RESEARCH MANUAL

2014-2015
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KEY DIRECTORIES AND WEBSITES

The MedStar Union Memorial Orthopedic Research Office can be reached at 410-554-2970.

The Orthopaedic Research website can be accessed at MedStarUnionMemorial.org/OrthopaedicResearch.

The MedStar Health research website, www.medstarresearch.org, can be accessed for MedStar Health Research Institute (MHRI) requirements
• IRB and IACUC forms, guidelines, and proposal submission instructions (see Appendix 6)
• Informed patient consent forms (required for clinical study)
• All applicable HIPAA (Health Insurance Portability and Accountability Act) requirements for research (CITI training exam)

MedStar Union Memorial Hospital on StarPort, StarPort.MedStar.net, can be accessed for Hospital protocols, policies, and procedures

The MedStar Union Memorial Hospital network, orthores on‘umhfs01\workgroups_2’ (S:), subfolder Orthopaedics can be accessed for:
• Research proposal application forms for the Orthopedic Research Committee
• Request for presentation or publication funds form
• Roger H. Michael (RHM) Research Award application form
• Orthopedic Research Manual
• Grant and external funding sources
• Annual Orthopedic and Hand publications and presentations

The National Library of Medicine’s Medline through PubMed can be accessed for literature searching at either Starport – Clinical Resources – Online Clinical Library – PubMed or at http://www.nlm.nih.gov/. Literature searches can also be requested from the medical Library at x2294.

The MicroSolv Technology Corporation website can be accessed for unit conversions at https://mtcusa.sslcert19.com/calculators_pres.asp

Frequently used acronyms:
• CITI: Collaborative Institutional Training Initiative
• IACUC: Institutional Animal Care and Use Committee
• IRB: Institutional Review Board
• MedStar UMH: MedStar Union Memorial Hospital
• MHRI: MedStar Health Research Institute
• MOA: Maryland Orthopaedic Association
• OBERD: Outcome Based Electronic Research Database
• OEL: Orthopedic Education Luncheon
• ORC: Orthopedic Research Committee
• ORI: Office of Research Integrity at MHRI
• PEER: Program for Ethics Education in Research
• SRB: Scientific Review Board
• STAT Lab: Surgical Techniques and Technology Lab
YOUR ORTHOPEDIC RESEARCH TIMELINE

Research is a mandatory component of our accredited residency and fellowship programs. You are responsible for planning and completing your project through presentation and publication during your time at MedStar UMH. Consult the Orthopedic Research Office for assistance.

Step 1
- Attend research orientation and receive guidelines to begin research process
- Work with attending and research staff on formulating hypothesis and writing study design
- Confirm research plan with faculty mentor and lab director (PGY-3 and 4 and fellows)
- Do a literature review on planned topic
- Meet research staff, see facilities, work with staff to write study budget
- Prepare and Submit proposal to the Orthopedic Research Committee (ORC)
- For clinical study, prepare Institutional Review Board (IRB) forms with lay summary
- For animal study, get approval of Dr. Ken means and prepare IACUC forms
- Submit completed copy to Orthopedic Research Office for the study file

Step 2
- Present study at ORC, revise, and resubmit if needed
- Review sources of outside funding
- Apply for outside funding if applicable with help of director of research
- Once study is approved, begin pilot studies and order supplies

Step 3
- Conduct study during research rotation
- Submit raw data for statistical analysis and meet with statistician to review and revise results
- During research rotation, draft Introduction, Materials and Methods, and Results sections
- Meet with medical editor

Step 4
- Present findings at an Orthopedic Education Luncheon
- Submit abstract to the Maryland Orthopedic Association (MOA) and a national or specialty meeting
- Submit abstract to the Orthopedic Research Society
- Give copy of submitted abstract(s) and final presentation(s) to editor
- Present study
- Discuss paper with sponsoring attending and revise based on attending comments

Step 5
- Give reviewed paper to editor with references, figures, and tables
- Revise edited paper, consult editor and attending as needed
- Residents should allocate time in the research rotation to write the rough draft of the paper and obtain the assistance of the editor to begin the editing process

Give the Orthopedic Research office your contact information for home and work upon graduation so that the research staff can contact you for later stages of paper publication.
Background

The clinical practice of orthopedic surgery has advanced markedly due to an explosion of knowledge in the basic sciences of the musculoskeletal system. To interpret this material and to review research and publications critically, it is necessary to understand scientific method. One must appreciate the intricacies of study design and have a basic understanding of how to collect/analyze data properly and to interpret the results correctly. Working with a mentor on a research project is the most efficient way to acquire these skills.

In 1985, The American Academy of Surgeons mandated that all accredited residency programs provide research experience for their orthopedic residents. To fulfill this requirement, each resident in the Department of Orthopaedics and Sports Medicine at MedStar UMH is expected to participate in at least one research project during his or her training. In full support of this mandate, the Department created a dedicated research rotation during which residents can conduct their research. Each research project is to be conducted under the guidance of a faculty member, and it is anticipated that the results of the project will be submitted for presentation at the national level with subsequent publication in a peer-reviewed journal.

Because the Department considers research an important aspect of training, each fellow is also expected to complete at least one research project. This research is to be conducted with a faculty advisor as a mentor, and it is anticipated that the results of the project will be submitted for presentation at the national level.

This Research Manual is designed to familiarize residents and fellows with the procedures for initiating and conducting a research project. It provides the steps for designing a research project, the procedure for obtaining funding for the project through the Orthopedic Research Committee (ORC), the available resources for conducting the project, and a guideline for timely completion of the project. Particular attention should be paid to the steps for designing a research project. The project will proceed much more smoothly if the preliminary work is completed and pilot studies are conducted before the research rotation.

Technology in orthopaedics is rapidly changing, and it is sometimes difficult to assimilate the continual stream of new information. The formulation and conduct of a formal research project enhances the level of critical thinking required when evaluating different surgical techniques, new prosthetic devices, drug therapies, or new biomaterials.

Goals

The specific objectives and assessment criteria of the research rotation for residents and fellows are listed in Appendix 1. The goals of the research project are multifaceted: 1) to gain knowledge regarding the scientific method; 2) to stimulate a level of critical thinking toward new technologies, materials, and techniques; 3) to formulate a research topic and design the study; 4) to conduct the project and collect and process the data; 5) to conduct data analyses and determine significance; 6) to interpret the results; 7) if a basic science project, to relate the results to clinical applicability, and 8) to present/publish the results of the study.
**Initiation of research Program**

Fellows should do a preliminary literature review in their area of research interest and should be prepared to choose a research study or studies upon arrival in August. In addition, they are often assigned a specific research project by the director of their fellowship program. Residents should begin to formulate research ideas at the beginning of their PGY-3 year. A list of potential projects for which pilot studies have already been completed can be requested from the Research Coordinator at x2970. Resident research prior to this time is possible with the consent of an orthopedic faculty advisor.

All studies that involve human subjects, including those involving previously collected specimens from live human subjects, must be submitted to the MedStar Health Research Institution (MHRI) Institutional Review Board (IRB) through the InfoEd web portal. All the required forms and instructions for their submission can be found on the MHRI website: [https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Institutional-Review-Board-IRB/IRB-Forms.aspx](https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Institutional-Review-Board-IRB/IRB-Forms.aspx) (see Appendix 6 for IRB Guidelines and further details). The IRB meets on a monthly basis.

All studies that involve animals must be submitted to the ORC for preliminary approval. If an investigator wishes to do an animal procedure in the Microsurgery Lab, it should be noted that the lab is approved only for non-survival surgery on rats; however, the MHRI’s Institutional Animal Care and Use Committee (IACUC) will grant approval for survival procedures on a case-by-case basis and those projects will require additional review by Dr. Ken Means, as part of the lab’s regulatory oversight. Projects for Dr Means’ review can be submitted electronically to Lorraine Zellers at loraine.zellers@medstar.net. Contact Lorraine Zellers for further information at x2486.

Once projects are approved by the ORC and Dr. Means, they are then submitted to the Office of Research Integrity Office of Research Integrity for final review by the Institutional Animal Care and Use Committee. It should be noted that IACUC training is a requirement for IACUC submission. In addition, anyone working in the lab must complete the Occupational Health Annual Survey – Animal Handlers & Caretakers questionnaire and receive clearance from the MedStar UMH Occupational Health Office (see Appendix 9).
RESEARCH ORIENTATION

All new residents and fellows meet the research team in a mandatory orientation session during their first month at the hospital. Orientation is required before any resident or fellow is eligible to apply for research funds through the ORC.

The primary investigator must attend a research orientation before embarking on a project to ensure that he or she understands all the issues and requirements involved. At the discretion of the Director of Research, a project requesting funding can be placed on hold until the primary investigator receives this training.

The orientation provides guidelines on how to do the following:

- Design a research project and submit it to the ORC for funding
- Use the medical library
- Conduct a literature search
- Submit requisitions for study supplies
- Organize data collection for appropriate statistical analysis
- Prepare to present and publish
- Present funding for presentations

The orientation provides an opportunity for residents and fellows to ask about the orthopedic research program and facilities. A member of the research team will contact each resident and fellow to schedule the orientation.
ORTHOPEDIC RESEARCH COMMITTEE / IRB REVIEW

The purpose of the Orthopedic Research Committee (ORC) is to critically review submitted research proposals for their scientific merit and to allocate funds to approved projects. Clinical studies are also submitted to the Institutional Review Board (IRB) for approval (See Appendix 6).

All projects should be submitted to the ORC prior to or at the same time they are submitted to the IRB for approval. IRB-approved projects that are initiated without ORC approval will not be eligible for publication or presentation funds.

Members
Committee members are appointed by the ORC Chairman and the Director of Research with the approval of the Department Chairman. There are two types of committee memberships, voting and nonvoting. Voting members are the ORC Chairman, the Director of Research, physicians on the committee, and Director of the STAT Laboratories. Nonvoting members are the Administrative Coordinators (Research and Fellowship), and the support staff. Ad Hoc committee members are those who do not attend meetings regularly but who may be asked to participate for special purposes. The Department Chairman is considered an Ad Hoc member and is kept apprised of all committee activities.

Schedule of Meetings
The ORC meets quarterly (August/September, November, February, and May). Generally, these meetings are held on Wednesdays at 7:00 am. Reminder memos are sent and signs are posted well in advance of each date designating the location.

Content of Meetings
ORC meetings consist of approval of minutes from previous meeting, publication report, financial report, proposal review, assorted other business.

If it is determined that there is not enough time to address all proposals presented at one meeting, a subcommittee (whose members are chosen at the discretion of the Director of Research and the ORC Chairman) will meet shortly thereafter to review the remaining proposal(s).

Submitting a Proposal to the ORC
The Research Proposal Application can be downloaded to your computer and filled in. It is available in Word format in the OrthoRes (S:) directory on the MedStar UMH network (Orthopaedics folder, Forms subfolder). The form and a sample are shown in Appendix 10. NOTE: Incomplete or late proposal forms will not be accepted.

Proposals for the ORC are due one (1) week before the meeting. An electronic copy of the proposal should be sent to the Administrative Research Coordinator x2970 (Debbie.Lee@Medstar.net) and the Director of Orthopedic Research x2619, (Janet.Yu.Yahiro@Medstar.net). No hard copies of the proposal are necessary. Notices of proposal due dates are sent by e-mail and posted prominently.

In the proposal, be sure to include your budget and your bibliography with the proposal. Attach any questionnaires and data collection sheets you plan to use in your study. Also, please include your current email and pager number should questions arise while reviewing your proposal.

When designing a questionnaire or data collection sheet for your study, be sure all data is quantifiable. For example, if you are specifying right and left sides, you can assign 1 = right, 2 = left. Likewise, diagnosis, surgical procedures, genders, etc., should all be designated as numerical codes. The research staff will be glad to assist you in designing your questionnaire or data collection form.
RESEARCH PROJECTS

All research project proposals, whether funded or non-funded must be conducted under the guidance of a faculty advisor (see list below) and submitted to the ORC for review. In this way, accurate records can be kept of all orthopedic research being conducted, and updated reports can be generated as required by the MedStar Health Research Institute (the parent organization), MedStar UMH, and the IRB.

Topic Options

A list of ongoing research projects and opportunities for resident and fellow involvement is available by contacting the Administrative Coordinator (Research or Fellowship), the Director of Research, or the Director of the STAT Laboratory. An investigator may become involved in some aspect of an ongoing or upcoming project or initiate his/her own project. Each investigator is responsible for determining and fulfilling compliance with IRB regulations (see section on “Institutional Review Board” below).

Research options can include, but are not limited to, the following:
1. Basic science research (animal research requires IACUC approval, see Appendix 9)
2. Clinical research (requires IRB approval, see Appendix 6)
3. Combination of basic and clinical research, i.e., reinforcing the clinical success of a certain procedure with a biomechanical study (requires IRB approval)
4. Outcomes studies using OBERD
5. A literature review or meta-analysis of a particular topic
6. A retrospective analysis (requires IRB approval)

Faculty Advisors

Selection

A faculty advisor may be chosen from a list of MedStar attendings. With prior approval from the Department Chairman, someone outside of the Orthopedic Department or at another institution may be chosen. The responsibilities of the faculty advisors are as follows:

1. Fully review the resident’s or fellow’s proposal before it is submitted to the ORC. Make sure that the project is asking a valid, novel question and that the study as designed will answer the question. Consider the feasibility of the study in light of the time involved, expenses, and availability of specimens or equipment with which to do it.
2. Ensure that a thorough literature search has been conducted.
3. Oversee the study. Advise regarding problems that arise after the protocol begins or modifications that must be made in the methods.
4. Aid in the interpretation of the data and provide guidance as to appropriate meetings and/or journals for presenting the findings.
5. Serve as the main point of contact for manuscripts not completed by advisees prior to their departure.

Resolving Scientific Disagreements

If a disagreement should arise between investigators about a proposed or approved research project, the faculty advisor should become involved in resolving the conflict. If the disagreement is between the investigator(s) and the faculty advisor and modifications cannot be made to reach an agreement, then the ORC Chairman should be consulted to resolve the conflict. If the faculty advisor is unwilling to continue with the project, a new faculty advisor may be appointed at the discretion of the ORC Chairman.
Designing a Research Project

Basic Steps

1. State hypothesis to be tested
2. Review the literature (see below)
3. Outline research protocol
4. Consider details of study design
   a. Operational definitions - determinants of which variables to measure
      1) Clinical relevance
      2) Ease of data collection
   b. Type of study
      1) Cohort study - follows the group longitudinally forward in time
         a) Prospective
         b) Retrospective
         c) Case control
      2) Controlled or comparison study
         a) Uncontrolled
         b) Historical control
         c) Concurrent control
   c. Definition of variables: functional and subjective outcomes must be numerically quantitated to perform statistical analyses (see below)
   d. Subject/specimen selection - if a certain subject population is proposed, to which population can the results be applied?
   e. Avoidance of bias
      1) Susceptibility bias - two prognostically dissimilar groups are chosen (avoided by randomization)
      2) Performance bias - unequal performance of procedures
      3) Detection bias - outcomes not measured in a comparable fashion
      4) Transfer bias - occurs when a different proportion of subjects per group are lost to follow-up
   f. Nature of control
      1) Internal control - something with a known measurement used as a standard
      2) External control - subject, specimens, animal, etc. on whom all study procedures are done except for treatment
5. Statistical consultation: A statistical consultation should be obtained to determine the appropriate sample size and what statistical tests will be used (see below)
6. Prepare a written copy of the final hypothesis and a detailed description of the methods to be followed, including the objectives and specific aims of the project. Get final approval from faculty mentor
   a. Consent form (see Appendix 2)
   b. Organization
7. Retrospective pilot study - (optional)
8. Dry run
9. Begin the study

Literature Search

Key references must be included with the research proposal. To help avoid duplication of efforts, a literature search should be conducted for each proposed project. Each resident or fellow should access the National Library of Medicine’s Medline through Ovid or PubMed from the library page. The Online Clinical Library can
be accessed within the MedStar network through the intranet, http://starport.medstar.net under Clinical Resources or http://library.medstar.net. Articles needed but not owned can be obtained by the library.

Internet access is available in the residents and fellows’ offices, the hospital and the Medical Library (410-554-2294). For remote access to resources, contact the library staff. The Medical Library, located in the 33rd street building, 1st floor, is staffed weekdays from 8:00 a.m. to 4:30 p.m. and can be accessed 24/7 with a hospital ID badge.

**Statistical Analyses**

During the developmental stages of the project, consult with the Director of Research for information regarding study design, sample size, format for data entry, and appropriate statistical treatment. A key published article, or another study with similar methods should be submitted to aid in sample size calculations. At this meeting, decisions will be made regarding data comparisons to be made and instructions in setting up a spreadsheet will be given to enable residents and fellows to enter their data into a personal computer.

Once the study has been initiated, data should be entered on an Excel worksheet according to the instructions in Appendix 3. The research computers located in the STAT lab offices and the fellows’ office on the 4th floor of the Johnston Professional Building have this program available for your use. Once data are entered, the file should be sent electronically or put on a disk and given to the Director of Research for statistical analysis. Basic statistical analyses are performed using SPSS or SigmaStat. (See Appendix 4 for notes on statistical analysis and choosing the appropriate sample size.)

**Informed Consent**

An informed consent form (see Appendix 2) is required any time a study will describe identified human subjects. This includes not only clinical studies involving direct patient contact but also questionnaires, studies that access patient radiographs or test results, and retrospective chart reviews where individual subjects are identified. The investigator must include the form with the study proposal submitted to the ORC and to the MedStar IRB.

To download the latest version of the informed consent form visit the MedStar Health Research Institute website log on to and complete the applicable forms and the Cover Memo IRB Form.

All residents, fellows, and attending physicians who are involved in human subject research in any capacity must complete the MedStar Health Research Institute PEER (Program for Ethics Education in Research) training. Upon completion of the training, a PEER number is issued which is required when submitting materials to the IRB. Incoming fellows all complete these during the afternoon of their orientation. The Orthopedic Research office can arrange for residents or attendings to take this training either in the hospital computer classroom or from their home PC. Please allow 3 to 4 hours for completion of this training.

Note: MHRI uses the Collaborative Institutional Training Initiative (CITI) for its ethics education. CITI training certification is good for three years and can be transferred to MHRI from your previous institution.

**Determining Authorship**

Authorship requires sufficient participation in the work to take public responsibility for the content and substantial contributions to all of the following:

- Conception and design, or acquisition of data, or analysis and interpretation of the data,
- Drafting the manuscript or revising it critically for important intellectual content, and
- Approval of the version of the manuscript to be published
In addition, each author must be able to defend at least the parts of the manuscript related to his or her professional discipline.

The first author is responsible for ensuring all authors are listed. The first author should consult the attending if a question about authorship arises.

**Author Order**
The first author is typically the one who has contributed the most to the work, with other authors listed in descending order according to their levels of contribution. By convention the senior author is listed last. Decisions about the order of authors should be made as early as possible (when the project is initiated). Author order is determined by the authors. Authors may provide a publishable footnote explaining the order of authorship. A journal may require documentation of authors’ specific contributions.

**Reassigning First Authorship**
The attending, Director of Research, and/or the Department Chairman may assign writing and first authorship to another co-author in the event the fellow or resident does not provide a manuscript ready for editing before graduation. Primary authorship by investigators no longer at MedStar UMH will be reassigned by the Research Director if the department editor does not receive an acceptable manuscript within a reasonable period after completion of data analysis.

**References Available**
Please consult these sources for guidance on research publishing. These references are available in the medical library.


**Intellectual Property**
The MedStar Health, Inc. Intellectual Property Policy covers all inventions and copyrightable work done while under the employment of MedStar Health. It discusses the process and policies of pursuing a patent or copyright for an invention and the distribution of future potential royalties. A full copy of this policy can be sent to you electronically upon request from Kumar Reddy Kumar.B.Reddy@medstar.net, Director, MHRI Office of Contracts and Grants Management, 301-560-7386.

Research collaborators and student interns coming into MedStar UMH laboratories from outside institutions must sign an Intellectual Property agreement before initiating a project in our facilities. Please see the Director of Research for a copy of this agreement.
**Resident Research**

The resident research rotations occur during the PGY-4 year. The resident doing research is required to submit a proposal of the project to the ORC meeting preceding the beginning of the research rotation. This will provide the resident with sufficient time to plan and pilot the project and will allow the department enough time to order supplies and tissues. Residents may submit proposals for more than one project. However, in the case of biomechanics projects one project’s data collection must be completed before a second project may be initiated.

All residents and fellows are required to present the findings of their research rotation project during one of the orthopedic educational luncheons. In addition, sometime during their residency, residents are required to submit their projects for presentation at the Maryland Orthopaedic Association (MOA) meeting held locally each May.

A suggested timetable for residents to complete their research project in a timely manner is shown in Table 1.

**Food and Drug Administration Rotation**

Beginning the academic year 2008-2009, our program was given the unique opportunity to complement the PGY-4 residents’ research experience with a rotation at the U.S. Food and Drug Administration. Residents spend two days per week of their research rotations serving as medical officers in the FDA’s Orthopedic Device Division. During this time they:

- Assist in the evaluation of orthopedic implants and other surgical devices used in orthopaedics by providing clinical consultation and review of clinical study designs and safety and effectiveness data for new orthopedic devices.
- Assist with the development of guidance documents and provide clinical input for Health Hazard Evaluations and subsequent recalls.
- Gain exposure to product areas including: total joints, fracture fixation devices, bone growth stimulation, spinal system, and other frequently used fixative and implantable equipment involved in the treatment of orthopedic related indications.

Upon completion of the FDA rotation residents are expected to be able to develop strategies to evaluate clinical and non-clinical aspects of medical device research based upon knowledge of the medical device industry gained through:

- market research
- risk assessment
- identification of innovative and emerging technologies
- information gathering and analysis
- identification of potential dangers with device use
- assessment of the industry's evolution, capabilities, and trends
- legal and regulatory trends
- political developments and economic conditions.

Residents will also have gained knowledge in the critical analysis of large data sets and the use of clinical information within a regulatory framework to recommend and guide judicious, crucial decision making. They should also be able to understand and analyze the post market medical device reporting role in public health and have gained exposure to and participation in a variety of public health issues and Offices within FDA related to orthopedic medicine.
Table 1. Suggested Timetable for Residents to Complete Research Project

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<th>Period</th>
<th>PGY-2</th>
<th>PGY-3</th>
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<th>PGY-3/PGY-4</th>
<th>PGY-4</th>
<th>PGY-5/PGY-6</th>
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<td>August</td>
<td>Research orientation. Introduction to key personnel involved with research and orientation to the research program/facilities. Take CITI training.</td>
<td>Select research topic. Meet with faculty advisor to formulate question and discuss scope of project. Meet with Director of Research and Director of STAT Laboratory (if doing a biomechanical project) to discuss study design. Literature search.</td>
<td>Along with faculty advisor, develop a written proposal. Develop a budget if required. Submit proposal and budget to ORC. Submit IRB forms (visit Clinical Research Coordinator), and/or IACUC forms (visit head of Microsurgery and see Appendix 9) to appropriate committee. All rat studies must be reviewed and approved by Dr. Ken Means before they can be initiated. Send a copy of the proposal for rat studies to the Microsurgical Lab researcher and to the head of the IACUC committee* to coordinate the obtaining and housing of animals. *IACUC studies must go to: 1. Dr. Ken Means, 2. Syed M. Rizvi , and 3. Sione Fanua</td>
<td>Order supplies for approved project. Submit request for anatomic tissue if required. If possible, conduct short pilot studies or dry runs of experiments.</td>
<td>Begin experiments/data collection. Optimize the 6-month research rotation. Begin and complete project, draft materials and methods section of paper. Complete data entry. Submit raw data to director of research for analysis and meet to review results. Draft results section of paper. Determine the deadline for abstract submission at a national meeting and begin preparation (podium or poster). Request publication/presentation funds. Present project to peers at an Orthopedic Educational Luncheon. Spend three days per week serving as medical officers in the FDA’s Orthopedic Device Division. Apply for the Roger H. Michael Research Award.</td>
<td>Submit abstract to the MOA and the ORS meeting. Present research at the MOA and at a national meeting. Submit paper to attending for review and comment, and then provide revised paper to Orthopedic Research editor. Complete all revisions required so editor can submit the paper to a journal. Present research at the Visiting Professor Lectureship Conference.</td>
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Fellow Research

Fellows are expected to participate in at least two research projects during their fellowship. On one of these projects, the fellow will serve as principal investigator taking the project from the inception of the idea to the completing of data analysis and publication of the findings. Fellows should formulate their ideas and submit proposals for review and present them at the regularly scheduled ORC meetings. Fellows should endeavor to have data analysis, abstract preparation, and a manuscript completed before finishing the year of training.

All fellows are encouraged to present their research at a national meeting during the year after fellowship training. Funding is available to attend this meeting once the introduction, methods, and results sections have been submitted to the editor. Additional funding may be available by applying for the Roger H. Michael Research Award.

The following tables summarize the recommended timetable for Sports Medicine, Foot and Ankle and Shoulder & Elbow Fellows

**Sports Medicine Fellow Research Requirements**

Within our sports medicine research facilities, we currently have expertise in performing clinical, epidemiological, and biomechanical research projects; however, we are also developing capabilities for motion analysis and orthobiologics (basic science, soft tissue, and animal) studies. At a minimum, the fellow will be responsible for one biomechanical/basic science project. It is also highly encouraged to be involved in at least one additional clinical, epidemiological, or orthobiologics project. The fellow MUST complete at least one study in which they are the principal investigator who completes all aspects of the study, including design, data collection, data analysis, manuscript preparation, manuscript submission, presentation, and publication.

For clinical studies, the fellow may perform a retrospective chart review or become involved in a multi-year prospective clinical trial, including our newly developed OBERD outcomes database. For epidemiology studies, the fellow may develop a short-term study with a focused research question or become involved in one of our multi-year studies that is already in progress. Our biomechanical studies are coordinated by the director of our Biomechanics Research Lab where we are developing static and dynamic models for the shoulder, elbow, and knee. The lab is equipped with MTS load frames, Tekscan/IScan pressure sensors, etc. Please refer to the Physical Plant section of this manual to view a more extensive list of available equipment and resources.

Sports Medicine Fellows will have scheduled meetings and evaluations (Appendix 16) with the Director of Sports Medicine Research, Lab Director, and the Director of Orthopedic Research to assure that the fellow is completing all research tasks in a timely manner. For those fellows who do not meet the research requirements, we will convene our sports medicine research committee, including the Sports Medicine Fellowship Director, the Director of Sports Medicine Research, and the Director of Orthopedic Research, to discuss the next course of action. As we believe that the research component to our fellowship is extremely valuable in the training process for our fellows, any deficiencies in completing the research requirements will be taken seriously and could result in suspension of clinical privileges and/or not graduating after a thorough review of each individual situation by our sports medicine research committee.
Table 2: Suggested Timetable for Sports Medicine Fellows to Complete Research Project

| May – mid-July | Take the CITI test to receive a PEER Number for the IRB.  
| August | Research orientation. Introduction to research personnel and orientation to the research program/facilities.  
| | Select a research topic with clinical faculty advisor.  
| | Meet with Clinical Faculty Advisor, Director of Sports Medicine Research, and Director of Orthopedic Research to formulate questions and discuss scope of project. Depending upon the type of project, meet with the corresponding Lab Director:  
| | 1. Clinical – Janet-Yu Yahirol (janet.yu.yahirol@medstar.net)  
| | 2. Epidemiology – Andy Lincoln (andy.lincoln@medstar.net)  
| | 3. Biomechanics – Brent Parks (bparks@comcast.net)  
| | 4. Motion Analysis – Pending  
| | 5. Orthobiologics – Zijun Zhang (zijun.zhang@medstar.net)  
| | 6. Outcomes – Gina Bissett (regina.bissett@medstar.net)  
| | Along with your project’s clinical faculty advisor and Lab Director develop a written proposal. Develop a budget if required. Submit proposal and budget to ORC. Submit IRB (Appendix 6) and/or IACUC forms (Appendix 9) to appropriate committee. Send a copy of the proposal for rat studies to the Microsurgical Lab researcher to coordinate the obtaining and housing of animals and to Dr. Ken Means for his approval.  
| Before project initiation | Order supplies for approved project. Submit request for anatomic tissue if required.  
| | If possible, conduct short pilot studies or dry runs of experiments.  
| Research rotation/research time allocated | Plan well to optimize your research time.  
| | Write your introduction and methods at the beginning of your data collection and review with your clinical faculty advisor, respective lab director (clinical, biomechanical, orthobiologic) and the Orthopedic Research Editor (Lyn Camire).  
| | Start and Complete Data Collection.  
| | Submit raw data to the Director of Orthopedic Research for analysis and meet to review results along with clinical faculty advisor.  
| | Discuss data collection results and analysis objectives with clinical faculty advisor, Director of Orthopedic Research, respective lab director (clinical, biomechanical, orthobiologic) and Orthopedic Research Editor.  
| | Write and submit abstract to the MOA (http://www.mdortho.org/) and a national meeting.
<table>
<thead>
<tr>
<th>Prepare project for presentation (oral or poster). Submit introduction, methods, and results sections to clinical faculty advisor and Orthopedic Research Editor. Request publication/presentation funds. Present project for peer review at the Departmental Orthopedic Educational luncheon before attending the MOA meeting.</th>
</tr>
</thead>
<tbody>
<tr>
<td>March - June</td>
</tr>
<tr>
<td>June - July</td>
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</table>

**Table 3. Specific Requirements for Sports Epidemiology Projects**

| Aug | Meet with Andy Lincoln to discuss the sports injury epidemiology project |
| Sept | Submit and present a research project to the ORC. Revise and resubmit any ORC proposals that are approved conditionally Draft an abstract of your study in 300 words or less and e-mail to Lyn. This is the basis of the required MOA abstract submission. Meet with Andy Lincoln to discuss setting up database and initiating data collection |
| Sept-Dec | Review the literature and write the Methods portion of the manuscript |
| Dec 1 & Feb 1 | Submit interim progress reports to Research Coordinator |
| Jan-Mar | Draft the manuscript. Schedule biweekly meetings with Lyn Camire and Andy Lincoln to discuss your findings and focus the paper |
**Table 4: Suggested Timetable for Foot and Ankle Fellows to Complete Research Project**

<table>
<thead>
<tr>
<th>August</th>
<th>Research orientation. Introduction to research personnel and orientation to the research program/facilities. Confirm research topic with attendings. Take the CITI test to receive a PEER Number for the IRB. Select a research topic with clinical faculty advisor. Meet with faculty advisor to formulate question and discuss scope of project. Meet with Director of Research and Director of STAT Laboratory to discuss study design. Along with your project’s faculty advisor and Lab Director develop a written proposal. Submit IRB (Appendix 6) and/or IACUC forms (Appendix 7) to appropriate committee. Send a copy of the proposal for rat studies to the Microsurgical Lab researcher to coordinate the obtaining and housing of animals and to Dr. Ken Means for his approval.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before research rotation</td>
<td>Do a more comprehensive literature search on your topic Order supplies for approved project. Submit request for anatomic tissue if required. If possible, conduct short pilot studies or dry runs of experiments.</td>
</tr>
<tr>
<td>Research rotation/ research time allocated</td>
<td>Plan well to optimize your research time. Write your introduction and methods at the beginning of your data collection and review with your clinical faculty advisor, respective lab director (clinical, biomechanical, orthobiologic) and the Orthopedic Research Editor (Lyn Camire). Start and Complete Data Collection. Submit raw data to the Director of Orthopedic Research for analysis and meet to review results along with clinical faculty advisor. Discuss data collection results and analysis objectives with clinical faculty advisor, Director of Orthopedic Research, respective lab director (clinical, biomechanical, orthobiologic) and Orthopedic Research Editor. Write and submit abstract to the MOA (<a href="http://www.mdortho.org/">http://www.mdortho.org/</a>) and a national meeting. Prepare project for presentation (oral or poster). Submit introduction, methods, and results sections to clinical faculty advisor and Orthopedic Research Editor. Request publication/presentation funds. Present project for peer review at the Departmental Orthopedic Educational luncheon before attending the MOA meeting.</td>
</tr>
<tr>
<td>March - June</td>
<td>Submit abstract to a national meeting. Write discussion. Submit rough draft paper to clinical faculty advisor and Lab Director for review and comment. Complete all requested revisions and send the paper to the Orthopedic Research Editor for editing. Present research at the Visiting Professor Lectureship Conference.</td>
</tr>
<tr>
<td>June - July</td>
<td>Complete work on paper with the Orthopedic Research Editor. Be sure that the Editor has all files relating to the manuscript prior to fellowship graduation.</td>
</tr>
</tbody>
</table>
Table 5: Suggested Timetable for Shoulder and Elbow Fellows to Complete Research Project

<table>
<thead>
<tr>
<th>Month</th>
<th>Description</th>
</tr>
</thead>
</table>
| August     | Research orientation. Introduction to research personnel and orientation to the research program/facilities. Confirm research topic with attendings. Take the CITI test to receive a PEER Number for the IRB.  
Select a research topic with clinical faculty advisor. Meet with faculty advisor to formulate question and discuss scope of project. Meet with Director of Research and Director of STAT Laboratory to discuss study design.  
Along with your project’s faculty advisor and Lab Director develop a written proposal. Develop a budget if required. Submit proposal and budget to ORC. Submit IRB (Appendix 6) and/or IACUC forms (Appendix 7) to appropriate committee. Send a copy of the proposal for rat studies to the Microsurgical Lab researcher to coordinate the obtaining and housing of animals and to Dr. Ken Means for his approval. |
| Before research rotation | Order supplies for approved project. Submit request for anatomic tissue if required. If possible, conduct short pilot studies or dry runs of experiments. |
| March - June | Submit abstract to a national meeting.  
Write discussion. Submit rough draft paper to clinical faculty advisor and Lab Director for review and comment. Complete all requested revisions and send the paper to the Orthopedic Research Editor for editing.  
Present research at the Visiting Professor Lectureship Conference. |
| June - July | Complete work on paper with the Orthopedic Research Editor. Be sure that the Editor has all files relating to the manuscript prior to fellowship graduation. |
FUNDING
All projects must be submitted to the ORC for review and approval before initiation.

Internal Sources

Orthopedic Research Committee
The ORC offers funding support for research projects. A resident or fellow may apply for these funds by completing the Proposal for Orthopaedics Research Project (see Appendix 10).

Presentation and Publication Fund
Only projects submitted to the ORC before initiation (funded or nonfunded), and which have received a project number, will be eligible for monetary support from the Presentation and Publication Fund after completion of the study.

Monies for expenses related to presentation and publication of approved proposals will be allocated from the Presentation and Publication Fund. The investigator must submit a form to access these funds (available in the Research Office) along with notification of acceptance of abstract for presentation. Approved expenses include:

1. Fees for poster preparation up to $200.00 per poster (see Appendix 11 for a list of vendors used by department members).
2. Fees for one investigator to travel to one meeting to present the major findings of the project ($1500.00 maximum).
3. Manuscript submission fees.
4. Fees for illustrations for publications. The maximum amount allowed per medical illustration is $150, with a limit of three illustrations per publication. The editor has a list of artists available.

Reimbursable expenses (a total of $1,500):
1. Airfare or mileage to the meeting
2. Two-night stay in hotel
3. Registration fee
4. Standard per diem for food and transit fees

External Sources

Researchers are encouraged to pursue outside sources of funding. Applications for and assistance with obtaining these funds are available from the Director of Research. Visit the Orthopaedic Research website at MedStarHealth.org/OrthopaedicResearch for a list of potential grant sources.

Possible sources include:
1. Orthopedic related foundations
   a. Orthopaedic Research and Education Foundation
   b. DePuy Orthopaedic Research Grants
   c. Arthritis Foundation (at the local and national levels)
   d. Specialty societies such as the Foot and Ankle Society and North American Spine Society
2. Private foundations
3. Commercial organizations such as orthopedic device manufacturers
Appropriate Use of Research Funds

It is the intention of the Department of Orthopaedics and Sports Medicine that projects funded by the ORC be performed by MedStar UMH personnel at UMH or other MedStar facilities. This does not preclude involvement in multicenter studies, but the intention is to not become a source of funding for research performed at other institutions.

Research funds will not be allocated for projects originating in an academic institution other than MedStar UMH, even if a faculty member, resident, or fellow is participating. Field studies may be conducted as long as the primary investigator is from MedStar UMH and a majority of the data analysis and manuscript preparation takes place in this Department. Taking research funds to another institution for the completion of a project will not be allowed.

After a project is approved for funding by the ORC, the investigator will receive a project number. Invoices for all items or services for that project should have the project number written on them and should be ordered through the Research Coordinator. The Research Coordinator will periodically send the principal investigator a statement of the research account. All research money must be used within the fiscal year in which it is received (July 1 to June 30). To maximize research funds, all supplies needed for a particular study should be ordered by May 15 and invoiced and received by June 30. Because the Department will lose any money not used by that date, each researcher must make an effort to anticipate needs and order supplies in advance.

Periodically, the investigator will be asked to give a status report of the research project. This allows the ORC to know whether a project is underway, inactivated, or near completion. The report is designed to be extremely easy for the investigator to complete. All recipients of ORC funds will be sent periodic project update forms that must be completed and returned within 2 weeks. If the forms are not received within that time, the investigator will be given a second notification. Investigators will not be allowed to use any of the project funds until the project update form has been completed and returned. Filing this report will help the ORC to determine which projects are completed, and it will provide a more accurate financial picture for the ORC meetings. It is imperative that investigators complete these brief forms in a prompt fashion and return them to the Administrative.

At the conclusion of the study, any funds remaining from a research grant must be returned to the ORC. Leftover funds may not be applied by the investigator to any other project. The ORC will redistribute the funds to other projects approved by the ORC. In addition, leftover funds may not be used for other unbudgeted related expenses, such as travel to a meeting.

Certain situations will mandate that research expenses be carried over into the following fiscal year. If this is the case, investigators will not lose their money, but less money will be available for other investigators the next fiscal year.

Guidelines for Patient Charges in Research Studies

Clinical studies often involve tests, visits, or procedures over and above what a patient would normally receive for a particular problem. A patient and/or his or her insurance can be charged only for those expenses that comprise the normal standard of care for the diagnosis. Research funds must pay for any extra radiographic procedures, blood tests, etc. even if they are of great benefit to the patient. In addition, patients should be reimbursed for parking expenses related to any extra visits made for study purposes. NOTE: Although it is standard practice to offer incentives or monetary gifts for participation in a research project, the ORC’s limited funds cannot cover these expenses.
STUDIES INVOLVING PATIENT CONTACT

Mandatory Preinitiation Approvals

Imaging
All projects involving the use of radiation (e.g., radiographs, MRI) must be submitted to, and approved by, the MedStar Union Memorial Hospital Radiation Safety Committee before submission to the IRB. The Committee meets quarterly therefore submissions should be done early. Contact Jane Machin, Imaging Services Supervisor (x2420), for deadline and submission requirements.

General Comments
Radiographs and magnetic resonance imaging can be obtained through the radiology facility of Greater Chesapeake Orthopaedic Associates on the fourth floor of the Johnston Professional Building. Bone density scans can be performed by the MedStar UMH facility located on the ground floor of the Johnston Professional Building. In addition, the research project number, as issued by the Research Coordinator, should be noted on all forms requesting radiographs for which payment will be made and the study has agreed to pay. In this way, patients are not charged for imaging that is required by the study but is above and beyond that allowed by their normal plans of care. The cost of imaging will be $1000.00 per type of test per project. For example, for a study of 25 specimens that need both CT scans and bone density tests, the cost for imaging services would be a total of $2000.00.

Policy on Radiation Risk
1. When extra ionizing radiation is involved in a research protocol, the consent form is ordinarily expected to include one of the two following statements:
   a. The amount of (extra) radiation you will receive as part of this research study is less than __% (calculated as the percentage of a total allowable 5 rads per year) of an annual occupational exposure limit that has not been associated with increased risk of cancer or birth defects.
   b. The amount of (extra) radiation you will receive as part of this research study is ________ (the investigator inserts a suitable analogy).

2. An additional qualifying statement is required, when radiation exposure for research purposes involves any of the following special groups of subjects:
   a. Normal volunteers
   b. Research subjects for who benefits of study are negligible
   c. Minors
   d. Women of childbearing potential
   e. Patients at risk for multiple studies

The preferred qualifying statement is as follows:
"The long term effects of low-level radiation, if any, are not clearly defined at present, but the chance that you personally will suffer ill consequences is considered to be very low."

In addition, if any subject in the above special groups receives more than 2 rads from participating in a single research study, he/she must receive an additional statement, as follows:
"You will receive (extra) radiation amounting to ____ rads in this study. For maximal safety, your research-related radiation exposure should not exceed 5 rads per year, which has been designated as the allowable annual occupational exposure limit."
INSTITUTIONAL REVIEW BOARD AND SCIENTIFIC REVIEW BOARD

Institutional Review Board

MHRI requires that research personnel submitting to the IRB must complete IRB training. This incorporates initial and continuing education in human research ethics, standards for the responsible conduct of research, pertinent regulations, and specific procedures. This is **MANDATORY** for the primary investigator, all co-investigators, the clinical coordinator and administrative personnel (data stewards, IT, etc). This training can be accessed on the MHRI website by selecting the Office of Research Integrity link for a full explanation of the requirements. Upon completion of IRB training, MedStar issues each individual a MedStar PEER (Program for Ethics Education in Research) number which is required on all IRB paperwork (see Appendix 6 for further details).

MHRI has partnered with Chesapeake IRB, a commercial IRB service. Chesapeake IRB will perform IRB reviews for commercially-sponsored, multicenter trials beginning in April 2012 (see Appendix 7 for policy and fee schedule and MHRI website for further details)

https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Institutional-Review-Board-IRB.aspx

Coordinated use of the Chesapeake IRB will be conducted by the ORI and Scientific Center Administrative directors. The MHRI IRBs will continue to review all federal, state, foundation, and investigator-initiated studies. ORI will continue to perform compliance reviews and monitoring.

For questions contact the MHRI Office of Research Integrity at 301-560-2912.

Scientific Review Board

Implemented in October of 2006, the MedStar Health Research Institute Scientific Review Board (SRB) is charged with ensuring that research submitted for review to MedStar Health Research Institute Institutional Review Boards is scientifically sound. In so doing the SRB will serve as the scientific advisor to the MHRI IRBs and will, therefore, play a key role in ensuring that the highest standards for the conduct of research involving human subjects are met throughout the MedStar community.

The Scientific Review Board (SRB) operates under the supervision of the MHRI Office of Scientific Affairs. The SRB is charged with advising the IRB on the scientific merit of projects submitted for ethical review. As a result, any questions or concerns regarding the scientific structure of a project are identified and addressed before the IRB meets. By ensuring that studies submitted to the IRB for ethical review are scientifically sound, the SRB will allow the IRB to focus on its role as an ethical oversight body. Submission to the SRB is optional.

All investigator-initiated studies that are more than minimal risk must be reviewed by the SRB prior to approval by the IRB. See Appendix 8 for policy and SRB website for details

https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Scientific-Review-Board-SRB.aspx

**Proposals for Submission for Full Review**

Projects approved by the ORC that use research involving patient information of any kind (including direct patient testing, chart reviews, and review of anonymous database information) must be submitted to the IRB for its approval. Guidelines and fees for submission to the IRB are found in Appendices 5, 6, and 7. Please refer to the MedStar website for updated guidelines.
A project that has IRB approval from another institution must still be approved by the MedStar IRB before it can be conducted at MedStar UMH. A project performed off-site must also be approved by the MedStar IRB.

For questions contact the Research Coordinator in the Orthopedic Research office at x2970.

**Proposals for Submission for Expedited Review**

The only human-subject proposals that are eligible for expedited review are chart review studies with no patient contact (including telephone conversations, sending written questionnaires, or patient follow-up visits). Any study involving patient contact MUST be processed through the full IRB review.

All IRB submissions must be submitted electronically to: IRBSubmissions@medstar.net with all required forms attached.

**Schedule for IRB submissions**

The Baltimore IRB meets the 4th Tuesday of each month at MedStar Union Memorial Hospital. Proposals are due two (2) weeks prior to the IRB meeting date on Mondays.

The Washington, DC IRB meets the 2nd Tuesday of each month at the Washington Hospital Center. Proposals are due two (2) weeks prior to the IRB meeting date on Fridays.

The IRB meeting dates are subject to change during holidays such as Thanksgiving and Christmas. Specific meeting dates and submission deadlines can be found at the [MHRI website](#).

The MedStar ORI highly recommends submitting proposals as early as possible. If the committee gets too many proposals they may reschedule some to the next month’s meeting even if they are received by the deadline.

**Contract Work**

Contract work does not need to be submitted to the IRB unless it involves research that meets the above criteria.

**Research Guidelines and Deadlines**

Proposals for the ORC must be submitted to the Research Coordinator at least one (1) week before the ORC meeting or they will not be considered for funding at that meeting. Proposals received after this deadline will be held for consideration at the next ORC meeting. Exceptions to this policy due to extenuating circumstances can be granted only by the Director of Research.

As soon as data collection is complete, the primary investigator should confirm that the completed data have been received by the Director of Research for statistical analysis.
RESOURCES

Research Conferences
Throughout the year, conferences are held for training in specific areas. The conferences early in the year focus on research, with lectures on study design (e.g., choosing the appropriate sample size), statistical analysis, and instrumentation. Conferences throughout the rest of the year address an array of orthopedic-related topics.

Journal clubs enable house staff to stay abreast of current research topics and to hone their skills in critically evaluating research with respect to study design, methods, and statistical analysis.

Educational luncheon conferences are held approximately six times per year. Past presentations have included: research by residents, fellows, physicians, and staff; seminars on IRB procedures; and publishing and audiovisual workshops. All residents, fellows, staff, and faculty are invited and encouraged to attend.

The Visiting Professor Laboratory and Lectureship is held annually in June. This conference provides a culminating activity for residents and fellows to showcase their research done at MedStar Union Memorial. Each year one orthopedist who is prominent for his research and clinical contributions in his subspecialty is invited to teach a special morning laboratory and then be a keynote luncheon speaker. This Research Day is attended by all of our orthopedic attendings, residents, fellows, research staff, and special invited guests. After the keynote address, research presentations are given by the departments’ graduating chief residents and fellows.

Libraries

MedStar Union Memorial Hospital Medical Library
The Library is located on the first floor of the 33rd street building. The library is staffed weekdays from 8:00 a.m. to 4:30 p.m. and can be accessed 24/7 with a hospital ID badge. The library can be reached at x2294. Along with the computers, copiers, and print materials available in the library, many resources are also available online. The Online Clinical Library within the MedStar network can be accessed through the intranet, StarPort.MedStar.net or http://library.medstar.net. Contact the library staff for remote access to the library resources. MedStar UMH offerings include PubMed with LinkOuts, Ovid, Access Surgery, Access Medicine, MDConsult, Cochrane Library, STATRef texts, Micromedex drug information, ePocrates Diseases UpToDate (within the network only), and over 400 e-journals.

The library staff can assist in literature searches and providing document delivery for those journal articles/book chapters that they do not own. This outside service can take a few days so please try to plan accordingly. Consumer Health information geared towards patients and their family is also available.

Orthopaedic Library
The Orthopaedic Library has a selection of orthopedic textbooks and is located in the Johnston Professional Building within the orthopedic offices. A compilation of publications by Department staff are maintained. Materials must remain in the library, which is made available to all staff and attendings.

Sports Medicine Library
The Sports Medicine Library is located on the fourth floor of the Johnston Professional Building in the fellows’ office. The collection has a diverse and up to date selection of sports medicine textbooks, reference books, and journal articles. Please sign out any books you borrow with the Fellowship Coordinator.
Laboratories

A total of 10,000 square feet of well-equipped research space is dedicated to orthopedic research and surgical skills training. Two separate areas provide a wide array of research and training opportunities ranging from biomechanical studies to tendon cell biology. These facilities support resident and fellow projects and education, company sponsored grants, and NIH and foundation funded research. After completion of their research rotation, all residents and fellows receive an annual evaluation by the lab director (see Appendix 16).

I. Biomechanical Research and Surgical Techniques and Technology Laboratory

The Biomechanical Research and Surgical Techniques and Technology (STAT) Laboratory is a state-of-the-art laboratory that offers multistation facilities for surgical techniques training and separate areas dedicated to biomechanical research studies. Research equipment and facilities are listed below. If there is a particular piece of equipment or capability that is needed but is not listed, please ask. Access to the equipment or a capability at another institution may be obtained.

Safety Requirements

Posted safety precautions must be followed at all times. Protocols and schedules have been established to assure that safety measures meet established criteria consistently and according to standard operating procedures. Refer to the Safety Manuals for information on:

Handling of chemicals: MedStar Union Memorial Safety Manual
Blood borne pathogens: Department of Infection Control Safety Manual
Radiographic markers: Department of Nuclear Medicine Safety Manual
Radiation safety: Department of Nuclear Medicine Safety Manual

The protocols can also be accessed online on the MedStar UMH StarPort at: http://starport4.medstar.net/UMH/HP/Home.aspx under Infection Control and Policies and Procedures.

Radiation Safety Requirements

IMPORTANT: Before using any of the fluoroscopic or x-ray equipment you must obtain a radiation badge from the lab director. You must also wear a lead gown anytime you are using this equipment. Projects may be terminated if a person is found in violation of these radiation safety rules.

Physical Plants

Biomechanical Testing

The mechanical testing facility includes the following equipment (see Appendix 12 for fees applicable to studies with outside funding):

1) Two MTS Systems mechanical load frames, one uniaxial electromechanical, and one biaxial servohydraulic. Servohydraulic test systems are capable of loading a sample to failure in a single catastrophic load, or fatigue loading a sample with repetitive load cycles
2) A Claron 3-dimensional tracking system is available to measure the relative motion between bone segments (or bones) with six degrees of freedom (three rotations, three translations)
3) A custom designed and fabricated Hand Flexor Tendon frame is available for investigating hand flexor tendon injuries as well as bony reconstructions of the hand
4) Custom designed and fabricated frame for testing ankle ligament stability
5) An array of fixtures is available to hold various anatomic specimens and orthopedic devices for biomechanical testing. Specialized fixtures can be designed and fabricated as required.

6) Strain/deformation measuring devices include: strain gauges, extensometers (including a non-contacting laser extensometer), linear variable differential transformers (LVDTs), rotational variable inductance transformer (RVIT).

7) Chemical hood

8) Data acquisition and reduction software packages for connection to any of the test machines

9) A Fluoroscan III mini C-arm is available to facilitate surgical procedures

10) Two large C-arms (Siemens) for training courses and facilitating surgical procedures


12) Cryogenic Soft Tissue grips for testing soft tissue samples such as ligaments and tendons.

13) A rapid rate torsion tester, which allows accurate testing of small bones (i.e., rat or mouse bones) in torsion.

14) The F-scan in-shoe pressure/force measurement system for in-shoe or under foot pressure measurements. This system can be used for both clinical and biomechanical studies.

15) The Tekscan ISCAN system for in-joint pressure measurement studies. Sensor maps are available for the knee, ankle, shoulder, and small joints.

16) Five full arthroscopy carts are available for training/practice/research purposes. A digital capture system is available to capture digital photographs and video clips of arthroscopic surgical procedures.

17) Specimens on which to practice dissection and arthroscopic techniques are kept in the freezers and are available by request through the Director of the Biomechanics Laboratory.

18) Three Stryker TPS power sets and two large Stryker power sets.

19) Data acquisition, reduction, and analysis capabilities include the following:
   a) Labview full-application software (on three computers)
   b) Microsoft Office Software, including Excel, PowerPoint, Word, and Access
   c) SPSS, SYSTAT, SigmaStat, and SigmaPlot statistical software packages
   d) MTS Testware

20) Space for preparation of, and training with, anatomic specimens obtained through the Maryland State Anatomy Board. Surgical equipment and all types of orthopedic devices and equipment are available.

21) Walk-in freezer for anatomic specimen storage, and two, two-body morgue refrigerators for temporary specimen storage.

22) Freezer area with three -20°C freezers for storage of anatomical and animals specimens for research, and four -80°C freezer for low temperature storage.

23) Two refrigerators for thawing and overnight storage of anatomic specimens.

24) Vertical milling machine that provides a rigid platform with x, y, z movements for experimental setups and minor modifications to test fixtures.

25) Small horizontal lathe

26) Ability to design and have fabricated custom testing devices as needed.

II. Biologics Laboratories for Orthopedic Research

Orthopedic Research Laboratory
The original orthopedic laboratory in this area was created to support research in the study of bone metabolism and translational research involving hip fracture recovery. Funded primarily through a series of NIH sponsored grants, this fully equipped laboratory has the capability to perform a wide range of serum and urine assays in both the human and animal model. These facilities also support a wide range of projects including those investigating animal models for the study of particular orthopedic problems and a variety of pharmaceutical and medical device company sponsored studies. Equipment available in this laboratory includes:

1. Three -80°C freezers
2. One -40°C freezer
3. One -20°C freezer
4. A Heraeus Labofuge 400R refrigerated centrifuge
5. A chemical hood
6. An Orion 520 pH Meter
7. An Olympus microscope fully equipped for photomicroscopy
8. A Zeiss dissecting microscope
9. A gamma counter
10. A wide variety of small laboratory equipment

**Orthobiologics Laboratory**

The mission of the Orthobiologics Lab (OBL) is to bridge the gap between the clinical and basic sciences in the domain of musculoskeletal disorders. The OBL specifically focuses on translating stem/progenitor cell technology and biologics to bone regeneration, cartilage repair, and tendinopathy treatment. Tissues, cells, DNA, RNA, and proteins are routinely used to investigate the clinical impact of orthobiologics, such as growth factors, stem cells, allografts, and synthetic matrices. The OBL supports research projects pertinent to general orthopaedics and foot and ankle surgery by means of cell biology and molecular biology, and provides necessary technical training and assistance in about 5,000 square feet of space.

The OBL is equipped with state-of-the-art molecular and cellular biology instruments:

1) **Tissue culture room.** This area is used for cell isolation and cell culture. The facility includes:
   a. Two CO₂ incubators
   b. Two Biosafety Class II laminar flow hoods that provide a sterile environment to allow safe handling of human tissues
   c. An inverted microscope for observing cell growth
   d. A water bath
   e. An oxygen chamber for hypoxic tissue culture

2) **Molecular biology room.** This area is used for RNA/protein extraction, gene expression analysis, and protein quantification. Instruments include:
   a. Real time PCR that amplifies gene expression at real time for quantification and analysis
   b. An MJ Research DNA Engine PTC-200 thermocycler used for gene amplification
   c. Labnet Gel XL Ultra V2 and Gel-PRO electrophoresis systems used for regular PCR and western blot
   d. A Bio-Rad spectrophotometer for RNA and DNA quantification
   e. A SpectraMax 190 spectrophotometer is used for ELISA to quantify the concentration of proteins
   f. A Glas-Col homogenizer and ceramic mortar and pestle are used for pulverizing tissues for extracting RNA and proteins
   g. An Eppendorf refrigerated centrifuge

3) **Histo/cytology room:** This area is used for processing tissue samples and staining tissue sections with immunohistochemistry and histochemistry. It includes:
   a. A flow cytometer for quantitative analysis of cell population and cell sorting

4) **Imaging room** that contains:
   a. An Olympus inverted microscope and digital imaging system
   b. A Bio-Rad ChemiDoc XRS system that is used to image protein and DNA gels for quantification

5) **Storage equipment includes:**
   a. Three 4°C refrigerators
   b. Two -20°C freezers
   c. One -80°C freezer
   d. One liquid nitrogen tank for long term storage

6) **Other facilities:**
   a. Two pH meters
   b. Two chemical hoods
   c. Two benchtop autoclaves
   d. Two benchtop incubators
   e. One water purifier

7) **Office area** is equipped with desktop computers, printers, and a fax machine
III. Other Research Resources

Microsurgical Laboratory
This laboratory, accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), is available for both survival and non-survival small animal research studies and training in microsurgical procedures. The facility can house small animals. The microsurgical lab contains three dissecting microscopes and related microsurgical instruments. In-depth microsurgery training courses are available.

Surgical Research Facilities
The University of Maryland Biotechnology Institute (UMBI) and the Thomas D. Morris, Inc. (TDMI) Surgical Research Center both offer excellent surgical research facilities for conducting in-vivo research. The UMBI facility, located in downtown Baltimore, offers animal housing and surgical facilities designed to manage small rodents through non-human primate models. The facility also offers excellent histology, immunocytochemistry, and cell biology laboratories.

The TDMI facility is located in Reisterstown, Maryland on 250 acres of farmland. The 10,000 square foot animal research and surgical training facility provides outstanding resources for domestic livestock models. This animal research facility has attracted and been used by a number of private industry companies for product research and development purposes. When beginning a new research project at TDMI it is important to arrive early the first morning to see a PowerPoint presentation and sign off on it before the study can begin. Further information is available at www.thomasdmorris.com.

These in-vivo research facilities are open to all MedStar UMH orthopedic residents and attendings for research projects. Both facilities are licensed by the United States Department of Agriculture, the NIH, and are approved by the AAALAC - the highest level obtainable by an animal research facility. Study protocols are first reviewed by the Institutional Animal Care and Use Committees (IACUC), which include veterinarians, laboratory scientists, and animal husbandry personnel. Protocols must be approved before study initiation. Both facilities contain sterile processing, electrosurgical units, fluoroscopes (C-Arm), x-ray, hydraulic operating room tables, and orthopedic surgical instruments. Postoperatively, study animals are maintained under climate-controlled conditions and/or in an open ranch environment, with animal husbandry technicians and veterinarians available to perform and/or assist with the postoperative care. Before initiating animal studies, an IACUC form must be completed. See Janet Yu-Yahiro, Director of Orthopedic Research for more information.

Osteoporosis Center
Houses a GE Lunar densitometer for assessing bone mineral density by dual x-ray absorptiometry. This equipment can be used for clinical studies, analysis of the density of excised cadaver material, small animal studies, and measurement of body composition. Contact the director of the Biomechanics Laboratory for obtaining DEXA scans.
1. Hand held dynamometer for analyzing grip strength
2. Skin fold calipers to determine body composition

Histology and Histomorphometry
1. Capacity to prepare and analyze undecalcified histologic slides.
2. Bioquant image analysis system (R&M Biometrics, Nashville, TN): this system includes an Olympus microscope with fluorescence capability, a Sigma Plot digitizing tablet, and an Optronics video camera. The system enables quantitative analysis of tissue structures on microscope slides, radiographs, or computed tomography scans using the light box attachment, or images on photographic film using the digitizing tablet. Quantitative information can be obtained semiautomatically by color, shape, or size.
Photomicrographs can be obtained through the microscope using a 35-mm camera attachment. Sigma Scan versions 3.10 and 3.90 for analysis of video material and x-ray data are located on the Bioquant image analysis system.

Histomorphometry of decalcified bone specimens is available through an outside laboratory for processing and staining. The Center for Bone and Periodontal Research at McGill University in Montreal provides a variety of services for embedding, sectioning, and staining of study samples. For information and academic pricing go to www.bone.mcgill.ca or 514-398-6028.

Preparation of histological slides from paraffin blocks is available through the MedStar UMH Department of Laboratory Medicine. Funds for slide preparation should be budgeted in the research proposal. A fee schedule is attached in Appendix 13. (For further information contact: Wanda Winebrenner, Supervisor, Histology, 410-554-2968).

**Human Cadaver Tissue**

The following procedures serve as protocol and are to be implemented for the procurement, handling, and disposal of human cadaver tissue.

**Procurement**

Human cadaver tissue for use in orthopedic research experiments can be obtained from the Maryland State Anatomy Board. To obtain tissue, contact the Director of the Biomechanics Research Lab. Provide the Director with the following information: project purpose and anticipated number of specimens required. Any contraindications for tissue must be included. (i.e., severe degenerative changes, previous surgeries, etc.). The lab director will arrange with the Anatomy Board (Mr. Ron Wade, 410-706-3313) for dates of availability and pick-up of the tissue. **Be aware of lag time: it may take 2 months to obtain 20 samples.** The lab director will arrange for the transport of the specimens. When going to retrieve specimens from the anatomy board please take the following: gloves, shoe covers, and gowns, and scalpels. A bag is located in the prep room with these items. Fees for anatomical specimens are located in Appendix 12.

It is important that the Anatomy Board’s laboratory be cleaned after each use, as must any instruments borrowed from the Biomechanics Lab. After obtaining tissue, any incisions made on the cadaver must be sutured and the cadaver must be handled in accordance with Mr. Wade’s instructions. The Anatomy Board serves as the only facility in the state from which tissue can be obtained; therefore, a good working relationship must be maintained. Tissue is to be wrapped in double-red bags and then placed in plastic, leak-proof containers for transport to MedStar UMH. Containers are located in the Biomechanics Research Lab. A specimen transfer document is needed and will be issued by Mr. Wade before tissue transport. Request the specimen demographics (age and sex) when obtaining the transfer document. Transfer documents should be given to the Director of the Biomechanics Lab.

**Storage**

Once transported to MedStar UMH, tissue is placed in the walk-in freezer located in the prep area of the Biomechanics Lab. Mark the bag with the specimen number, researcher’s name, date, specimen type, and project. **TISSUE THAT IS NOT WELL MARKED WILL BE DISCARDED!**

A white-board is located adjacent to the freezer in the prep room. When tissue is stored (in marked red bags) in the refrigerator (for thawing or overnight storage during testing) – note on the board your name, the specimen numbers, and in which refrigerator unit the tissue has been placed.

**Handling of Tissue and Equipment in the Lab**

Specimen thawing time depends on size; however, most tissue should be given approximately 18 to 24 hours. Place tissue (still in at least one red bag) in the sink in the preparation area the day before needed. Procedures
for handling of the tissue in the lab are very simple. When working with tissue, do not touch anything that you do not intend to thoroughly clean. For example, an individual working on a specimen must remove his/her gloves before retrieving an instrument from the toolbox or using the telephone. Also, one must be aware of tracking tissue out and about the lab. Please view the tissue as a definite source of contamination and treat everything in the laboratory as if it were a personal possession.

All instruments used during the study are to be cleaned with detergent, rinsed and then sprayed with a 25% bleach and rinsed again. Afterward, these instruments are to be dried and returned to where they were found. As with study preparation, ample time must be set aside at the end of the day for cleaning the lab. Please do not leave the lab in a mess for someone else to clean. Proper handling of tissue is of utmost concern to laboratory personnel. Thank you for your cooperation.

Disposal
All consumable items (such as chux, gloves, paper towels, foot covers, etc.) used in the study are to be discarded in red bags for pick-up (available in the laboratory). Tissue from the study must be placed in double red bags for pick-up by hazardous waste disposal. Tissue for disposal is only picked up by request. Please see Appendix 14 for additional information regarding tissue disposal.

Sharps Containers
Sharps containers are placed throughout the lab. Place ALL SHARPS in the sharps containers.

Siliconized Specimens
For a nominal fee, Mr. Ron Wade of the Maryland State Anatomy Board will siliconize a dissected specimen. This is a process that preserves bone and soft tissue in a silicone material. The specimens are excellent for training and demonstration purposes. Contact Mr. Wade for the details of the process and procedure for obtaining siliconized specimens.

Infection Control/Hazardous Waste
This section is pertinent to personal safety and hazardous waste. Before opening any instrument drawers in the Biomechanics Laboratory, gloves worn while working on any tissue parts should be removed. It is unsanitary to open the tool drawers and remove necessary instruments while wearing blood-covered gloves. The laboratory does not have a surgical nurse to hand instruments to the residents/fellows nor does the laboratory have support personnel to come in afterwards and clean every item in the drawers that have been thus contaminated. In addition, no one should handle anything in the laboratory that does not pertain to that individual’s project. When moving tissue samples from the preparation area to the test area, the samples must be covered.
III. Other Research Resources (continued)

Sports Medicine Center  x2253
1. A KinCom system is available to measure concentric and eccentric forces of various major muscle groups
2. Body composition can be measured by electrical bioimpedance
3. Dynamic Video Gait Analysis uses multiple high speed cameras and reflective markers to measure joint function during walking or running

Research Fellows and Residents Office
An office for Research fellows and residents is located in the STAT Lab that is equipped with the following:

1. Three personal computers on the hospital network system
2. HP color printer and laser printer
3. Microsoft Office (Word, Excel, PowerPoint, Access)
4. Adobe PhotoShop

Clinical Fellows Office
An office for clinical fellows is located on the 4th floor of the Johnston Professional Building across from the chief residents’ offices. A key will be provided. This room contains two computers and other electronic resources.

Other Presentation/Publication Resources
The following pieces of equipment/software can be accessed by contacting the Research Coordinator:

1. Digital projector
2. Laptop computer (1)
3. Digital camera (2)
4. Primal Pictures 3-D anatomical software package (Hand, Knee, Foot/ankle, Hip, Shoulder, and Spine)
5. Color printer
6. Fax

All department members are encouraged to use digital photography whenever possible. Two departmental digital cameras are available for use.

OBERD: Outcome Based Electronic Research Database

During the past decade, there has been a growing interest in measuring outcomes after medical treatment. The creation of a longitudinal outcomes database to measure surgical outcomes provides a tool to follow patients over time and objectively evaluate functional status, satisfaction with treatment, and health care costs associated with various surgical procedures. Recently, MedStar Union Memorial Orthopaedics has begun to implement a series of specialty specific outcomes measures using a powerful electronic platform called OBERD (Outcomes Based Electronic Research Database). Through OBERD, we created and launched a web-based clinical outcomes program for spine, total joint, and shoulder. OBERD modules for foot and ankle and sports medicine are currently in the development stage and it is planned to have OBERD modules in all of the Orthopaedic subspecialties in our department by the end of calendar year 2014.
Patients scheduled for specific orthopaedic procedures receive electronic consents and validated instruments which they can complete on their home computers. Alternatively, patients are given the opportunity to complete the questionnaires on iPads during their office visit. Standardized protocols have been developed for intervals of follow-up which will allow researchers to collect consistent information. Eventually, this information will allow physicians and other researchers to answer specific research questions for retrospective research studies. In addition, OBERD can currently be used for designing customized prospective studies in addition to the ongoing routine outcomes data collection protocols.

**Statistical Evaluation**

Guidance is available for the following:

1. Research project design
2. Determining correct sample size
3. Statistical analysis of collected data
4. Basic statistical analysis of research data is performed on a personal computer using SPSS, SigmaStat, and Microsoft Excel software packages

Before collecting data, investigators should meet with the Director of Research who will aid in the design of a database to collect the data in a controlled, easy-to-analyze fashion (Appendix 3). Investigators are responsible for entering data onto a spreadsheet from patient records or questionnaires. In addition, investigators may be asked to modify the data before statistical analyses are performed.

**Editorial Office**

The Department of Orthopaedics and Sports Medicine at MedStar UMH has a full-time editor and an assistant editor to help with the research and publication process. The editor assists in development and editing of research papers for publication for all -approved studies, including those written after graduation. The editor assists in the following areas:

1. Assistance with manuscript development and copyediting for research studies.
2. Manuscript submission and publications management in collaboration with investigators.
3. Maintenance of publications database including published articles.
4. Editing of abstracts, posters, and preliminary papers for meetings.

**Manuscript Guidelines**

1. Please do not embed tables or figures in your manuscript from other programs! Create your tables in Word. Please consult the editor if you need help in developing a table.
2. IRB approval is required for clinical papers, including retrospective studies.
3. Figures: Take high-resolution pictures during your study. For each figure, provide a separate JPEG or TIFF file at 300 dpi resolution or higher at approximately 5” x 7.” Send figures to the editor as separate files in the original format.
4. Report standard deviation for each mean value.
5. Consult the journal author guidelines before you begin writing.
6. Create your manuscript in Normal style. Please don’t use boldface, italics, special size fonts, or the Word Styles feature. All of these special features have to be removed by the editor before submission.

Use of editorial services requires the following:

1. The study must have been reviewed by and approved by the ORC and must have a project number.
2. At least one author of a manuscript, abstract, etc. must be a faculty advisor from the Department of Orthopaedics and Sports Medicine.
3. The study, review, or work must have been performed at least in part at MedStar UMH or by Department of Orthopaedics and Sports Medicine personnel. Other-site or multiple-site work is acceptable as long as MedStar UMH is acknowledged as the affiliation of the MUMH investigator.
ROGER H. MICHAEL ANNUAL RESEARCH AWARD

Background
In 1995, Dr. Leslie S. Matthews, current Chairman of Orthopedic Surgery, announced the creation of a research award named in honor of Dr. Roger H. Michael, former Chairman of Orthopaedics. The award is given annually to one resident and one clinical fellow in an ACGME-accredited program who have made outstanding contributions in orthopedic research during their training at MedStar Union Memorial Hospital. Each award total of $2,500 is designated as $1,000 cash and $1,500 for travel to present the award-winning research at a national conference. Applications are included in Appendix 15 of this Research Manual and must be submitted by May 1 of the academic year in which they are to be considered for the award. Presentation of the award will be made at the Residents’ Farewell Dinner. The names of past winners are displayed on a plaque in the Orthopedic Library.

Choosing the Recipients
All current residents and ACGME-accredited clinical fellows may apply. The award decision will be made by members of the Orthopedic Research Committee. The applicant may be involved in either clinical or basic science research in orthopaedics and must display the ability to design and conduct sound, scientific investigations. Award decisions will also be made based on the importance of the contribution to the existing body of knowledge as well as on whether the applicant displays potential for pursuing orthopedic research in the future.

Grading forms and proposals are distributed to all members of the ORC. For a committee member to vote, he or she must have submitted grading sheets for all applicants by the voting deadline. Incomplete grading sheets will not be used to determine the winner. Likewise, all applicants must be graded by a committee member for any of the committee members’ scores to be counted. Award winners are the resident and fellow applicants with the highest numerical scores. In the event of a tie, the recipient will be determined by rank order, i.e., whether graders deemed the project 1st, 2nd, 3rd, or 4th best, etc. Should ties occur by both methods, two people will share the award and split the monetary award.

Recipients can receive more than one annual award if his/her project and productivity warrants receiving the award multiple times. When a resident and fellow are working on the same project, the one who submitted the original proposal will be the one to receive the award, unless otherwise designated.
The goal of the research rotation is to allow the resident to gain knowledge regarding good scientific methods and to initiate and conduct a study in orthopedic research. Although these are the assessment criteria for a resident research rotation, these objectives are also applicable to fellows research.

**Objective 1:** The resident will be able to identify appropriate research questions and design a well-controlled study to answer the research questions. This would include understanding the definition of independent and dependent variables and recognizing potential sources of error.

**Assessment 1:** Prior to the research rotation, the resident will have submitted a research proposal which demonstrates his ability to identify an appropriate research question and design a well-controlled study. The proposal should exhibit an understanding of independent and dependent variables, and how to control for potential sources of error.

**Objective 2:** The resident will gain knowledge of how to conduct a literature search, critically read the literature (understanding the difference between peer-reviewed and non peer-reviewed literature), and interpret current pertinent research in order to formulate a scientific hypothesis.

**Assessment 2:** In the research proposal, the resident will have reviewed, summarized, and cited key research papers related to the topic and stated a well-formulated hypothesis.

**Objective 3:** The resident will evaluate the project’s facility and equipment needs including staffing, time frame, and budget for the study. The resident will develop awareness of laboratory techniques and new materials/equipment for the investigation.

**Assessment 3:** In the research proposal, the resident will have determined the capabilities of the laboratory and clinical facilities including assessment of staffing needs, estimated start and completion dates, and budget requirements for the study.

**Objective 4:** The resident will develop specific objectives to address the hypothesis, acquire a basic understanding of the statistical tests necessary to analyze the data, develop methodology to address each objective, and gain an understanding of basic technologies associated with the area of orthopaedics being investigated.

**Assessment 4:** In the research proposal, the resident will have defined well-developed objectives to address the hypothesis, provided a statistical plan, and described precise materials and methods of the study.

**Objective 5:** The resident will select an appropriate sample size, design questionnaires and/or data collection sheets that include quantifiable data, and conduct pilot studies, when applicable, to assess effectiveness of the procedures. In clinical trials, the resident will present a professional manner and show respect for the patient. In laboratory trials, the resident will work methodically, practice safety, clean up, and use research etiquette. In both cases, the resident should work in a repeatable manner and understand the importance of handling all patients, specimens, and data collection consistently.

**Assessment 5:** In the research proposal, the resident will have identified an appropriate sample size, provided well-designed data collection sheets, and presented results of the pilot study when applicable. The resident will have obtained a statistical consultation prior to writing the proposal. Throughout the trials, the resident will have demonstrated good clinical and laboratory research techniques.
Objective 6: The resident will develop a basic understanding of the statistical tests used for the study and why they are appropriate. This includes understanding the relevance of a p value, alpha and beta error, standard deviation, standard error of the mean, and confidence intervals.

Assessment 6: During or prior to the research rotation, usually during the chief’s conferences in PGY1 and 2, the resident will have attended lectures on statistical design and demonstrated knowledge of skills in data collection methods and appropriate use of statistical tests.

Objective 7: The resident will be able to interpret the data and results. The resident will also apply the findings to the original questions, determine if the results have answered the basic research question, evaluate whether the objectives have been met, and accept or reject the hypothesis based on these findings.

Assessment 7: At the completion of the project, the resident will have presented the data clearly, demonstrated an understanding of the findings, and interpreted the results with subsequent acceptance or rejection of the hypothesis.

Objective 8: The resident will discuss the results in light of existing research, compare the methodology and findings to other papers, and generate conclusions. This would include understanding the contribution of the results to the general body of knowledge, their relation to clinical applications, and their implications for future studies.

Assessment 8: In a project summary, the resident will have interpreted the results and demonstrated how the methodology and findings compare to similar projects while contributing to the general body of knowledge. The resident will have understood how the results can be applied to clinical practice and what their implications are for future studies.

Objective 9: The resident will publish the results and/or present the findings of the study at the Orthopedic Educational Luncheon. With agreement of the faculty advisor, the resident will submit the study for presentation at a national meeting. If the abstract is accepted, the study findings will be communicated in a poster or podium presentation. For a written paper for publication, the resident will obtain the advice of the editor in the selection of an appropriate journal based on the scope/results of study and the journal audience. Following the journal format for submission of articles, the resident will gain an understanding of the publishing process including editing and creating effective figures and tables to depict the collected data.

Assessment 9: At the completion of the project, the resident will have presented the findings of the study at the Orthopedic Educational luncheon, submitted the study for presentation at a national meeting, and/or submitted the study for publication in an appropriate journal with advice of the editor.

Objective 10: During the FDA rotation, residents will assist in the evaluation of orthopedic implants and other orthopedic surgical devices by providing clinical consultation and review of clinical study designs and safety and effectiveness data. The residents will also gain exposure to frequently used fixative and implantable equipment involved in the treatment of orthopedic related indications.

Assessment 10: Upon completion of the FDA rotation, residents will be able to develop strategies to evaluate clinical and non-clinical aspects of medical device research based upon knowledge of the medical device industry. They will also have gained knowledge in the critical analysis of large data sets and of the use of clinical information within a regulatory framework to recommend and guide judicious, crucial decision making.
APPENDIX 2: INFORMED CONSENT

The informed consent template can be found on the MHRI website. Forms are subject to change so please download the latest version and follow the format carefully.

Informed consent includes the following elements:
1. A statement that the study involves research
2. An explanation of the purposes of the research and the expected duration of the subject’s participation
3. A description of the procedures to be followed and identification of any procedures that are experimental
4. A description of any reasonably foreseeable risks or discomforts to the subjects
5. A description of any benefits to the subject or others that may reasonably be expected from the research
6. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
7. A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records
8. An explanation of whether compensation or medical treatment is available if injury occurs and, if so, what it encompasses, or where further information may be obtained
9. An explanation of who to contact for answers to pertinent questions about the research and research subject’s rights, and who to contact in the event of a research-related injury to the subject
10. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent that may be included are:
1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently not foreseeable
2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent
3. Any additional costs to the subject that may result from participation in the research
4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. A statement that new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject
6. The approximate number of subjects involved in the study

The documentation of informed consent:
1. Use of oral consent procedures
2. Use of abbreviated written consent with oral explanation
3. Written narrative of information to be provided orally
4. Use of long written consent
5. Providing the subject a copy of the consent information
6. Who will obtain informed consent
7. Provision for witness as needed
8. Signature by subject or subject representative
9. Signature by investigator
10. Signature by person obtaining consent
11. Signature by witness
APPENDIX 3: EXCEL

Requirements for Entering Data into Excel for Statistical Analyses by SPSS:

Headers should be no more than eight characters in length and must be a single word or abbreviation. Do not use spaces or interletter punctuation (e.g., “Post-op,” but Postop is OK), symbols (e.g., $, -, *, @), or combinations of letters and numbers (e.g., A1, B2).

The data being entered into a spreadsheet must be in numerical format only.

By convention, yes and no responses are coded as follows: yes = 1; no = 0.

Missing data should be left blank. Do not make up any special number to represent missing data.

Do not left-justify or right-justify data.

Calculated formulas will not transfer from Excel into SPSS. Please copy the results of a calculated formula into the new column. When copying data in Excel to be used in SPSS, use “Values” from the “Paste Special” function in the “Edit” menu to avoid copying the formula.

When data entry is complete, save the worksheet in the current software version.

The key for the codes should be entered in a separate file, either an additional worksheet or a Word file. Including the key in the data worksheet can cause problems during analysis.

IMPORTANT: Please do not embed graphs or keys in your worksheet. Make these a separate worksheet.

The department also has a second statistical package called SigmaStat. This program enables investigators to analyze data using a multi-variate analysis of variance. Requirements for data entry for SPSS are very similar to those of SigmaStat.
APPENDIX 4: DETERMINING SAMPLE SIZE FOR STUDY

Four factors affect whether the data will be significant:
1. \( \alpha \) level (=Type 1 error = p value)
2. \( \beta \) level (or Power = 1-\( \beta \))
3. \( n \) = number of subjects in the study (or per group)
4. \( \sigma \) = population standard deviation measure of the underlying variability of the data

To calculate the number of subjects needed in a study to prove significance if the hypothesis is correct, decisions (or educated guesses) have to be made about the other three variables (\( \alpha \), \( \beta \), \( \sigma \)).

1. \( \alpha \) level = false positive = the chance that you will call significant or effective when it really is not. In the medical literature, by convention, the level or \( p \) is = 0.05, meaning there is only a 5% likelihood that the data will appear significant when they really are not. Although the usual level is 0.05, the \( \alpha \) level is something you select, the level of risking the report of a false positive. There are situations in which you may choose a higher or lower \( \alpha \) level. For instance, you are working on a new quick and easy AIDS detection test. Are you willing to tell 1 in 20 subjects that they are AIDS-positive when they really aren’t? In this case, you may want to choose an \( \alpha \) of 0.01 or even 0.001.

Anytime you lower \( \alpha \) (make the requirements for significance more stringent), the \( n \) required is increased.

2. \( \beta \) level = false negative = the chance of saying a treatment is not significant when it really is. By medical convention, the largest \( \beta \) level accepted is usually 0.10, i.e., a 10% chance that you will fail to detect significance when it actually exists. \( \beta \) is also something you select and there may be situations in which a \( \beta \) higher or lower than 0.10 is acceptable. For example, I am studying a treatment for end-stage multiple myeloma. I may be willing to accept a \( \beta \) of 0.20 because I may be willing to accept a large risk of finding that a treatment is not working when it really is. Therefore, fewer subjects would be required. As with \( \alpha \), the lower the \( \beta \) or the more stringent the criteria for the smaller \( n \) in a study, the larger the existing \( \beta \) error. In other words, in medical studies with small sample sizes, a distinction must be made between:
   a. proving that a treatment had no effect, and
   b. failing to demonstrate that a treatment had an effect because of lack of power (in other words, the sample size was too small)

\[
\text{Power} = (1-\beta) \times 100
\]
\[
(1-.10) \times 100 = 90\%
\]

When all is said and done, you can believe that your data are 90% reliable.

3. \( \sigma \) = the variability within the population. Population = everyone in the universe that meets the specifications of your study. Because this is an impossible number to obtain, this is where you make an educated guess based on the information you do have available.

\( \sigma \) can be approximated based on:
   a. a previous study in which you have looked at this variable.
   b. other studies in the literature that have looked at this problem.
   c. your past clinical experience, etc.

This information concerns dependent variables only, not independent variables. An independent variable is one that is experimentally manipulated, for example, drug dosages, surgical technique, etc., as opposed to dependent variables -- those changes (hopefully) observed as the independent variables are manipulated.

What if the study has more than one dependent variable? Make a list of all of them. There are two courses of action from which to choose: a) choose the one with the most variability, that is, the widest range of
values (this method is cited by most statistics books), or b) choose the one that is most important to the study's outcome.

What if the variability of my measurement is unknown and no one has ever done it before? Again, there are two courses of action from which to choose. The best choice is:
  a. Do a small pilot study. If no one else has ever measured this variable, then chances are there are a number of bugs to work out of the system anyway. If a pilot study is out of the question, then the next best thing is:
  b. Base your guess on a similar measurement that has already been made. For example, this measurement has never been made on the shoulder but there are five papers in the literature describing this measurement on the knee.

As you would expect, the greater the inherent variability of the data, the larger the n required. The final piece of information in the equation is:

4. What is the magnitude of the difference that is clinically or scientifically acceptable? For example, the average bone mineral density of a 55-year-old, postmenopausal woman is 1.02 g/cm². Because I had 1000 subjects per group, or a large enough n, I obtained statistical significance. However, does a 0.01g/cm² increase in bone mineral density actually mean anything about the strength of a bone? In another investigation, I am experimenting with a new antihypertensive medication. I decided that I want to see at least a 10 mm Hg difference in systolic blood pressure to say that my findings are clinically significant. If any difference is acceptable, then μ₁ = 1.

To review how the different variables affect n:
  a. The greater the inherent variability of the data, the larger the n required.
  b. The lower the α or β error (the more stringent) the larger the n required.
  c. The larger the difference required to attain clinical significance, the greater the n required.
There are no IRB fees charged for resident or fellow projects. The IRB fees listed below are for projects sponsored by attendings and grants or companies. Please be aware that for company-sponsored projects, it is generally standard practice to budget for the IRB fees in the proposal so that they are paid by the sponsor.

### Full Board Review

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
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<tr>
<td>Initial IRB Review</td>
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<tr>
<td>Reviewed at Regularly Scheduled IRB</td>
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<tr>
<td>Out of Cycle or Emergency Meeting</td>
<td>$3,500</td>
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<td>Amendments</td>
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<td>Continuing Review</td>
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<td>Closure Fee (Includes maintenance of file)</td>
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### Expedited Review

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<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td>$1,000</td>
</tr>
<tr>
<td>Amendments</td>
<td>$350</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>$500</td>
</tr>
<tr>
<td>Closure Fee (Includes maintenance of file)</td>
<td>$500</td>
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</table>

### Other Review Items

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement and Promotional Materials</td>
<td>$200</td>
</tr>
<tr>
<td>Official Determination of “Engagement in Research”</td>
<td>$200</td>
</tr>
<tr>
<td>HIPAA (Independent Review)</td>
<td>$200</td>
</tr>
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</table>
# Chesapeake IRB Fee Schedule (Single Site)

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Fee</th>
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</thead>
<tbody>
<tr>
<td>Initial Review of Protocol &amp; Site-Institution</td>
<td>$1,825</td>
</tr>
<tr>
<td>Continuing Review of Protocol &amp; Site-Institution</td>
<td>$1,250</td>
</tr>
<tr>
<td>Modification/Update Review (per document per site)</td>
<td>$285</td>
</tr>
<tr>
<td>- Protocol Amendment</td>
<td></td>
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<tr>
<td>- Product Information Update</td>
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</tr>
<tr>
<td>- Informed Consent Revision</td>
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<tr>
<td>- Additional Informed Consent</td>
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<tr>
<td>- Subject Materials</td>
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<tr>
<td>Recruitment Materials</td>
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<tr>
<td>- Review of Recruitment Materials (per item)</td>
<td>$250</td>
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<tr>
<td>Translation fee</td>
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<tr>
<td>Release of translated document</td>
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<tr>
<td>- Informed Consent (per document per site)</td>
<td>$285</td>
</tr>
<tr>
<td>- Recruitment/Subject Material (per submission per site)</td>
<td>$185</td>
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<tr>
<td>Administrative Services (IRB review is not required)</td>
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<tr>
<td>- Informed Consent administrative changes (per document per site)</td>
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<tr>
<td>- Administrative change memo's (per document per site)</td>
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<td>- Final Format of recruitment material (per submission per site)</td>
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<td>Site Closeout (per site)</td>
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<tr>
<td>Additional Locations Conducting Research (per location)</td>
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</tr>
<tr>
<td>Massachusetts Investigator (Phase 1, 2 and 3 IND Studies) (per site)</td>
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<tr>
<td>24/7 Access all documents via the electronic platform (CIRBi)</td>
<td>No Cost</td>
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7063 Columbia Gateway Drive, Suite 110 · Columbia · Maryland · 21046-3403 · USA
www.chesapeakeirb.com · (410) 884-2900 voice · (410) 884-9190 fax

V2-CIRBi_Jan2013
APPENDIX 6: INSTITUTIONAL REVIEW BOARD GUIDELINES

MedStar Union Memorial Hospital is under the jurisdiction of the MedStar Health Research Institute’s Institutional Review Board (IRB).

All IRB submissions must be submitted electronically via the InfoEd Web Portal with all required forms attached. Visit the MedStar Health Research Institute website and complete the applicable forms and the Cover Memo IRB Form.

Help with IRB submissions can be obtained by contacting the Clinical Research Coordinator in orthopaedics at craig.f.murrill@Medstar.net

The Baltimore IRB meets the 4th Tuesday of each month. Proposals are due two (2) weeks prior to the IRB meeting date on Mondays. The IRB meeting dates are subject to change during holidays such as Thanksgiving and Christmas. For questions concerning IRB submissions contact MHRI at 301-560-7338.

The MHRI Baltimore liaison, Ashlee Tidwell, is also available to help with IRB submissions. Contact her at: 301-560-2979 or ashlee.tidwell@medstar.net

Online Training
All investigators and research staff must successfully complete the Human Subjects Protections and Good Clinical Practice CITI Program. Upon completion, a PEER number will be issued which is valid for three years. PEER numbers must be on file for proposals to be considered and remain valid in order for researchers to conduct research. Instructions are as follows:

Go to https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Institutional-Review-Board-IRB.aspx
Scroll down to: Human Subjects Protection and HIPPA Training (PEER Number)

The Collaborative Institutional Training Initiative (CITI)
CITI was founded in March 2000 as collaboration between the University of Miami and the Fred Hutchinson Cancer Research Center to develop a web based training program in human research subjects’ protections.

Go to CITI Training Website: https://www.citiprogram.org
New users select: Create an account
Enter Participating Institutions as: MedStar Health Research Institute
Continue on to the Test. Note that this test could take several hours.

Print out The CITI Course Completion Record and give it to the MedStar UMH Research Coordinator in the Research Office. She will obtain your PEER number from MHRI.

Any study involving contact with human subjects (including any phone interviews or written questionnaires) must undergo the full review process by the MedStar Health IRB. Expedited approval may be requested for chart review studies. The expedited review form can be submitted at any time during the month. Review time is approximately 2 weeks.
A new consent must be obtained any time a patient’s sample is being used for study purposes other than those outlined in his/her original consent. However, it is possible in your original consent to make a provision for the future, for example, state that the blood will be tested for substances A, B, and C and any markers of A, B, and C that are discovered in the future.

The following signatures are required:
- Principal investigator
- All co-principal investigators
- Department Chairman
- Department Administrator (Director of Research)
Purpose
The purpose of this policy is to define the requirements for the management and review of certain MedStar Health Research Institute (MHRI) protocols by a commercial Institutional Review Board (IRB).

Policy
All research using human subjects or human-derived materials conducted at a MedStar Health facility or by MedStar Health investigators must receive appropriate Institutional Review Board (IRB) review and approval prior to initiation of any research activity. MHRI, as the research arm of MedStar Health, may contract with a commercial IRB to oversee the management and review of certain protocols when specific criteria are met. When entering into a relationship with a commercial IRB, MHRI will evaluate whether the commercial IRB has equivalent human subject protections in place. A fully executed agreement is required before MHRI may rely on a commercial IRB for review.

This policy applies to all commercially-sponsored protocols for which the following apply:
- The study is Phase II, III or IV,
- The study is industry-initiated,
- The study is industry-funded,
- The protocol is a multi-site protocol, and
- The study is not already approved by the MHRI IRB.

A research study will not be considered for review by a cIRB if the study involves any of the following types of research:
- Phase I clinical trials
- Embryonic stem cells
- Xenotransplantation
- Review and approval by the MHRI Institutional Biosafety Committee is required for the protocol
- Investigator-initiated
- Research funded by sources other than a for-profit entity/company

Scope
This policy applies to all research conducted at a MedStar Health facility or by a MedStar Health employee or staff member.

Responsibilities
The investigator must follow all the MHRI policies related to IRB review and approval including, but not limited to, prompt reporting to the commercial IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others. The investigator must assure that he or she will not make any
changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

The Office of Research Integrity is responsible for reviewing the human subjects training and conflict of interest disclosures of the investigators and members of the research team to ensure compliance with federal, state and local regulations.

Exceptions
None

What Constitutes Non-Compliance
Use of an IRB not approved by MedStar Health Research Institute constitutes non-compliance.

Consequences of Non-Compliance
Research activities can be suspended for a period of time or indefinitely and/or investigators may lose their privileges to do research at MedStar Health facilities.

Explanations and Details/Examples
None

Related Policies
IRB.O-020: IRB of Record Policy
OPS.O-001: Investigator Responsibilities: Protecting the Rights, Safety and Welfare of Study Subjects

Procedures Related To Policy
None

Legal Reporting Requirements
None

Reference to Laws or Regulations of Outside Bodies
None

Right to Change or Retire Policy
Modifications to this policy may be made through the process outlined in the MedStar Health Research Institute Policy on Policies. If a technical change is required in order to remain compliant with either MedStar Health policies or federal regulatory requirements, changes may be made by the President of the MedStar Health Research Institute.

Signed

Date

Signature on file

3/26/12

Neil J Weissman, MD
APPENDIX 8: SCIENTIFIC REVIEW BOARD POLICY

Purpose
Unlike industry-sponsored research protocols, investigator-initiated studies may not have received scientific review before submission to the Institutional Review Board (IRB) and may not have a method for monitoring of the ongoing research process. Therefore, investigator-initiated research protocols which have not undergone external scientific review should be submitted to Scientific Review Board (SRB) before submission to the IRB. This policy describes the roles, activities and procedures of the SRB operating under the authority of the MedStar Health Research Institute (MHRI).

Policy
The SRB ensures that investigator-initiated research submitted for review to the MHRI IRB is scientifically sound and ensures that the conduct of research conforms to the highest standards of research methodology and minimizes the risks to volunteer participants. The SRB plays a key role in ensuring that the highest standards for the conduct of research involving human subjects are met within the MedStar Health system.

All investigator-initiated studies that are considered by the IRB to be greater than minimal risk must receive SRB review if the protocol has not already undergone external scientific peer review, as defined below. The SRB review will primarily focus on the elements of good scientific study design. Proposals will be evaluated for the following criteria:

- Importance and novelty of the research question
- Clarity of the research question
- Appropriateness and efficiency of design
- Rigor and feasibility of methods
- Scholarship and pertinence of background material and rationale
- Adequacy of sample size
- Validity of the statistical analysis plan
- Balance of scientific benefit and potential risk
- Qualifications of the investigator(s) and resources available to conduct the research

In addition, the Committee may desire to comment on the proposal’s scientific and medical relevance or compelling ethical or participant safety issues.

Scope
This policy applies to all research involving human subjects, human specimens or human data being conducted within the MedStar Health System, except for studies determined by the IRB to be exempt or those studies currently reviewed and overseen by external IRBs for MedStar Health Research Institute.
Definitions
Scientific Review – the review of the actual clinical research protocol (not grant) that will be reviewed by the IRB.

Peer Review: An objective assessment of a project’s scientific merit by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose projects they are reviewing, that is, reviewers who are the professional equals of the PI for the proposed project and who often are engaged or were previously engaged in comparable activities.

External scientific peer review – This type of review includes review by such agencies as National Institutes of Health (NIH), National Science Foundation (NSF), and Agency for Healthcare Research and Quality (AHRQ), Food and Drug Administration (FDA), as well as the Georgetown-Howard Universities Clinical and Translational Science consortium peer review committee (SEPCOM) and the Georgetown Oncology Clinical Research Committee.

Responsibilities
The SRB ensures that the scientific question being asked within a protocol is relevant and that the design of the protocol is appropriate to answer that question. It ensures that the principal investigator and the research team are qualified to undertake the proposed research.

The Office of Research Integrity (ORI) is responsible for providing administrative support to the SRB. The ORI will work closely with the SRB Chair to establish policies and operating procedures.

Exceptions
Any exceptions to this policy must be granted by the SRB Chairperson with concurrence in writing from the IRB Chairperson.

What Constitutes Non-Compliance
Failure to conduct a study in accordance with this policy will constitute non-compliance of this policy.

Consequences of Non-Compliance
Failure to comply with the terms and conditions of this policy may result in the suspension or loss of research privileges at MedStar Health Institutions.

Explanations and Details/Examples
N/A

Related Policies
MedStar Health Research Policy

Procedures Related To Policy
Constitution and Meetings of the SRB:

The SRB will consist of a Chairperson appointed by the President of MHRI. The Chairperson will appoint SRB members whose appointments will be approved by the President of MHRI. At least one of the SRB members will have expertise in statistics related to clinical research design and analysis. Meetings of the SRB will occur either face-to-face or by teleconference and will be held as needed as determined by the SRB Chairperson and the Director of ORI.

Scientific Review Board Submission and Review Procedure:

Requests for SRB reviews may be submitted to the Office of Research Integrity (ORI) by the investigator or one of the IRB Chairs. The reason for the IRB-requested SRB review will be provided on the “Request for
Scientific Review” sheet (attached). ORI will forward the completed request form with the protocol to the SRB Chairperson.

The SRB Chairperson will assign the review to an appropriate SRB member. The Chairperson or the member may determine that an outside reviewer would be more appropriate because of the special expertise required. The SRB Chairperson may designate other scientific experts in the MedStar community to act as ad hoc reviewers for specific protocols.

All relevant documents submitted to the IRB by the investigator will be forwarded to the SRB Chairperson. The assigned reviewer may contact the investigator for more information as needed. Reviews will be documented on the “MHRI SRB Review Checklist and Comments Sheet” (attached) and returned to ORI. ORI will forward the completed reviews to the SRB Chairperson for action (approval or request for modifications).

**Every attempt will be made to have SRB reviews completed and submitted within seven (7) business days.** This timeline may not be possible if the review involves complicated scientific issues or if an outside reviewer is utilized.

**Procedures linked to Policy**
None

**Legal Reporting Requirements**
None

**Reference to Laws or Regulations of Outside Bodies**
Department of Defense Requirement for Scientific Review
21 CFR 56.109 IRB Review of Research

**Right to Change or Retire Policy**
Modifications to this policy may be made through the process outlined in the MHRI Policy on Policies. If a technical change is required in order to remain compliant with either MedStar Health policies or federal regulatory requirements, changes may be made by the President of the MHRI.

Signed  Date
_________________________________  ______________________
Neil Weissman, M.D.
President
APPENDIX 9: INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

The Institutional Animal Care and Use Committee (IACUC) of the MedStar Health Research Institute has set the following guidelines for submitting a proposal to use laboratory animals in research and teaching:

1. **Who Must Submit** - An IACUC proposal must be submitted by any investigator planning to house or use vertebrate animals at the Microsurgery Research & Training Facility at MedStar Union Memorial Hospital. If any animal work is to be done at another institution, then proof that the proposal has been reviewed and approved by that institution’s animal care and use committee must be provided.

2. **Proposal Submission** – Please contact Dr. Ken Means, the director of the microsurgical research laboratory as all projects to be conducted in the microsurgery lab must also be reviewed and approved by Dr. Means.

   **NOTE:** The lab is approved only for non-survival surgery on rats. However, the IACUC will grant approval for survival procedures on a case-by-case basis.

3. **Additional Information** - The PI is responsible for providing sufficient information to the IACUC about the purpose and plan to use laboratory animals so that the committee may make a reasonable evaluation of the activity. Between submission and the formal review of the IACUC proposal, additional information or clarification may be requested from the PI in an effort to facilitate the approval process. All personnel named on an animal use protocol must complete the assigned online training prior to protocol approval.

   In addition, per new AAALAC guidelines for the lab, any personnel who works(handles animals (training included) must now received clearance from Occupational Health. The process is simple and involves completion of the **Occupational Health Annual Survey – Animal Handlers & Caretakers**, which can be obtained directly from Occupational Health at 410-554-2546. The form is also available electronically and can be printed out, filled in and faxed directly back to Occupational Health at 410-554-6658. No one will be permitted to work in the lab without clearance.

4. **Committee Action** - PIs are notified in writing of the IACUC action and may proceed with their activities only upon receipt of committee approval. There is no expedited approval process for new proposals.

5. **Annual Review** - A proposal is granted approval for a period of 1 year from the IACUC approval date, and application for renewal must be submitted by the PI on an annual basis. For long-term projects, a completely new IACUC protocol must be submitted every 3 years (three renewals maximum).

6. **Reporting Responsibilities** - To modify any aspect of the approved IACUC proposal, the PI must request permission from the IACUC by submission of an amendment specifying the changes intended.

7. **IACUC Protocol and application forms** may be obtained from the Hand Research Coordinator or a template can be found on the MHRI website ([https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Institutional-Animal-Care-and-Use-Committee-IACUC.aspx](https://www.medstarhealth.org/research/Pages/Administrative-Services/Office-of-Research-Integrity/Institutional-Animal-Care-and-Use-Committee-IACUC.aspx)). Forms are subject to change so please download the latest version and follow the format carefully.
Medstar Health Research Institute Web-Based Orientation Training Modules

A portion of the MHRI orientation and training program for investigators, co-investigators, collaborators and their staff working directly with research animals includes completion of the AALAS Learning Library (ALL) training modules as described below. All personnel named on an animal use protocol must complete the assigned online training prior to protocol approval.


- **Species-specific training:** Online training modules from AALAS Learning Library, based on the species to be used. For example: “Introduction to Swine”, “Introduction to Sheep and Goats”, “Introduction to Rabbits”, “Introduction to Mice”, “Working with the Laboratory Mouse”, “Introduction to Rats”, “Working with the Laboratory Rat”, and Post Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress”.

**To Sign-In**
1) The website is found at [https://www.aalaslearninglibrary.org/](https://www.aalaslearninglibrary.org/)
2) Click on “Enroll Now” in the middle of the home page.
3) Defaults to “Enroll as an individual in group using access code.
4) Enter access code “GUMCHoya” unless the investigator has their own code
5) Select a username and password.
6) Complete all sign-in information, then click “continue”.

**To Begin Training Modules**
Go to “Libraries” at the top of the page and select “Animal Care and Use Courses”
Selections are under AALAS Track

1) To complete the “Working With the IACUC – non VA” module:
   a) Select “Regulatory and IACUC Compliance”
   b) Select “Working with the IACUC”
   c) Select “Working with the IACUC – Non-VA Version”

2) To complete the “Common Compliance Issues” module:
   a) Select “Regulatory and IACUC Compliance”
   b) Select “Working with the IACUC”
   c) Select “Common Compliance Issues” module

3) To complete the “Occupational Health and Safety in the Care and Use of Research Animals” module:
   a) Select “Regulatory and IACUC Compliance”
   b) Select “US Mandates and Guidelines”
   c) Select “Occupational Health and Safety in the Care and Use of Research Animals” module

1) To complete the “Euthanasia of Research Animals: AVMA Guidelines”:
   a) Select “Regulatory and IACUC Compliance”
   b) Select “US Mandates and Guidelines”
   c) Select “Euthanasia of Research Animals: AVMA Guidelines” module
2) To complete the “Introduction to Ergonomics” module
   a) Select “Occupational Health and Safety”
   b) Select “Ergonomics Courses”
   c) Select “Introduction to Ergonomics in the Laboratory Animal Facility” module

6) To complete Species Modules
   a) Select “Animal Use Methodologies”
   b) Select “Introduction to Research Animal Methodologies”
   c) Select module(s) for assigned species – Introduction to Rats

7) To complete “Pain Recognition and Alleviation in Laboratory Animals” module:
   a) Select “Animal Use Methodologies”
   b) Select “Anesthesia and Analgesia”
   c) Select ”Pain Recognition and Alleviation in Laboratory Animals”

At the end of each module, follow instructions for completing the exam.
Print out a completion certificate for each module completed.

All certificates must be faxed to the MHRI Office of Research Integrity Fax (301) 560-7336 or emailed to Brandon Jonson at brandon.l.jonson@MedStar.net. Please contact the IACUC coordinator at 301-560-7338 with any questions.
APPENDIX 10: PROPOSAL FOR ORTHOPEDIC RESEARCH PROJECTS

Date submitted: Total Amount Requested:

Project Title:

Primary Investigator: Phone/Pager:

PI E-mail:

If Fellow/Resident, PGY? – Current Rotation

Faculty Advisor: Phone/Pager:

Co-Investigators:

1. **Introduction** - Write a one-paragraph synopsis of the research project. Discuss the existing state of knowledge on the topic and the need for the proposed research. If possible, cite 2 or 3 key references pertaining to the proposed project.

2. **Hypothesis(es) and Objectives**

3. **Methods** - Briefly outline the methods to be used for the study. Include a description of the study design, the rationale for the design, and the specific aims of the project. Attach additional pages when necessary.

   Please provide a photocopy of at least one reference that can be used for the power analysis to estimate sample size. Pilot data can also be submitted in lieu of a reference. The reference study should have measured an outcome variable that is the same as one of the most important outcome variables in your study.
4. **Materials and Supplies** - Estimate what equipment/supplies (large and small) will be required for the project. Prepare a budget if equipment, supplies, animals, or cadaver tissue will have to be purchased. A cost schedule for biomechanical testing is included in the Research Manual.

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<th>ITEM</th>
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**Total**

Please answer the following questions

5. Check the type of study
   Retrospective _______   Prospective _______

6. Sample size required ____________
   (see Appendix 4 of Research Manual for sample size calculation)

7. Indicate the information source(s)

   ___ Medical Records
   ___ Animal Model    Which animal _________________
   ___ Human Subjects
   ___ Human Cadavers
   ___ Other           Please specify _________________

If using animals or humans, what age, sex, weight and species animal will you use? Why? Where will the subjects or specimens be obtained? Please include the appropriate IRB or IACUC forms.
What is the expected time needed for data collection?

_____ (please initial) As primary investigator, I accept the responsibility of writing up this study as a research paper after the data are analyzed.

Results - What comparisons will be made after collecting all of the data? How will these comparisons be made? What type of statistical analyses will be conducted? Please be as specific as possible.

Indicate whether there will be a control group  Yes ___  No ___

If yes, what experimental group will serve as the control? Why was this group chosen as the control?

Do you, your mentor, or any other investigator on this study have a conflict of interest to disclose concerning this project? No ___  Yes ___ (please list)___________________

Residents only: Please include a schedule of your rotations for the next year.

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All portions of this proposal have been discussed with all investigators and the Faculty Advisor. The order of authorship for presentations and publications resulting from this project has been discussed and determined by all involved. We agree to abide by the rules and regulations as stated in the Research Manual of the Department of Orthopaedic Surgery in carrying out all portions of this study. Those issues not covered in the manual will be subject to the authority of MedStar, The Union Memorial Hospital, the Department of Orthopaedic Surgery, and the Orthopaedic Research Committee.

Signature: Primary Investigator  Date

Signature: Faculty Advisor  Date
Sample Completed Research Proposal

Date submitted: 1/26/2010  Total Amount Requested: $5,580.26

Project Title:  Photoelastic Strain Analysis of Biomechanical Properties of the Femur with two Intramedullary devices.

Primary Investigator:  John Smith, MD  Phone/Pager: 410-932-0000
PI E-mail:  Johnsmith@medstar.net

If Fellow/Resident, PGY? 3

Faculty Advisor:  Jim Q. Public, MD  Phone/Pager: 410-932-0001

Co-Investigators:  Jane Doe, MD

1. Introduction - Write a one paragraph synopsis of the research project. Discuss the existing state of knowledge on the topic and the need for the proposed research. If possible, cite 2 or 3 key references pertaining to the proposed project.

Supracondylar femur fractures are common fractures seen in our elderly, osteoporotic population. Numerous studies have shown similar outcomes between retrograde nailing and side plating for these patients, and as a result, nailing presents an attractive option in the treatment of these fractures, given that it is less invasive than side plating. However, joint replacement surgery is on the rise, and many of these patients already have a hip replacement in the affected extremity, and therefore presents a challenge when considering internal fixation strategies.

The most optimal strategy for internal fixation of fractures with already existing hardware is currently unknown. In a biomechanical study in 2003, Harris et al. (1) showed that the optimal configuration between retrograde nail and compression hip screw (CHS) was overlapping the components. Strain in the bone increased as configuration changed from overlapping, to kissing, to gapped. In patients in whom there are two intramedullary devices an overlapping configuration is not possible and therefore, an optimal configuration is still to be determined. A recent biomechanical study showed that in a bone with two intramedullary devices, the load to failure is decreased by up to 20% when implants are placed in a “kissing” position (2). As a result, the authors claimed that intramedullary nails should not be used to treat fractures where there is already an intramedullary device.

Theoretically, load to failure is decreased as the stress-riser of two Intramedullary devices is concentrated over a small area, and therefore, we believe that if we separate these individual stress-rises far enough, we can restore load to failure strength to pre-fixation levels. To our knowledge, there are no studies that have looked at the effect of increasing distance between the intramedullary devices.

2. Hypothesis(es) and Objectives

The purpose of this study is to identify the most biomechanically advantageous configuration between two Intramedullary devices in a single bone. Our hypothesis is that strain and construct strength are inversely proportional to inter-prosthetic distance. As a result, there may be a biomechanically favorable configuration that allows for Intramedullary nailing for periprosthetic supracondylar femur fractures without decreasing fracture strength.

3. Methods - Briefly outline the methods to be used for the study. Include a description of the study design, the rationale for the design, and the specific aims of the project. Attach additional pages when necessary.

Phase I: validation of study model

It is not currently known whether interlocking the proximal screw on retrograde nail decreases fracture strength. Moreover, it is not known whether A/P screws are different biomechanically than Medial/lateral screws. The purpose of
Phase I is to establish whether load to failure is the same in femora where A/P screws are placed vs. medial/lateral. The purpose for this is to show that if both configurations are equivalent, we can study our model with A/P screws, which would decrease the amount of artifact in our measurement.

In order to accomplish this, 15 composite femora will be used. Load to failure testing on 3-point bending will be assessed in 3 configurations: 1. No interlocked screws, 2. A/P screws, 3. medial/lateral screws.

Phase II:
15 Composite Femora will be used in this biomechanical study. Composite femora were selected over cadaveric bone for several reasons: 1. They have similar properties to native bone. 2. As they are all built in the same fashion, we expect minimal inter-sample variability in mechanical properties. 3. Photoelastic coating process may be more accurately reproducible in composite femora than in cadaveric bone.

**Biomechanical configurations:**
1. Hip Stem + Nail in “kissing” configuration
2. Hip Stem + Nail two cortical diameters apart
3. Hip Stem + Nail four cortical diameters apart

**Photo-elastic coating technique**
Each femur will be coated with photo-elastic material using birefringent PLI resin and PCI reflective cement (Measurements Group, Raleigh, NC) using a procedure described previously by previous studies (3,4). The photoelastic apparatus used consists of a 030 series reflection polariscope consisting of a white light source, a polarizer assembly, an analyzer assembly and a still camera. The two assemblies included a linear polarizer, a quarter-wave retardation plate and a null balance compensator to accurately measure the fringe order.

**Measurement of strain**
The color fringe patterns in the photo-elastic coating will be recorded in a darkened room with a 35 – mm single lens reflex camera using 64 ASA Tungsten slide film. These fringe patterns reflected the patterns of strain across the surface of the coated section of the femur. The color changes from black at 0 strain to purple, which is defined to be at a fringe order of 1, to a repeat of purple at a fringe order of 2.

**Test set-up**
The femora will mounted on a servo-hydraulic materials testing system (MTS Mini Bionix, Minneapolis, MN) in a configuration simulating single leg-stance.
Loading Parameters
A load of 600N will be applied and measurements were recorded from the intact femur. The load was then removed and reapplied twice and two further sets of measurements recorded. The mean values from these three sets of observations were used for subsequent calculations.

Implantation of stems.
After determining the stem size using radiographic templates a trial broach stem will be inserted into the femur. A radiograph will be obtained after implantation to confirm satisfactory positioning of the stem. Measurements of strain will obtained for the following implant configurations:
1. Implants in a "kissing" configuration
2. Implants two cortical diameters apart
3. Implants 5 cm apart

Finally, once strain measurement is complete, femur epoxy coating will be removed and load-to-failure testing will be conducted in all configurations.

4. Materials and Supplies - Estimate what equipment/supplies (large and small) will be required for the project. Prepare a budget if equipment, supplies, animals, or cadaver tissue will have to be purchased. A cost schedule for biomechanical testing is included in the Research Manual.

<table>
<thead>
<tr>
<th>ITEM</th>
<th>Cost/unit</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite femurs</td>
<td>168.25</td>
<td>$5,047.50</td>
</tr>
<tr>
<td>Plastic mixing cups</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Hole punch</td>
<td>13.38</td>
<td>$13.38</td>
</tr>
<tr>
<td>PL-8 Resin</td>
<td>98</td>
<td>$196.00</td>
</tr>
<tr>
<td>PC-1 Adhesive</td>
<td>106</td>
<td>$106.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>5580.26</strong></td>
</tr>
</tbody>
</table>

Please answer the following questions

7. Check the type of study
   Retrospective _______ Prospective _______

8. Sample size required ____________
   (see Appendix 4 of Research Manual for sample size calculation)

7. Indicate the information source(s)
   ___ Medical Records
   ___ Animal Model Which One ________________
   ___ Human Subjects
   ___ Human Cadavers
   __X_ Other Please Specify ___Composite femora______________

If using animals or humans, what age, sex, weight and species animal will you use? Why? Where will the subjects or specimens be obtained? Please include the appropriate IRB or IACUC forms.
What is the estimated length of the study?
1 month

Results - What comparisons will be made after collecting all of the data? How will these comparisons be made? What type of statistical analyses will be conducted? Please be as specific as possible.

Strain measurements for intact femurs will be compared using Student’s t test. Strain measurements for intact and implanted femurs were compared using analysis of variance. Statistical significance was accepted at P<0.05.

Indicate whether there will be a control group Yes ___ No _X__

If yes, what experimental group will serve as the control? Why was this group chosen as the control?

Residents only: Please include a schedule of your rotations for the next year.

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/11</td>
<td>1/3/11</td>
<td>Hand</td>
</tr>
<tr>
<td>4/1/11</td>
<td>1/6/11</td>
<td>Sports</td>
</tr>
<tr>
<td>7/1/11</td>
<td>6/30/12</td>
<td>research</td>
</tr>
</tbody>
</table>

All portions of this proposal have been discussed with all investigators and the Faculty Advisor. The order of authorship for presentations and publications resulting from this project has been discussed and determined by all involved. We agree to abide by the rules and regulations as stated in the Research Manual of the Department of Orthopaedics and Sports Medicine in carrying out all portions of this study. Those issues not covered in the manual will be subject to the authority of MedStar, The Union Memorial Hospital, the Department of Orthopaedics and Sports Medicine, and the Orthopedic Research Committee.

Signature: Primary Investigator Date

Signature: Faculty Advisor Date

References

(1) Harris, Timothy MD; Ruth, John T. MD; Szivek, John PhD; Haywood, Brett MD. The effect of implant overlap on the mechanical properties of the femur. Journal of Trauma-Injury Infection & Critical Care. 54(5):930-935, May 2003


APPENDIX 11: LIST OF VENDORS FOR POSTER PRODUCTION

1. PhD Posters
   Several locations
   www.phdposters.com

2. FedEx Office (formerly Kinko’s)
   Can do same day posters
   www.FedExOffice.com

3. MakeSigns.com by Graphicsland, Inc.
   1-800-347-2744
   www.makesigns.com

4. Severn Graphics
   7590 Ritchie Highway
   Glen Burnie, MD 21061
   410-768-6118
   410-768-2763 Fax
   www.sevgraph.com

5. Artography Labs
   2419 St. Paul St.
   Baltimore, MD 21218
   410-467-5575
   www.artography.com

6. SciFor Inc.
   The Science Forum
   www.scifor.com
   4 New King St.
   White Plains, NY 10604
   800-446-4966

Poster costs can range from $30 to $600. A typical poster size is approximately 36x48 inches. In many cases posters can be delivered overnight. Data can be emailed to some vendors and the posters designed for an extra charge.

Examples of posters are hanging in the 7th-floor hallway of the Bauernschmidt building. After a poster has been presented at a meeting it may be displayed in the Bauernschmidt hallway.

The editor is available to review posters.
APPENDIX 12: FEES FOR USE OF BIOMECHANICAL RESEARCH FACILITIES

Fees are waived for residents, fellows, or attendings with departmental funding. When receiving funding from an outside source please budget for these expenses.

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost/Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>General lab fee</td>
<td>$600/day</td>
</tr>
<tr>
<td>MTS Bionix load frames</td>
<td>$150/hr or $750/day</td>
</tr>
<tr>
<td>Tekscan ISCAN equipment</td>
<td>$100/hr ($500/day)</td>
</tr>
<tr>
<td>Tekscan ISCAN sensors</td>
<td>$200 each ($125 for in-house studies)</td>
</tr>
<tr>
<td>Research assistant</td>
<td>$65/hr</td>
</tr>
<tr>
<td>Cadaver tissue</td>
<td>$650/sample ($210.00/sample for in-house studies). $1300.00 for upper/lower torso ($344.00 for in-house studies). Full spine $1300.00 ($410.00 for in-house studies)</td>
</tr>
<tr>
<td>Complete cadaver</td>
<td>$670 for orthopedic resident training</td>
</tr>
<tr>
<td>Special equipment or fixtures</td>
<td>Cost + (depends on type of equipment or fixture)</td>
</tr>
<tr>
<td>Lab supplies</td>
<td>$200/project or 5% of budget whichever is greater</td>
</tr>
<tr>
<td>Mini Fluoroscopy Unit</td>
<td>$700/day</td>
</tr>
<tr>
<td>Large Fluoroscopy Unit</td>
<td>$1300/day</td>
</tr>
</tbody>
</table>
APPENDIX 13: HISTOLOGY FEE SCHEDULE

Funds for slide preparation should be budgeted in the research proposal. For further information and current pricing contact: Wanda Winebrenner, Supervisor, Histology, 410-554-2757.

<table>
<thead>
<tr>
<th>Process</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process, embed in paraffin and section 1 block (includes 1st H&amp;E slide)</td>
<td>$9.00</td>
</tr>
<tr>
<td>Each additional level or recut (2nd H&amp;E slide on same tissue block)</td>
<td>$2.00</td>
</tr>
<tr>
<td>Special stains</td>
<td></td>
</tr>
<tr>
<td>SSI (microorganisms)</td>
<td>$81.27</td>
</tr>
<tr>
<td>SSII</td>
<td>$71.87</td>
</tr>
<tr>
<td>Immunohistochemistry Stains</td>
<td>$68.00</td>
</tr>
<tr>
<td>Estrogen/Progesterone Antibodies</td>
<td>$76.47</td>
</tr>
</tbody>
</table>
APPENDIX 14: CADAVER TISSUE DISPOSAL

Principle:

This procedure covers proper disposal of recognizable parts and other human anatomic material (exclusive of blood). This procedure complements the “Management of Special Waste” in The MedStar Union Memorial Hospital Infection Control manual.

The procedure ensures compliance with local, state, and federal ordinances, in particular Maryland Department of Health and Mental Hygiene (COMAR Title 10 and COMAR Title 26).

Procedure:

Human body tissue, including pathologic specimens, must be delivered to the laboratory in accordance with the "Infection Control Procedure for Special Medical Waste”. Specifically, smaller specimens should be submitted in sealed specimen containers without leakage. Larger specimens must be in leak-proof, sealed, double biohazard (red) bags, each 3 ml thick. It is imperative that specimens be accepted by the laboratory and deposited in a secure area. Tissue specimens are not to be left in hallways or other unsecured areas.

The laboratory will freeze all tissue until the time of disposal. The tissue will be double red-bagged and placed in the bin within the walk-in freezer for pick up by environmental services. The environmental services supervisor will call the incinerator service and arrange for material pick up.
APPENDIX 15: ROGER H. MICHAEL RESEARCH AWARD
APPLICATION FORMS

Applications are available from the Department of Orthopedic Research or the MedStar UMH network orthores on’umhfs01\workgroups_2’ (S:); subfolder Orthopaedics\Forms, and are due to the Director of Research each year by May 1.

Name: ____________________________________________________________

Date: ____________________________________________________________

Year of Training: ________________________________________________

Phone Number: _________________________________________________

1. List all research activity while at MedStar Union Memorial Hospital.

2. List all presentations and publications resulting from this work.

3. Highlight your single most significant project. On one page (on a separate sheet), include the title, hypothesis, purpose, and a summary of its findings. Describe your percentage of participation in this project and who else was involved in this study. Include how you believe this project contributes to the existing body of orthopaedic knowledge. If applicable, describe how these findings may lead to future research projects.

4. RHM applications must be submitted electronically to Debbie.Lee@Medstar.net and to Janet.Yu.Yahiro@Medstar.net.

P:/research/rhm application
updated: 4/11/14
APPENDIX 16: RESEARCH / BIOMECHANICAL LAB EVALUATION

DEPARTMENT OF ORTHOPAEDICS AND SPORTS MEDICINE

Trainee's Name: ___________________________ Rotation: ___________________________

Evaluator's Name: ___________________________ Month (s) of ______ Year ______

Please evaluate the trainee's performance of each component of clinical competence. Circle the rating that best describes the trainer's skills and abilities. Appended are descriptions to help define the extremes of behavior in each component. It is anticipated that few individuals will merit a rating of either 1 or 9; most will receive ratings between these gradations. Identify the major strengths and weaknesses you have observed in the trainer's performance under the "comments" portion at the end of this evaluation form.

I. LABORATORY SKILLS

General Competency: Fellow must be able to demonstrate proficiency in performing required laboratory skills in safe and efficient manor.

<table>
<thead>
<tr>
<th>A. Laboratory Skills</th>
<th>Not Observed</th>
<th>Unsatisfactory</th>
<th>Satisfactory</th>
<th>Superior</th>
</tr>
</thead>
</table>

1. Procedural Skills

| | | | | |
| Has poor manual dexterity. | 0 | 1 2 3 | 4 5 6 | 7 8 9 |
| Frequently ignores sterile technique, and handles tissues roughly. | 0 | 1 2 3 | 4 5 6 | 7 8 9 |
| Has a vague knowledge of pertinent anatomy leading to overly cautious or reckless dissection. | 0 | 1 2 3 | 4 5 6 | 7 8 9 |
| Uses instruments and lab equipment inappropriately. | 0 | 1 2 3 | 4 5 6 | 7 8 9 |
| Handles and disposes of biohazardous materials ineffectively. | 0 | 1 2 3 | 4 5 6 | 7 8 9 |

Has excellent manual dexterity. Always attends carefully to sterile technique, and gentle tissue handling.

Has a thorough knowledge of anatomy.

Always uses instruments and lab equipment appropriately.

Handles and disposes of biohazardous materials effectively.
II. MEDICAL KNOWLEDGE

**General Competency:** Fellow must demonstrate knowledge about established and evolving biomedical, clinical, and cognate (e.g., epidemiological and social-behavioral) sciences and the application to the field of orthopaedics.

<table>
<thead>
<tr>
<th></th>
<th>Not Observed</th>
<th>Unsatisfactory</th>
<th>Satisfactory</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possesses knowledge that dates or</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>cites literature inaccurately.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does not investigate topics needed</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>for clinical assignments.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Exhibits knowledge that is up-to-date and cites literature appropriately. Investigates topics needed for clinical assignments.

III. INTERPERSONAL AND COMMUNICATION SKILLS

**General Competency:** Fellow must be able to demonstrate interpersonal and communication skills that result in effective information exchange and learning with professional associates.

<table>
<thead>
<tr>
<th></th>
<th>Not Observed</th>
<th>Unsatisfactory</th>
<th>Satisfactory</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not listen to information</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>provided by other members of the</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>health care team.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records information inaccurately</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>or incompetently</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Listens to information provided by</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>other members of the health care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>team.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records information accurately and</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>competently.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IV. PRACTICE BASED LEARNING AND IMPROVEMENT

**General Competency:** Fellow must be able to investigate and evaluate his or her practices, appraise, and assimilate scientific evidence, and improve practices.

<table>
<thead>
<tr>
<th></th>
<th>Not Observed</th>
<th>Unsatisfactory</th>
<th>Satisfactory</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ignores scientific evidence for care</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>of patients' problems.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appraises the usefulness of scientific evidence for the care of patients' problems.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is unaware of study designs and</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>statistical methods necessary to</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>evaluate scientific studies.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates knowledge of study design and statistical methods necessary to evaluate scientific studies.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never analyzes effectiveness of own</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>practices.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always analyzes effectiveness of own practices.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
V. PROFESSIONALISM

**General Competency:** Fellow must demonstrate a commitment to carrying out professional responsibilities, and adherence to ethical principles.

<table>
<thead>
<tr>
<th>Description</th>
<th>Not Observed</th>
<th>Unsatisfactory</th>
<th>Satisfactory</th>
<th>Superior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never improves own practice based on appropriately gathered data and feedback.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Always improves own practice based on appropriately gathered data and feedback.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never uses available information technology to obtain and manage information.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Uses available information technology to obtain and manage information.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fails to educate students and other health care professionals.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Educates students and other health care professionals.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fellow's performance requires constant faculty supervision.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Fellow functions independently with little need for faculty supervision.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is uniformly self-centered.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Exhibits unselfish regard for the welfare of others.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demonstrates consistent lack of adherence to a code of moral and ethical values.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Demonstrate firm adherence to a code of moral and ethical values.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does not respect other members of the research team.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Respects the other members of the research team.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to requests for consultation frequently delayed.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Provides prompt consultations upon request.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is not accountable for own actions.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Is accountable for own actions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is unreliable.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Is reliable.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is frequently late.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Is punctual.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is satisfied with mediocre performance.</td>
<td>0</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
<tr>
<td>Is committed to excellence.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Based on the above ratings of each component skill, please provide an overall rating of and comments about the trainee's clinical performance.


Suggest subjects to be emphasized in a brief personal learning plan.


This Evaluation was based on: Direct observation of the fellow Recall or overall impression of performance _______

Trainee's Signature: ___________________________ Evaluator's Signature: ___________________________ Date: _______

[Modified from "Evaluation of Clinical Competence; a resource document for cardiology program directors." American Board of Internal Medicine, Clinical Competence and Communication Programs. 1995]

[Cujec B. Johnson, DH, Behaviorally anchored rating scales are preferable to global rating scales in the evaluation of medical fellows, Annals RCPSC 30(2):81, 1997]