MCW/FMLH Research Curriculum

Description Educational Experience:
Fellows enter our program with a wide range of interest in research. Some fellows need exposure to cardiovascular research but are more focused on clinical work. Other fellows are planning to embark on academic careers. These fellows require in-depth research experience during the fellowship period under the mentorship of an experienced investigator to allow their skills to develop to a point where they are in position to apply for an NIH K Award. As such, the research curriculum is divided into two sets of experiences: 1) the clinically-focused cardiologist track and 2) the research-focused cardiologist track. Fellows on the clinically focused track may obtain a more in depth experience by using their electives to increase research exposure and depth of their research experience. The following description of the research training experience applies specifically to the clinically focused fellows. The research-focused fellows spend two years of dedicated time learning a specific field of research in cardiovascular medicine and have individualized research training plans designed by their mentors and supported by an Institutional T32 grant. Copies of these individualized plans are available from the individual mentors.

Patient Care
There is no patient contact occurring during the research rotation related to clinical care. Fellows may interact with participants in studies in which they are co-investigators. The training for ethical conduct of research is outlined below in the “Research Training/Medical Knowledge” section.

Medical Knowledge/Cardiovascular Research Knowledge:

Goal: Fellows will become familiar with common research methods applied in cardiovascular research. Each fellow will engage in a research project under the direction of a mentor with the goal of presenting their work in a public academic forum.

Competencies:
- Understand the ethical issues surrounding clinical research, including the concept of justice, beneficence, and respect for persons as delineated in the Belmont report.
- Understand with the common clinical study formats, including randomized clinical trials, cohort studies, case-control studies, and case reports, and be able to delineate the strengths and weakness of each study design.
- Understand important concepts in clinical epidemiology, including sensitivity, specificity, positive and negative predictive value, ROC curves, and net reclassification index.
- Understand the importance of appropriate statistical design and analyses for studies and be familiar with the importance of study power to the interpretation of study results.
- Understand the construction and interpretation of meta-analyses and cost-effectiveness studies.
- Understand how to translate their research ideas into feasible and ethical proposal for an institutional research board.
- Learn how to write a succinct abstract for submission to local, regional, or national
Objectives: First Year Fellows:
- Within the 1st 3 months of fellowship, all 1st year fellows on this track will meet with fellowship research director to discuss their research interests and potential avenues through which their research may be performed.
- Within the 1st 4 months of fellowship, the fellow will have interviewed several potential mentors for their research project and identified a mentor for their project.
- The fellow will complete MCW’s ethical research training course (https://www.citiprogram.org/Default.asp). This training material contains general topics related to the ethical conduct of clinical research as well as units specific for conducting clinical research at the Medical College of Wisconsin.
- By the end of their 1st year of fellowship, the fellow will have submitted a full protocol to the MCW Institutional Research Board if required for their project.
- ≥90% attendance at the monthly journal club where didactics with respect to research study design, analysis, and interpretation are given.
- ≥90% attendance at research oriented cardiology grand rounds sessions (~10/year) and all research oriented fellow didactic talks. These include lectures on cardiac physiology, vascular endothelial function, cardiovascular genetics, cardiovascular molecular biology, cardiovascular metabolism, and cardiovascular pharmacology.
- The fellow will present one article at journal club and be able to critically review the article thoroughly.

Objectives: Second Year Fellows:
- Fellows will complete ≥75% of their analyses (for data mining studies) or 75% of their study recruitment (for prospective studies) by the end of 24 months of fellowship.
- Fellows learn how to write a well-organized abstract under the supervision of their research mentor.
- ≥90% attendance at the monthly journal club where didactics with respect to research study design, analysis, and interpretation are given.
- ≥90% attendance at research oriented cardiology grand rounds sessions (~10/year) and all research oriented fellow didactic talks. These include lectures on cardiac physiology, vascular endothelial function, cardiovascular genetics, cardiovascular molecular biology, cardiovascular metabolism, and cardiovascular pharmacology.

Objectives: Third Year Fellows:
- Fellows will complete the analyses of their data and study recruitment and.
- Fellows will submit an abstract on the basis of their work to a local, regional, or national meeting.
- The overall goal of the curriculum is to have at least 50% of these abstract presents at local, regional, and/or national meetings. Further, our goal is to have 50% of fellow write up their research and submit the manuscript for publication.
- ≥90% attendance at the monthly journal club where didactics with respect to research study design, analysis, and interpretation are given.
- ≥90% attendance at research oriented cardiology grand rounds sessions (~10/year) and all
research oriented fellow didactic talks. These include lectures on cardiac physiology, vascular endothelial function, cardiovascular genetics, cardiovascular molecular biology, cardiovascular metabolism, and cardiovascular pharmacology.

**Practice Based Learning and Improvement:**

**Goal:** Fellows will demonstrate the ability to efficiently and thoroughly learn and summarize the available background data on their chosen area of research. Fellows will learn how to evaluate their knowledge base for potential gaps and identify skills and habits to fill those gaps

**Competencies:**
- Identifying the strengths and weakness in their knowledge base in their area of research
- Setting realistic goals for learning and improvement
- Integrate skills learned regarding critical appraisal of the literature and apply them to their area of research to better identify knowledge gaps
- Use information technology to enhance their research efficiency

**Objectives: 1st Year Fellows:**
- Following identification of their chosen area of research and mentor identification, fellows will do a thorough literature search to better hone their research questions
- Fellows will learn how to apply Ovid, PubMed, Embase, and Cochrane Reviews to efficient access the relevant literature
- Fellow will apply knowledge gained from didactics during journal club sessions to help critically appraise the literature
- Fellows will learn the importance of appropriate goal and benchmark setting for the timely completion of their research projects.

**Objectives: 2nd Year Fellows:**
- Fellow will apply knowledge gained from didactics during journal club sessions to help critically appraise the literature
- Fellows will learn to critically appraise their own progress on the basis of their own set goals and benchmarks and learn how to adjust them as necessary
- Fellows will continue following the literature in their chosen area of research to monitor for new findings relevant to their work
- Fellows will begin to learn the process of scientific writing under the their mentor’s guidance and learn the importance of the peer-review process

**Objectives: 3rd Year Fellows:**
- Whenever possible, fellows will be included in the critical appraisal of literature in their chosen field by reviewing novel submitted scientific works under the their mentor’s guidance.
- Fellows continue to learn to appraise their own progress on the basis of their own set goals and benchmarks and tune their ability to set realistic goals and benchmarks
- Fellows will continue following the literature in their chosen area of research to monitor for new findings relevant to their work
- Fellows continue learning the process of scientific writing while learning the merits of having abstracts and manuscripts peer-reviewed in order to improve study results and conclusions.

**Interpersonal Skills and Communication:**
**Goal:** Successful clinical cardiovascular researchers know a central component of a successful research program is effective communication with collaborating investigators, statisticians, regulatory bodies, and study participants. Fellows demonstrate effectiveness in communicating with all of these key contributors to their research projects.

**Competencies:**
- Fellows will demonstrate the ability to communicate efficiently and effectively with their research mentors to complete study objectives.
- Fellows will demonstrate the ability to effectively communicate with the MCW Institutional Research Board or equivalent bodies.
- Fellows will demonstrate the ability to communicate with project collaborators in order to complete key components of their projects.
- As applicable, fellows will demonstrate the ability to communicate with study participants so that participants understand their study and are comfortable with participation. Fellows will also demonstrate culturally competent communication with study participants.

**Objectives: 1st Year Fellows:**
- The fellow, with the help of the research mentor, will develop a research question of mutual interest that can be answered during the fellow’s 3 year commitment.
- In development of the research protocol, the fellow will meet with potential collaborators and statisticians to optimize study design.
- By the end of their 1st year, fellows will have successfully submitted a proposal to the IRB and received approval of this following appropriate communication with the IRB.

**Objectives: 2nd Year Fellows:**
- The fellow will communicate frequently with his/her mentor to discuss study progress and evaluate any preliminary results.
- The fellow will work closely with collaborators on his/her project in order to make continued progress and make sure their work is progressing appropriately.
- The fellow will, if necessary, prepare and submit a continuing progress report for the IRB at the end of the 1st year of their project.
- The fellow will begin to learn the process of scientific writing under the their mentor’s guidance and learn the importance of the peer-review process.
- The fellow, if necessary for the project, will participate in the recruitment of participants, the informed consent process, and any study procedures relevant to his/her proposal.

**Objectives: 3rd Year Fellows:**
- The fellow will complete his/her project and report on its results to his/her mentor and collaborators.
- The fellow will work with his/her mentor and collaborators to finalize an abstract for submission to a relevant local, regional, or national meeting.
- If the fellow, mentor, and collaborators agree, the fellow will begin to write a scientific manuscript on their work and learn the process of putting together a scientific paper on their work.
- The fellow will file any amendment and reports to the IRB on his/her research project as necessary.
Professionalism:

Goal: Fellows must demonstrate a commitment to carrying out their research and maintain accepted ethical standards. Fellow are expected to demonstrate:

Competencies:
- Understanding of the Belmont Principles, including justice, beneficence, and respect for persons
- Understanding of the Healthcare Portability and Accountability Act (HIPAA) as it applies to clinical research
- Integrity and respect for both their work and their co-workers
- For fellows engaged in prospective studies with participant interaction: sensitivity and responsiveness to a diverse population of participants

Objectives: 1st Year Fellows:
- The fellow will complete their ethic training in human subjects research (CITI program) which includes detained training on the Belmont Principles and HIPAA.
- If necessary for his/her project, the fellow will learn how to write an appropriate informed consent form with the help of the mentor
- The fellow expected to be punctual for meetings
- The fellow should show appropriate respect for their mentor and collaborators, and in his/her communications with IRB.

Objectives: 2nd and 3rd Fellows:
- Practice sound and ethical research procedures under the supervision of the mentor
- Show respect for persons, privacy, and autonomy in their interaction with study participants
- Show respect in his/her interaction with the IRB and regulatory bodies that may involved with monitoring the fellow’s research
- Analyze and report study results in an ethical and professional matter
- Dress professionally for public presentations of his/her research

Systems Based Practice:

Goal: Fellows will demonstrate an awareness of and responsiveness to the larger context and system of health care (and research), as well as the ability to effectively call on other resources at MCW and elsewhere to optimize their research project. Fellows are expected to:

Competencies:
- Understand the general principles of cost-effectiveness and cost-benefit analyses to be able to understand this literature and apply it to their research if necessary
- Coordinate clear communication between collaborators on their project
- Coordinate with the Human Subjects Protection Program at MCW to maximize participant safety in any study
- Learn how to monitor their studies to limit any potential systemic errors in data ascertainment

Objectives: All Fellows:
- Through didactic sessions at journal club, fellows will learn how cost-benefit analyses are derived and how they can be applied both in research and clinical settings
• Have open and frequent communication with the mentor and collaborators on the research question, study design, and study execution
• Learn how to monitor a study from the mentor and pick up potential errors being made and correct these as necessary
• File appropriate amendments and protocol deviations with the IRB under the oversight of the mentor
• Through their literature search and monitoring of the literature, fellows will learn how to place their research in the context of the greater body of work related to

Teaching Methods:
Teaching in the research curriculum involves both didactic sessions (at least 1x/month with journal club meetings) that discuss formal topics on study design and analysis. Human subjects training is done under the auspices of the Human Subject Protection Program at MCW and the individual mentor. Day-to-day informal training in research methodology, from the formulation of research questions to study design, execution, and reporting, will be done primarily by the fellow’s mentor and his/her collaborators.

Assessment Methods (Fellows):
Fellows will be given verbal feedback on their performance during their research rotation by their mentor both at the mid point and end of their rotation. Formal written feedback based on this verbal communication will be based on the fellow’s competencies in the areas of Patient Care, Medical Knowledge/Research

The fellows will also receive verbal feedback from the program coordinator every 6 months. At the every six month meeting with the program coordinators, fellows will be asked to present the current state of research as well as discuss potential current and future barriers to research completion and set realistic goals for the next 6-12 months of research.

Assessment Method (Program Evaluation):
Fellows will assess the research curriculum overall at the end of each individual research rotation as well as their mentors. These will be written evaluations that are shared with the Chair of the Division as well as the Fellowship Program Director. Feedback from the fellows will all for correction of any problems with the rotation as well as allow for the integration of enhancements to the curriculum.

Level of Supervision:
Coordinating Faculty: Michael Widlansky MD, MPH

Participating Faculty: Marcie Berger MD, Bill Choi MD, Michael Cinquegrani MD, Michael Earing MD, Panayotis Fasseas MD, Stacey Gardiner MD, David Gutterman MD, James Kleczka MD, James Macioch MD, Catherine Malmstein MD, David Marks MD, Amitoj Marwaha MD, Joshua Meskin MD, Mary Ann Papp MD, James Roth MD, Jason Rubenstein MD, Linda Scaffidi MD, Ronald Siegel MD, Dalip Singh MD, Jennifer Strande MD, Timothy Woods MD

Fellows are encouraged to seek out faculty that match their research interests within the 1st 3 months of their fellowship. Faculty members serving as mentors will provide primary supervision of their fellow’s progress on their individual project. This includes helping with the formation of the research question, reinforcing ethical training in clinical research,
of an IRB proposal, overseeing data accrual and analysis, and overseeing the writing of an
abstract based on this research and submission to a local, regional, or national meeting.

### Educational Resources:

**Textbooks:**


**Websites:**

- **Human Subjects Protection Training:**
  - CITI Training: [https://www.citiprogram.org/Default.asp](https://www.citiprogram.org/Default.asp)

- **Literature Searches:**
  - The Cochrane Collaboration: [http://www.cochrane.org/](http://www.cochrane.org/)

- **Local Sources for Help with Data Capture and Analysis:**
  - MCW Epidemiology Data Service Center: [http://www.mcw.edu/edsc.htm](http://www.mcw.edu/edsc.htm)
  - MCW Biostatistical Consulting Service: [http://www.mcw.edu/biostatsconsult.htm](http://www.mcw.edu/biostatsconsult.htm)

- **Full Information on Clinical and Translational Research Resources at MCW:**
  - Clinical and Translation Science Institute of Southeast Wisconsin: [http://www.ctsi.mcw.edu/](http://www.ctsi.mcw.edu/)