. Learned about modern advances and neuro endovascular techniques." "Good variety of topics today." "Phenomenal speakers-each had fantastic presentations and I feel I was able to gather pearls from each speaker."



Left to right: Blair Foreman, MD; Nicolas W. Shammas, MD; Rafat Padaria, MD; Vijay Rajendran, MD; Ziyad Hijazi, MD

Education News

On behalf of the Foundation, Dr Shammas presented numerous lectures locally and nationally over the past three months as part of the educational mission to health care providers and the public. A list of these lectures is listed below:

Invited Lectures:

- CIPG 2013: Edovenous management of patients with peripheral venous disease
- ▼ CIPG 2013: Lariat procedure. LAA clipping to prevent strokes
- CIPG 2013: management of patients with ACS. The role of antiplatelets
- CIPG 2013: Superficial Venous treatment in the management of patients with venous ulcers
- Genesis Cath Lab Conference 2013: The LARIAT procedure. First in Iowa
- Genesis Cath Lab Conference 2013: May-Thurner diagnosis and treatment; Role of FFR preoperatively
- Genesis Cath Lab Conference 2013: Syntax vs STS for multivessel treatment. Review of guidelines
- ♥ Rock Island, Illinois 2013: Grand Rounds, Trinity Medical Center. Guidelines in antiplatelet therapy in patients with acute coronary syndrome
- ▶ Davenport, Iowa 2013: Management of the critical limb ischemia patient. Co-hosted with Dr. Matthew Wilber, September 23, 2013
- ◆ Chicago, Illinois 2013: Dr. Shammas was an invited faculty discussing "Establishing Your Office Based Vein Practice, Workshop" on September 20-21, 2013
- ▶ Dallas, Texas 2013: Dr. Shammas is an invited faculty at Dallas Cardiovascular Innovations 2013 on December 7, 2013. Dr. Shammas discussed current and upcoming techniques to treat in-stent restenosis of the infrainguinal arteries.

Annual Conference

Stay tuned for more information on CIPG 2014 and Cardiology at the Bix 2014 annual conferences.

Physician Training Courses

MCRF is involved in training physicians on different techniques and procedures in the cardiac cath lab. Several of these sessions have been conducted over the past three months at Trinity Medical Center, Bettendorf Campus and Cardiovascular Medicine, PC. Training was conducted on behalf of Covidien and Bayer for their new devices used to treat venous and arterial disease.

MCRF Educational Article

Treatment of chronic stable angina patients: What do the guidelines say?

Nicolas W. Shammas, MD, MS, FACC, FSCAI

It is estimated that 17 million Americans have coronary artery disease (CAD), 10 millions of whom have angina. In 2006 there was over 1.3 millions angioplasty and 448,000 bypass surgery to treat patients with CAD.

Angina is defined as typical, atypical or non cardiac. Typical angina is defined by a. chest pain with characteristic quality and duration, b. provoked by stress (physical or emotional) and c. resolved by rest or nitroglycerin. Atypical angina meets 2 of the criteria of typical angina whereas non cardiac pain meets only 1 or none of these criteria. Angina is classified in severity by the Canadian Cardiovascular Society Classification into 4 classes: Class I=no angina with ordinary activity, Class II=slightly limiting angina (after meals, in cold, walking rapidly, and climbing stairs fast), Class III=marked limitations in activity (climb 1 flight of stairs or walking 1-2 blocks), Class IV=with any activity or at rest. Angina can present as stable or unstable. Unstable angina is defined as rest angina (lasting more than 20 minutes within 1 week of presentation at rest), new onset angina (Class III within 2 months of presentation), and accelerated angina (more frequent, longer in duration and lower in threshold).

In this article, we focus on patients with stable angina with no rest symptoms or progressive symptoms. These are patients with stable ischemic heart disease (SIHD). These patients can fall into 2 categories: suspected SIHD or known SIHD. Diagnostic testing for patients with suspected or known SIHD is outlined below:

A. Patients with **suspected** SIHD

- a. If these patients have never had a stress test or coronary revascularization prior to their presentation and their ECG at baseline is interpretable and are able to exercise then a routine exercise stress test is indicated if they are low or intermediate risk, or an imaging exercise test is indicated if they are intermediate to high risk
- b. If they had a prior revascularization and their ECG is interpretable, then they should have an imaging exercise test
- c. If they are unable to exercise then pharmacologic stress imaging is indicated
- d. If there is contraindication to stress testing in general, then a CT angiogram to the coronaries can be considered
- e. If these patients had unprotected left main stent, prior ventricular arrhythmias or sudden death, or the clinical assessment suggest high risk findings, OR if any of the noninvasive stress testing indicates high risk findings, then these patients should be initiated on guideline-based medical therapy and considered for angiography and revascularization to improve survival

B. Patients with known SIHD

- a. If these patients are able to exercise and their resting ECG is interpretable, a regular exercise stress test or an imaging exercise test is indicated
- b. If their resting ECG is uninterpretable (including LBBB), then patients can be considered for an imaging exercise stress test or pharmacologic cardiac magnetic resonance stress test (CMR).
- c. If these patients are unable to exercise, or has a known stenosis from prior angiography of unclear significance, then a pharmacologic imaging test can be performed
- d. If high risk findings on stress testing are seen, then angiography with revascularization is indicated for survival improvement. A high risk finding on non invasive testing indicates more than 3% annual risk of MI or death. High risk findings exist if:
 - i. 10% of myocardium is ischemic
 - ii. Multivessel disease more than 70% stenotic lesions

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- iii. Left main stenosis of more or equal 50%
- iv. Stress induced left ventricular dysfunction (<45% or drop by 10%)
- v. ST depression of 2 mm or more at low workload or persistent in recovery
- vi. Exercise induced VT, VF or ST elevation
- vii. Left ventricular ejection fraction less or equal 35%
- viii. Calcium score more than 400
- ix. Stress induced ventricular dilatation
- x. Inducible wall motion in 2 coronary territories
- xi. Inducible wall motion at low dose dobutamine or at a HR less than 120

In general, failure of guideline-based medical treatment requires revascularization for symptom improvement. The goal of medical therapy is to have patients free or near free of symptoms so they have no functional limitations in their daily activity.

C. Guideline-based medical therapy in patients with SIHD

- a. Aspirin 75-162 mg (clopidogrel as an alternative if cannot take ASA)
- b. Smoking cessation program
- c. Life style modification including diet (reduce sat fat to less than 7% of total calories, cholesterol to less than 200 mg per day, and transfat to less than 1%), weight loss(BMI target 18.5 to 24.9 Kg/m2), physical activity (30-60 minutes of moderate intensity at least 5 days a week)
- d. Moderate to high dose statins (if not tolerated bile-sequestrant or niacin)
- e. BP control to less than 140/90. Consider ACEI or ARB if reduced left ventricular function, diabetes or chronic kidney disease
- f. Appropriate control of diabetes (HbA1C of less than 7%)
- g. An annual influenza vaccine is strongly recommended
- h. Evaluate and treat major depressive episodes
- i. Beta blockers as first line therapy (particularly if post MI or in patients with left ventricular dysfunction) followed by calcium channel blockers and/or long acting nitrate therapy followed by ranolazine (In patients who cannot tolerate beta blockers ranolazine can be used as a substitute. Also ranolazine in combination with beta blockers can be used)
- j. If symptoms persist despite medical therapy, revascularization is considered for symptom control

In general, stable IHD patients need to be treated conservatively unless they have high risk findings clinically or on stress testing. Angioplasty is not indicated and may even be inappropriate in asymptomatic low risk patients. It is also uncertain if there is benefit for angioplasty in asymptomatic patients who are intermediate risk. These patients are also best treated conservatively and followed closely.

Reference:

2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons.

Fihn SD, Gardin JM, Abrams J, et al. J Am Coll Cardiol. 2012 Dec 18;60(24):e44-e164. doi: 10.1016/j.jacc.2012.07.013.

With Great Appreciation



The foundation is very grateful for several individuals and organizations in the community:



<u>Mr. Richard Bittner</u> who has been a wonderful supporter to the foundation providing free legal services and advise and supporting many of the projects that the foundation has undertaken over the past several years. Mr. Bittner has strongly believed in the mission and vision of the foundation and his support led to its countless achievements including numerous educational activities, training research students, numerous sponsored and investigator initiated protocols, over 100 publications (manuscripts, books and

book chapter) and countless national presentations. Mr. Bittner is on the advisory board of the foundation and its legal advisor. Mr. Bittner through the Bechtel trust has provided predictable support to the student research program over the years and has given the foundation several generous financial grants.



<u>Mr. Steve Landauer</u> who has been our accountant and our advisor when it comes to the foundation's non profit transactions. He also has been willing to work with the foundation at a reduced accounting rate emerging from his strong belief of the role of the foundation in our community. His contributions and support are highly appreciated.

Genesis Health System Research Program for their continued support to the Foundation mission and vision.

<u>Cardiovascular Medicine</u>, <u>PC</u> for their support to the foundation in general by facilitating research conducted at the offices of CVM.

<u>Trinity Medical Center</u> for their support in conducting state of the art research at their cardiac catheterization facility in Bettendorf, IA.

MCRF Welcomes New Board Member!

The foundation welcomes our new addition to Board of Directors: *Bradley J. Crosson*. Mr. Crosson is a civilian attorney for the Department of Army providing legal counsel and business advice to Department of Army Acquisition, Technology and Logistics professionals. He has twenty-seven years experience in Government contracting, with the emphasis in defense contracting. He advises acquisition professionals in the areas of contract formation, contract administration and contract disputes. He advises program offices for the acquisition of Ammunition, Weapons Systems, and Foreign Military Sales. He earned his J.D. from Creighton University School of Law, Omaha NE. He has been involved in a variety of volunteer community and civic organizations.



Recent Publications Carrying MCRF Name



- ♥ Shammas NW. JetStream Atherectomy for Treating Introgenic Occlusion of a Stented Common Femoral Artery Following Deployment of Angio-Seal Closure Device. *J Invasive Cardiol* 2013; 25(9):475-7
- ♦ de Borst GH, Shammas NW. Commentary: the search for reliable markers for increased carotid artery stenting-induced cerebral embolism. J Endovasc Ther. 2013 Oct;20(5):695-8. doi: 10.1583/13-4354C.1.
- ▶ Shammas NW. Editorial: Optimizing strategy in peripheral vascular interventions: the role of JETSTREAM atherectomy. J Invasive Cardiol 2013; 25 (Supplement B):2B
- ♥ Shammas NW. Addressing challenges in the treatment of infrainguinal arterial disease: an endovascular specialist's perspective. J Invasive Cardiol 2013; 25 (Supplement B):3B-6B
- ▶ Dippel EJ, Shammas NW. Atherectomy for femoropopliteal in-stent restenosis. A review of the current data on the role of atherectomy devices in debulking these difficult lesions. Endovascular Today, August 2013, Volume 12 (8), pages 59-62.
- ▶ Banerjee S, Sarode K, Das T, Hadidi O, Thomas R, Vinas A, Garg P, Mohammad A, Baig MS, Shammas NW, Brilakis ES. Endovascular Treatment of Infrainguinal Peripheral Arterial Chronic Total Occlusions with the TruePath Device: Featured Case Series, Device Features, Handling and Procedural Outcomes. *J Endovasc Ther* 2014;(In Print)
- ♥ Shammas NW, Shammas GA, Jerin M. Differences in Patients' Selection and Outcomes of SilverHawk Atherectomy versus Laser Atherectomy in Treating In-Stent Restenosis of the Femoropopliteal Arteries: A Retrospective Analysis from a Single Center. *J Endovasc Ther* 2013;(In Print)
- ▶ Shammas NW. Role of Distal Protection in Percutaneous Renal Intervention for Atherosclerotic Renovascular Disease. *Vascular Disease Management*, 2013: (In print)
- ▶ Shammas NW, Shammas,GA, Jerin M._Differences in patients' selection and outcomes of Silverhawk atherectomy versus laser atherectomy in treating in-stent restenosis of the femoropopliteal arteries: a retrospective analysis from a single center. Presented at TCT 2013, San Francisco, October 27-Nov 1. J. Am Coll Cardiol. 2013; Vol. 62, Issue 18, Supplement 1, Page B163
- ▶ Shammas NW, Gray W, Garcia L, Dave R, Meltser H, Kasper G. Preliminary results from the <u>Jetstream</u> navitus system <u>E</u>ndovascular Therapy post-market (JET) registry. Presented at TCT 2013, San Francisco, October 27-Nov 1. J. Am Coll Cardiol. 2013; Vol. 62, Issue 18, Supplement 1, Page B163
- ▼ Sarode K, Mohammad A, Hadidi OF, Thomas R, Thomas M. Das, Jeomi Maduka, Mazen Abu-Fadel, Mirza S. Baig, Osvaldo Gigliotti, Robert Dieter, Thomas T. Tsai, M Ishti Ali, Andrew Klein, Dharam J. Kumbhani, Michael Luna, Nicolas W. Shammas, Anand Prasad, Jeffrey L. Hastings, Tayo Addo, Emmanouil Brilakis, Subhash Banerjee Das TM, Maduka J, Abu-Fadel M, Baig MS, Gigliotti O, Dieter R, TsaiTT, Ali MI, Klein A, Kumbhani DJ, Luna M, Shammas NW, Prasad A, Hastings JL, Addo T, Brilakis E, Banerjee S. Multicenter Registry for Peripheral Arterial Disease Interventions and Outcomes (XLPAD Registry). Presented at TCT 2013, San Francisco, October 27-Nov 1. J. Am. Coll. Cardiol. Vol. 62, Issue 18, Supplement 1, Pages B158-B159

Editorial Board and Conferences

Dr. Shammas has been recently elected as the Section Editor of *Advances in Vein Therapies* of the Journal of Invasive Cardiology. Also Dr. Shammas was recently elected as a co-director of the national conference **VEINS** Chicago 2014.

MCRF Board of Directors

President and Research Director Nicolas W. Shammas, MD, MS, is an interventional cardiologist with Cardiovascular Medicine, P.C., Davenport, IA, and a Clinical Associate Professor at the University of Iowa in Iowa City. He founded MCRF in 2002 to facilitate cardiovascular clinical research and education. He has been active as principal or co-investigator in over 200 research trials, has been a participating author in over 250 publications, and is a popular presenter at international professional meetings.

Director Nicholas S. Coin, Rock Island, IL, is the manager of the investment department and treasurer at Modern Woodmen of America based in Rock Island, Illinois. He is also responsible for all outside banking relationships and activities and shares his expertise on a variety of other community volunteer organizations.

Director Bradley J. Crosson, Bettendorf, IA, is a civilian attorney for the Department of Army providing leagal counsel and business advice to Department of Army Acquisition, Technology and Logistics professionals. He has been involved in a variety of volunteer community and civic organizations.

Director Blair Foreman, MD, is a cardiologist and electrophysiologist with Cardiovascular Medicine, P.C., Davenport, IA. He actively participates in cardiovascular research projects focusing on electrophysiology.

Director James Kapalis, Bettendorf, IA, is a retired executive of Deere & Company, Moline, IL, and is currently President of Global Supply Chain Solutions, Inc., Bettendorf, IA. He serves as a member of the American Red Cross Disaster Team, and is an active member on many community organization boards.

Our Mission

Midwest Cardiovascular Research Foundation (MCRF) is engaged in the continuous active conduct of medical research, including investigations, experiments, and studies to discover,

develop or verify knowledge relating to the causes, diagnosis, treatment, prevention or control of cardiovascular disease. By conducting these clinical trials, Midwest Cardiovascular Research Foundation will generate data leading to a higher quality of life, increased longevity of life and prevention of cardiac illness in both cardiovascular patients and the general public.

TO CONTACT MCRF.....

Feel free to contact us regarding submitting manuscripts or articles, obtaining publications, booking a speaker, contributing funds or other matters.

To submit manuscripts, discuss research possibilities, etc., contact:

Dr. Nicolas W. Shammas, MD Founder & Research Director Editor-in-Chief, Editorial Board shammas@mchsi.com

For other assistance or information, contact:

Maureen Koepke Office Manager 563.324.2828 koepkem@mcrfmd.com



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100% of all gifts are applied to research and education for heart health in this community.

For more information about MCRF visit www.mcrfmd.com or phone 563.324.2828