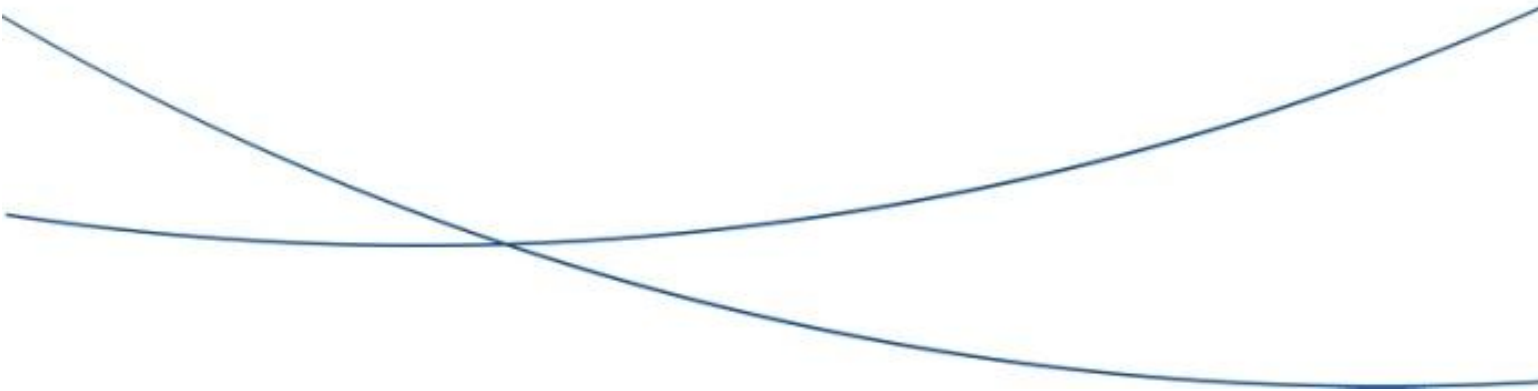




MedStar Orthopaedic
Institute

MedStar Union Memorial Hospital Orthopaedic Research Manual

2018-2019



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KEY DIRECTORIES AND WEBSITES

Frequently used acronyms:

- CITI Collaborative Institutional Training Initiative
- GCP Good Clinical Practice
- IACUC Institutional Animal Care and Use Committee
- IRB Institutional Review Board
- MHRI MedStar Health Research Institute
- MOA Maryland Orthopaedic Association
- MUMH MedStar Union Memorial Hospital
- OBERD Outcome Based Electronic Research Database
- OEL Orthopaedic Education Luncheon
- ORC Orthopaedic Research Committee
- ORI Office of Research Integrity at MHRI
- STAT Lab Surgical Techniques and Technology Lab at MUMH

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

The Orthopaedic Research website can be accessed from the MedStar Union Memorial Hospital web site: <http://www.medstarunionmemorial.org> under For Physicians, select Orthopaedic Research.

The MedStar Health Research Institute (MHRI) website <http://www.medstarhealth.org/mhri> can be accessed for MHRI requirements

- IRB and IACUC forms, guidelines, and proposal submission instructions
- Informed patient consent forms (required for clinical study)
- All applicable HIPAA requirements for research (CITI training exam)
- Direct all question and inquiries to the general email MHRI-ORIHHelpDesk@medstar.net

MedStar Union Memorial Hospital on StarPort, <http://starport.medstar.net>, can be accessed for Hospital protocols, policies, and procedures.

The MedStar Union Memorial Hospital network shared drive, subfolder Orthopaedics can be accessed for:

- Research proposal application forms for the Orthopaedic Research Committee
- Request for presentation or publication funds form
- Roger H. Michael (RHM) Research Award application form
- Orthopaedic Research Manual
- Grant and external funding sources
- Annual Orthopaedic and Hand publications and presentations

The National Library of Medicine's Medline through PubMed can be accessed at <http://www.nlm.nih.gov/>
The Library Resources can be accessed at <http://starport.medstar.net> under Clinical Enterprise.
Literature searches can also be requested from the medical Library at x2294.

YOUR ORTHOPAEDIC 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. The following timeline provides an overview of each step and further details can be found throughout this manual.

Step 1

- Take Collaborative Institutional Training Initiative (CITI) training unless already completed
- 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 if applicable, lab director, director of research, or clinical research coordinator
- Do a literature review on planned topic
- Meet research staff, see facilities, work with staff to write study budget, and determine sample size
- Prepare and submit proposal to the Orthopaedic Research Committee (ORC)
- For clinical study, prepare Institutional Review Board (IRB) forms with lay summary
- For animal study, obtain approval of Dr. Ken Means and prepare IACUC forms
- Prior to deadline, submit completed copy electronically to Amelia and Janet Yu-Yahiro

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
- Begin pilot studies and order supplies once study is approved. Clinical studies must receive IRB approval prior to conducting any research activities

Step 3

- Conduct study according to approved specifications
- Meet with statistician to review and revise results
- Talk with attending to interpret the study findings

Step 4

- Present findings at an Orthopaedic Education Luncheon
- Submit abstract to the Maryland Orthopaedic Association (MOA) and/or the MedStar Research Symposium as well as to a national or specialty meeting
- Write paper for journal submission and work with editor to finalize

Step 5

- Present findings at end of the year Visiting Professor Lectureship
- Conduct exit interview with Director of Research to determine status of project and finalize plans for project completion and manuscript submission. Provide a generic abstract prior to leaving the program.

Your responsibilities for the paper may extend well beyond your graduation date. Give the Orthopaedic 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 orthopaedic 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 the 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 orthopaedic residents. To fulfill this requirement, each resident in the Department of Orthopaedics at MedStar Union Memorial Hospital is expected to participate in at least one research project during his or her training. In full support of this mandate, the Department employs a full-time research staff and has 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. Publishable results will be submitted for presentation at the national level with subsequent submission for publication in a peer-reviewed journal. All research projects will be completed in accordance with established research methods, including interpreting the findings and writing an abstract and a paper.

Each fellow is also expected to complete at least one research project. This research is to be conducted with a faculty advisor mentor, and it is anticipated that publishable results will be submitted for presentation at the national level and to a peer-reviewed journal for publication. As noted above, research projects will be completed in accordance with established research methods, which include writing an abstract and a paper.

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 Orthopaedic 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.

CONTACTS

| Position | Name | Phone | Email |
|---|-----------------------|--------------|--|
| Orthopaedic Research | | | |
| Director of Orthopaedic Research | Janet Yu-Yahiro, PhD | 410-554-2619 | janet.yu.yahiro@medstar.net |
| Director, STAT Laboratory | Brent Parks, MSc | 410-554-6622 | bparkski@comcast.net |
| Researcher, STAT Laboratory | Pooyan Abbasi, MS | 410-554-4568 | pooyan.abbasi@medstar.net |
| Director, Orthobiologics laboratory | Zijun Zhang, MD PhD | 410-554-2830 | zijun.zhang@medstar.net |
| Research Assistant, Orthobiologics Lab | Sharada Paudel PhD | 410-554-2830 | paudelshara@gmail.com |
| Director, laboratory dedicated to spine research under construction | Bryan Cunningham PhD | 410-554-4368 | bryan.w.cunningham@medstar.net |
| Researcher, Biomedical Engineer | Daina Brooks, MS | TBD | daina.m.brooks@medstar.net |
| Chairman, Orthopaedic Research Committee | Greg Guyton, MD | 410-554-6844 | gguyton@gmail.com |
| Administrative Coordinator, Research | Amelia Stierstorfer | 410-554-2970 | amelia.e.stierstorfer@medstar.net |
| Administrative Coordinator, Fellowship | Patricia Koehler | 410-554-6865 | patricia.koehler@medstar.net |
| Administrative Coordinator, Residency | Kathy Lind | 410-554-2857 | kathy.lind@medstar.net |
| Editor, Orthopaedics | Lyn Camire, MA, ELS | 410-554-6668 | lyn.camire@medstar.net |
| Assistant Editor, Orthopaedics | Grace Nasrallah, MS | 410-554-2159 | grace.nasrallah@medstar.net |
| Clinical Research Coordinator | Casey Fisher, MS | 410-554-2893 | casey.fisher@medstar.net |
| Outcomes Research Coordinator | Chuck Amos, MBA | 410-554-8638 | charles.s.amos@medstar.net |
| Hand Research | | | |
| Research Director | Aviram Giladi, MD, MS | 410-261-8551 | giladi@curtishand.com |
| Clinical Research Consultant | Ken Means Jr., MD | 410-261-8144 | kennethrmeans@yahoo.com |
| Clinical Research Coordinator III, Hand | Ike Fleming, CCRC | 410-554-2486 | ike.c.fleming@medstar.net |
| Editor, Hand | Anne Mattson, MA | 410-261-8413 | anne.mattson@medstar.net |
| Researcher, Microsurgical Laboratory | Sione Fanua, MS | 410-554-2726 | sione.fanua@medstar.net |
| MedStar Health Research Institute | | | |
| VP, Research Operations | Mary Anne Hinkson | 410-236-3394 | maryanne.hinkson@medstar.net |
| Director, System-wide Orthopaedics/ Sports Health Research | Andrew Lincoln, ScD | 301-560-2927 | andrew.e.lincoln@medstar.net |
| Director of Research Compliance | Katherine Cohen, JD | 301-560-7396 | katherine.b.cohen@medstar.net |
| Scientific Center Director | Ron Miguez, MD | 202-877-2379 | ron.m.miguez@medstar.net |
| Clinical Research Coordinator | Flossine Brown | 410-554-4451 | flossine.brown@medstar.net |
| Other Resources | | | |
| Director, Practice Operations – MedStar Orthopaedics | Christa Feola | 410-751-7903 | christa.feola@medstar.net |
| Director, Library Services | Karen Jennings, MLS | 410-554-2817 | karen.l.jennings@medstar.net |
| Director, Radiologic Services | Deb Windsor | 410-554-6696 | deb.windsor@medstar.net |
| Director, Human Resources | Ashley Handwerk | 410-554-2543 | ashley.k.handwerk@medstar.net |

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, fellows are often assigned a specific research project by the director of their fellowship program. Residents can participate in research projects at any point in their careers; however, they must begin to formulate an idea for a research project on which they will serve as primary investigator. Residents/fellows cannot serve as primary investigators on interventional clinical studies per the MHRI regulations and the Collaborative Institutional Training Initiative (CITI) training Good Clinical Practice (GCP) guidelines by the end of their PGY-2 year. A list of potential projects is distributed at orientation or can be requested from the Administrative Coordinator at x2970. Resident research prior to this time is possible with the consent of an orthopaedic faculty advisor. All researchers are required to take the CITI training. This training incorporates initial and continuing education in human research ethics, standards for the responsible conduct of research, pertinent regulations, and specific procedures. CITI training instructions can be found in at https://ct1.medstarhealth.org/content/uploads/sites/116/2015/01/Website.Frequently-Asked-Questions.Training-final-2.28.18.pdf?_ga=2.99799769.637741283.1529509239-1283023663.1529341835

Clinical Studies

All studies that involve human subjects must be submitted to the MedStar Health Research Institution (MHRI) Institutional Review Board (IRB) through the InfoEd web portal for review and approval before any research can begin. All the required forms and instructions for their submission can be found on the MHRI website: <http://www.medstarhealth.org/mhri/research-support/office-of-research-integrity-and-irb-information/institutional-review-board> (see Appendix 2 for IRB Guidelines and further details). The IRB meets on a monthly basis. Please meet with the Clinical Research Coordinator x2893 for help in identifying and submitting the proper forms.

Animal Studies

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*. All animal projects will require initial review by Dr. Ken Means prior to IACUC submission as part of the lab's regulatory oversight. Projects for Dr Means' review can be submitted electronically to Ike Fleming at ike.c.fleming@medstar.net. For further information contact Ike Fleming at x2486.

Once projects are approved by the ORC and Dr. Means, they are then submitted to the Office of Research Integrity <http://www.medstarhealth.org/mhri/research-support/office-of-research-integrity-and-irb-information/institutional-review-board/#q={> for final review by the Institutional Animal Care and Use Committee. It will be necessary to schedule a pre-study meeting prior to study start-up. Contact Ike Fleming ike.c.fleming@medstar.net or call x2486. 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 3).

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:

- Find online resources
- 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 orthopaedic research program and facilities. A member of the research team will contact each resident and fellow to schedule the orientation.

The primary means of communication with residents and fellows is via MedStar email. All incoming residents and fellows are given a MedStar email address which they are expected to check on a regular basis for important information about research opportunities, meetings, and deadlines.

ORTHOPAEDIC RESEARCH COMMITTEE / IRB REVIEW

The purpose of the Orthopaedic Research Committee (ORC) is to critically review submitted research proposals for their scientific merit and to allocate funds to approved projects. Even if projects do not require funding they must still be reviewed by the ORC for their scientific merit. Clinical studies **MUST** also be submitted to the IRB for approval (See Appendix 2) and investigators must receive IRB approval prior to conducting any research activities.

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, Medical Editor, 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 (September, November, February, and May). Generally, these meetings are held on Thursdays at 6:30 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

Research Proposal Applications can be downloaded and filled in. They are available in Word format in the Orthopaedic Research shared drive directory on the MedStar UMH network (Orthopaedics folder, Forms subfolder). The forms are shown in Appendix 4.

Proposals for the ORC are due by one 1 week before the quarterly meeting. Submitting proposals early allows the research staff time to go over them, and provide feedback and fine tuning prior to being reviewed by the ORC committee. An electronic copy of the proposal should be sent to the Administrative Research Coordinator x2970 (Amelia.e.stierstorfer@medstar.net), to the Clinical Research Coordinator x2893 (casey.fisher@medstar.net) and to the Director of Orthopaedic 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. 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 orthopaedic 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 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. When research involves human subjects 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 3)
2. Clinical research (requires IRB approval prior to starting research activity, see Appendix 2)
3. Combination of basic and clinical research, i.e., reinforcing the clinical success of a certain procedure with a biomechanical study (the clinical research portion requires IRB approval prior to starting research activity)
4. Outcomes studies using OBERD
5. A literature review or meta-analysis of a particular topic
6. A retrospective analysis (requires IRB approval prior to starting research activity)

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 Orthopaedic 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.

Faculty Advisors

| Faculty Advisor | Specialty/Area of Interest | Phone Number |
|-----------------------------|------------------------------------|--------------|
| Antoniades, Spiro, MD | Spine | TBD |
| Asdourian, Paul L., MD | Disorders of the Spine | 410-554-2867 |
| Boucher, Henry R., MD | Joint Replacement | 410-554-6890 |
| Brumback, Robert J., MD | Trauma | 410-554-6645 |
| Cunningham, Bryan PhD | Spine | 410-554-4368 |
| Curl, Leighann, MD | Sports Medicine | 410-350-8336 |
| Dorai, Zeena, MD | Neurosurgery | 410-554-2247 |
| Douoguih, Wiemi A., MD | Sports Medicine | 202-291-5220 |
| Dreese, James, MD | Sports Medicine | 410-554-2221 |
| Ebert, Frank R., MD | Joint Replacement | 410-554-2850 |
| Fillar, Allison, MD | Sports Medicine | 410-554-2865 |
| Forthman, Christopher, MD | Hand/Upper Extremity | 410-296-6232 |
| Giladi, Aviram, MD, MS | Hand/Upper Extremity | 410-261-8551 |
| Guyton, Gregory P., MD | Foot & Ankle | 410-554-6844 |
| Hammond, Jason W., MD | Orthopaedic & Sports Medicine | 410-751-8800 |
| Hembree, Chad W. MD | Foot and Ankle | TBD |
| Higgins, James P., MD | Hand/ Upper Extremity/Microsurgery | 410-554-4563 |
| Hinton, Richard Y., MD, MPH | Adult/Pediatric Sports Medicine | 410-554-2161 |
| Innis, Peter, MD | Hand/Upper Extremity | 410-296-6232 |
| Katz, Ryan D., MD | Hand/Upper Extremity/Microsurgery | 410-235-5405 |
| Levine, Richard, MD | Sports Medicine | 410-308-0840 |
| Lemma, Mesfin, MD | Spine | 443-444-4786 |
| Looze, Christopher | Sports Medicine | 413-6873872 |
| Marchant, Milford, MD | Sports Medicine | 410-350-8336 |
| Matthews, Leslie S., MD | Sports Medicine | 410-554-2270 |
| McKinstry, Robert, MD | Joint Replacement | 410-554-2270 |
| Means, Kenneth R., MD | Hand/Upper Extremity | 410-554-5405 |
| Miller, Stuart D., MD | Foot & Ankle | 410-554-6530 |
| Moatz, Brad, MD | Spine | 410-554-2867 |
| Murthi, Anand M., MD | Shoulder & Elbow | 410-554-4382 |
| Nayfeh, Tariq, MD | Total Joint | 410-550-2180 |
| O'Donnell, John B., MD | Sports Medicine | 410-554-2860 |
| Parks, Brent G., MSc | Biomechanics | 410-554-6622 |
| Richardson, Mark W., MD | Trauma | 410-554-6679 |
| Schon, Lew C., MD | Foot & Ankle | 410-554-2891 |
| Segalman, Keith, MD | Hand/Upper Extremity | 410-296-6232 |
| Stein, Jason, MD | Shoulder & Elbow | 410-554-6867 |
| Tepper, Ken, MD | Sports Medicine | 410-751-8800 |
| Tortolani, P. Justin, MD | Spine & Orthopaedic Trauma | 410-554-2175 |
| Tucker, Andrew M., MD | Sports Injury Epidemiology | 410-821-8062 |
| Wisbeck, Jacob M.D. | Foot & Ankle | 410-554-6844 |
| Yu-Yahiro, Janet A., PhD | Research Methods & Statistics | 410-554-2619 |
| Zhang, Zijun, MD | Orthobiologics | 410-554-2830 |
| Zimmerman, Neal, MD | Hand/Upper Extremity | 410-296-6232 |
| Zimmerman, Ryan, MD | Hand/Upper Extremity | 410-296-6232 |

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
 - 3) Randomized clinical trials
 - a) Double-blind study
 - b) Single-blind study
 - c) Double-dummy = cross-over design
 - 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
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 5)
 - b. Organization
7. Retrospective pilot study - (optimal)
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 Library Resources can be accessed within the MedStar network through the intranet, <http://starport.medstar.net> under Clinical Enterprise. 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 all 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 4:00 p.m. and can be accessed 24/7 with a MUMH hospital ID badge.

Statistical Analyses

During the developmental stages of the project, consult with Dr Yu-Yahiro 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 6. 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. Data collected for biomechanical studies are organized and checked by a member of the research staff before being sent to the Director for statistical analysis. Data files for all other types of projects should be sent electronically to Dr. Yu-Yahiro for statistical analysis. Basic statistical analyses are performed at no cost using SPSS or SigmaStat. (See Appendix 7 for notes on statistical analysis and choosing the appropriate sample size.)

Additionally, after consultation with Dr Yu-Yahiro, residents and fellows may use statistical support provided through the MHRI Biostatistics and Bioinformatics Department (301-560-2981). Forty hours of support per project are provided at no cost. Copies of any analyses performed through MHRI must be given to Dr Yu-Yahiro. To request statistical support a Biostatistic and Biomedical Informatics Request Form should be filled out at <https://researchdata.medstar.net/redcap/surveys/?s=JU345>.

Informed Consent

An informed consent form (see Appendix 5) or waiver of informed consent is required any time a study will include human subjects. This includes not only clinical studies involving direct patient contact but studies that access patient radiographs or test results, and retrospective chart reviews that include identifiable human subjects. The investigator must include the form with the study proposal submitted to the ORC and with the IRB submission.

To download the latest version of the informed consent form from the MHRI website log on to <http://www.medstarhealth.org/mhri/research-support/office-of-research-integrity-and-irb-information/institutional-review-board/irb-forms/>.

All residents, fellows, and attending physicians who are involved in human subject research in any capacity must complete the CITI training and a Conflict of Interest Disclosure.

Quarterly, Mid-year, and End of Year Project Reviews

The Director of Research holds quarterly meetings with residents. The purpose of the meeting is to evaluate study status, establish a timeline for completion, assess the budget and supplies still needed for the project, review abstract submission deadlines, schedule a presentation at a departmental research meeting, and review requirements for writing the manuscript.

In January, mid-year project evaluation forms are distributed to all residents and fellows with active ORC funded projects. Complete the form and bring it to the mid-year review meeting with the Director of Research.

End of year project evaluation meetings will be held to make sure the research staff has all data, abstracts, and manuscripts or drafts for all projects. Contact information will be obtained and plans for completing any unfinished portions of projects will be made.

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
- Approving the final version of the manuscript to be submitted

In addition, each author must be able to defend at least the parts of the manuscript related to his or her professional discipline.

The faculty mentor is responsible for ensuring that all authors are listed. For some studies, previous residents or fellows might have done substantive work and should be included as authors. On biomechanical projects, the faculty mentor should assess the biomechanical engineers' involvement in the project and decide upon their inclusion as co-authors.

The principle investigator of a clinical project must take responsibility for submission of his or her own IRB paperwork and may not delegate this responsibility to an international researcher.

Author Order

The first author is the investigator who has contributed the most to the work including writing the paper. Other authors are listed in descending order of involvement. By convention the senior author is listed last.

Decisions about author order are the responsibility of the investigators.

Be prepared to document each author's specific contributions.

Reassigning First Authorship

The attending, Director of Research, and/or the Department Chairman may reassign writing and first authorship to another person if the first author does not provide a manuscript ready for editing before graduation or within a reasonable time after graduation.

Non-MUMH Investigators

Visiting residents, fellows, observers, or medical students may not serve as first author on ORC-funded projects due to limited resources. International researchers are prohibited from any patient contact which includes contact by phone. They are not eligible for ORC funding but may assist on ORC-funded projects on which clinical residents or fellows serve as primary investigator. Likewise international researchers may not serve as first author on any ORC funded project but can be listed as a co-author on a manuscript as appropriate to their contribution to the project. Please see the Director of Research, Dr. Janet Yu-Yahiro, to sign the appropriate waiver and agreement forms

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 Christina Stanger, christina.m.stanger@medstar.net Director, MHRI Office of Contracts and Grants, 301-560-7335.

Research collaborators, visiting international researchers and student interns coming into MedStar UMH laboratories from outside institutions must sign an Intellectual Property agreement before initiating a project in our facilities acknowledging that:

1. The MUMH resident or fellow or faculty member serving as primary investigator on the project will be listed as first author on any publications resulting from projects being funded by the MedStar Union Memorial Hospital Orthopaedic Research Committee.
2. All inventions or intellectual property resulting from ORC funded research projects are the property of the MedStar Union Memorial Hospital and MedStar Health and the MedStar Union Memorial Department of Orthopaedics will be acknowledged in any presentation of the project findings.
3. A resident, fellow, or faculty member must be present for 100% of the laboratory testing.
4. All appropriate on-line training requirements to conduct projects safely, including HIPAA and confidentiality training have been successfully completed before starting any research work.
5. Projects can be discontinued at any time by the laboratory director without warning if stated work obligations are not met.

Please see the Director of Research for a copy of this agreement.

Resident Research and Project Timetable

The resident research rotations occur during the PGY-3 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 with a research rotation beginning in September or October must submit a proposal during the end of their PGY-2 year at the May ORC meeting. 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 regularly scheduled Orthopaedic 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 February, and are strongly encouraged to present their project at the MedStar Health Research Symposium held in the spring. If a study does not yield publishable data, the resident will write a paper including an abstract, detailed methods and results, and a discussion of what was learned from the study to be presented at the visiting professor lectureship in June.

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

Table 1. Suggested Timetable for Residents to Complete Research Project

| | |
|---|---|
| <p>August PGY-1</p> | <p>Research orientation. Introduction to key personnel involved with research and orientation to the research program/facilities.</p> <p>Take CITI training.</p> |
| <p>Must submit a proposal to the ORC meeting anytime in PGY-1 year or by May of PGY-2 year.</p> | <p>Select research topic. Meet with faculty advisor to formulate question and discuss scope of project. Meet with Director of Research and if applicable, Clinical Research Coordinator or Lab Director to discuss study design. Literature search.</p> <p>Along with faculty advisor, develop a written proposal. Develop a budget if required. Submit proposal and budget to ORC. Submit IRB forms and/or IACUC forms (see Appendix 3) to appropriate committee. On clinical studies, research may not start until IRB approval has been received.</p> <p>All rat studies must be reviewed and approved by Dr. Ken Means before they can be initiated. Send a copy of the proposal to the Microsurgical Lab researcher and to the head of the IACUC committee to coordinate the obtaining and housing of animals.</p> |
| <p>No later than November PGY-3</p> | <p>Order supplies for approved project. Submit request for anatomic tissue if required. If possible, conduct short pilot studies or dry runs of experiments.</p> |
| <p>Research Rotation PGY-3</p> | <p>Begin experiments/data collection. Optimize the 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.</p> <p>Determine the deadline for abstract submission to the MOA, the MedStar Health Research Symposium, and a national meeting and begin preparation (podium or poster). Request publication/ presentation funds. Present project to peers at an Orthopaedic Educational Luncheon.</p> |
| <p>PGY-1 to PGY-5</p> | <p>Apply for the Roger H. Michael Research Award.</p> |
| <p>PGY-1 to PGY-5</p> | <p>Submit paper to attending for review and comment, and then provide revised paper to the editor. Complete all revisions required so editor can submit the paper to a journal.</p> |
| <p>PGY-5</p> | <p>Present research at the Visiting Professor Lectureship Conference.</p> |

Fellow Research and Project Timetable

Fellows are expected to participate in at least one research project during their fellowship on which the fellow will serve as principal investigator taking the project from the inception of the idea to the completion 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. If a study does not yield publishable data, the fellow will write a paper including an abstract, detailed methods and results, and a discussion of what was learned from the study to be presented at the Visiting Fellowship Lectureship in June.

Fellows will meet quarterly with the research staff to assure that all research tasks are completed in a timely fashion. As we believe that the research component to our fellowship is extremely valuable in the training process of our fellows any deficiencies in completing the research requirements will be taken seriously

All fellows are encouraged to present their research at a national meeting during the year after fellowship training. Funding may be available by applying for the Roger H. Michael Research Award.

The following table summarizes the recommended timetable for all fellowships.

Table 2: Suggested Timetable for Fellows to Complete Research Project

| | |
|-------------------------------------|--|
| <p>May – mid-July</p> <p>August</p> | <p>Complete CITI Training (3-4 hour online course) and create Conflict of Interest (COI) account and report any financial disclosures.</p> <p>Research orientation. Introduction to research personnel and orientation to the research program/facilities.</p> <p>Select a research topic with clinical faculty advisor.</p> <p>Meet with Clinical Faculty Advisor, Director of Sports Medicine Research, and Director of Orthopaedic Research to formulate questions and discuss scope of project. Depending upon the type of project, meet with the corresponding person:</p> <ol style="list-style-type: none"> 1. Clinical – Casey Fisher (casey.fisher@medstar.net) 2. Biomechanics – Brent Parks (bparkski@comcast.net) 3. Orthobiologics – Zijun Zhang (zijun.zhang@medstar.net) 4. Spine – Bryan Cunningham (bryan.w.cunningham@medstar.net) 5. Outcomes – Chuck Amos (charles.s.amos@medstar.net) <p>Along with your project’s faculty advisor develop a written proposal. Develop a budget if required. Submit proposal and budget to ORC. Submit IRB (Appendix 2) and/or IACUC forms (Appendix 3) 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. On clinical studies, research may not start until IRB approval has been received which can take 4-6 weeks depending on the detail of your proposal (e.g., study methodology). ORC approval is not IRB approval, but you can start working on IRB paperwork prior to ORC approval.</p> |
|-------------------------------------|--|

| | |
|---|---|
| <p>Before project initiation</p> | <p>If provisional approval of project is received from the ORC, make requested changes and submit them in writing to the Director of Research prior to project initiation.</p> <p>Order supplies for approved project. Submit request for anatomic tissue if required.</p> <p>If possible, conduct short pilot studies or dry runs of experiments.</p> |
| <p>Research rotation/ research time allocated</p> | <p>Plan well to optimize your research time.</p> <p>Write your introduction and methods at the beginning of your data collection and review with your faculty advisor, respective lab director (clinical, biomechanical, orthobiologic) and the editor. Start and complete data collection.</p> <p>Submit raw data to the Director of Orthopaedic Research for analysis and meet to review results along with faculty advisor.</p> <p>Discuss data collection results and analysis objectives with faculty advisor, Director of Orthopaedic Research, respective lab director (clinical, biomechanical, orthobiologic) and editor.</p> <p>Write and submit abstract to the MOA (http://www.mdortho.org/), the MedStar Health Research Symposium (https://www.medstarhealth.org), and a national meeting.</p> <p>Prepare project for presentation (oral or poster). Submit introduction, methods, and results sections to clinical faculty advisor and the editor. Request publication/ presentation funds. Present project for peer review at the Departmental Orthopaedic Educational luncheon before attending the MOA and MedStar Research Symposium meetings.</p> |
| <p>February</p> | <p>Schedule mid-Year update with the Director of Orthopaedic Research</p> |
| <p>March - June</p> | <p>Submit abstract to a national meeting.</p> <p>Write discussion. Submit rough draft paper to faculty advisor and Lab Director for review and comment. Complete all requested revisions and send the paper to the editor for editing.</p> <p>Present research at the Visiting Professor Lectureship Conference.</p> |
| <p>June - July</p> | <p>Complete work on paper with the editor. Be sure that the editor has all files relating to the manuscript prior to fellowship graduation.</p> <p>Have exit interview with the Director of Research and other research personnel. Be sure that Director has all raw data for the project.</p> |

FUNDING

All projects must be submitted to the ORC for review and approval before initiation.

Internal Sources

Orthopaedic Research Committee

The ORC offers funding support for research projects. A clinical resident or fellow may apply for these funds by completing a Proposal for Orthopaedic Research Project (see Appendix 4). Please note that there are separate forms for clinical and non-clinical projects. Acceptance of ORC funds by the primary investigator acknowledges that he or she will do the majority of the work on a project and plans to serve as first author on any manuscript resulting from the work. If the primary investigator role changes during the conduct of the study, the ORC should be informed and an amendment for the project submitted to the ORC.

Presentation and Publication Fund

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

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 9 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

The Orthopaedic Research Department cannot provide funds for graduating residents or fellows to present findings of research done at MUMH at a scientific meeting. We will however provide both financial support and technical assistance for poster production. Also, a graduating resident or fellow who has received the Roger H. Michael Award and has funds remaining, can access these funds to attend a meeting.

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. A list of potential grant sources is available on the MUMH Orthopaedic Research website <http://www.medstarunionmemorial.org/our-services/orthopaedics/clinical-research/#q={f}> under Grant and External Funding, or by contacting Grace Nasrallah at x 2159 or grace.nasrallah@medstar.net.

Possible sources include:

1. Orthopaedic 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 orthopaedic device manufacturers

Appropriate Use of Research Funds

It is the intention of the Department of Orthopaedics 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.

Only MUMH orthopaedics clinical residents and fellows are eligible for ORC funding. ORC resources are not sufficient to allow project funding for outside visiting scholars including foreign medical students or fellows

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 Administrative Research Coordinator. The 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. Any studies that involve tests, visits, or procedures, even if standard of care, need to go through Ron Miguez at MHRI (ron.m.miguez@medstar.net or 202-877-2379) for analysis of what can be billed to insurance (i.e. Medicare Coverage Analysis) and for entry into OnCore to ensure bills for the patient are held and handled appropriately.

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 Pre-initiation Approvals

International researchers are prohibited from any patient contact including contact by phone. They may assist on ORC-funded projects on which clinical residents or fellows serve as primary investigator. Please see the Director of Research, Dr. Janet Yu-Yahiro, to sign the appropriate waiver and agreement forms.

Imaging

All projects involving the use of radiation (e.g., CT, radiographs) 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. Please contact Ron Miguez at MHRI (ron.m.miguez@medstar.net or 202-877-2379) regarding billing aspects.

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

Institutional Review Board

MHRI requires that research personnel submitting to the IRB must complete CITI training and a Conflict of Interest Disclosure (COI).

CITI training

The CITI training incorporates initial and continuing education in human research ethics, standards for the responsible conduct of research, pertinent regulations, and specific procedures. CITI training 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 MedStar website

(<http://www.medstarhealth.org/mhri/research-support/office-of-research-integrity-and-irb-information/institutional-review-board/>) or <https://www.citiprogram.org/>. For inquiries please contact Clinical Research Coordinator, Casey Fisher at 410-554-2893 or by email casey.fisher@medstar.net.

Conflict of Interest Disclosure

The COI aims to assure that relationships with industry are ethical, do not impair professional judgment, and do not create conflicts of interest (or conflicts of commitment, as applicable) that could endanger patient safety, impair objectivity or data integrity, or damage the reputation of MedStar Health its affiliated entities or its representatives. MedStar Health uses the COISmart program for these disclosures. COISmart requires an individual account. Please contact Kate Cohen, Research Compliance Director,

katherine.b.cohen@medstar.net to have an account created for you. For individuals with existing research accounts in COISmart the COI Disclosure can be found at <https://medstar.coi-smart.com/login.php>

Commercially Sponsored Studies

Studies that are commercially sponsored MUST be processed through MHRI. If you would like to participate in such a study please contact the MHRI Scientific Center Director Ron Miguez at 202-877-2379 or by email at ron.m.miguez@medstar.net.

Multi-center studies

If you are interested in participating in a multi-center study and/or are relying on an outside IRB for your project you must get approval from MHRI prior to study implementation. Please contact Clinical Research Coordinator, Casey Fisher at 410-554-2893 or by email casey.fisher@medstar.net for details.

Research Guidelines and Deadlines

Proposals for the ORC must be submitted to the Administrative 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 orthopaedic-related topics.

Journal club enables 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 an 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 key note luncheon speaker. This Research Day is attended by all of our orthopaedic 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 4:00 p.m. and can be accessed 24/7 with a MUMH hospital ID badge. The library can be reached at x2294 or carole.lever@medstar.net.

Along with the computers, copiers, and print materials available in the library, most resources are also available online. The Library Resources within the MedStar network can be accessed through the intranet, <http://starport.medstar.net> under Clinical Enterprise. Contact the library staff for remote access to the library resources. MedStar UMH offerings include PubMed with LinkOuts, Ovid, Scientific American Surgery, Access Surgery, Access Medicine, Clinical Key, Cochrane Library, Micromedex drug information, ePocrates Drugs and Diseases, UpToDate, and over 1300 e-journals and over 1400 e-books.

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

Orthopaedic Library

The Orthopaedic Library has a selection of orthopaedic textbooks and is located in the Johnston Professional Building within the orthopaedic 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 orthopaedic 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 evaluation by the lab director (see Appendix 8).

Non-MUMH investigators (i.e. visiting residents, fellows, observers, international researchers, or medical students) may not serve as first author on any project but can be listed as a co-author as appropriate to their contribution to the project. Please see the Director of Research, Dr. Janet Yu-Yahiro, to sign the appropriate waiver and agreement forms

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. The protocols can be accessed online on the MedStar UMH StarPort at:

<http://starport.medstar.net/MUMH/PP/Pages/InfectionControlPoliciesProcedures.aspx>.

Refer to this website for information on: Occupational Exposure to Blood Borne Pathogens; Needlesticks and Other Sharp Injuries Control Plan; Radiation Safety Guidelines; and Chemical Hygiene Plan.

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 11 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) Custom designed and fabricated Shoulder test frame
- 3) 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)
- 4) 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
- 5) Custom designed and fabricated frame for testing ankle ligament stability
- 6) An array of fixtures is available to hold various anatomic specimens and orthopaedic devices for biomechanical testing. Specialized fixtures can be designed and fabricated as required

- 7) Strain/deformation measuring devices include: strain gauges, extensometers (including a non-contacting laser extensometer), linear variable differential transformers (LVDTs), rotational variable inductance transformer (RVIT)
- 8) Chemical hood
- 9) Data acquisition and reduction software packages for connection to any of the test machines
- 10) Two mini C-arms are available to facilitate surgical procedures
- 11) Two large C-arms (Siemens) for training courses and facilitating surgical procedures
- 12) A portable x-ray machine for *in vitro* radiographic analysis of specimens
- 13) Cryogenic Soft Tissue grips for testing soft tissue samples such as ligaments and tendons
- 14) A rapid rate torsion tester, which allows accurate testing of small bones (i.e., rat or mouse bones) in torsion
- 15) 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
- 16) The Tekscan ISCAN system for in-joint pressure measurement studies. Sensor maps are available for the knee, ankle, shoulder, and small joints
- 17) Five full arthroscopy carts are available for training/practice/research purposes. The FAST system (arthroscopic training models) from SAWBONES is available for arthroscopic training. A digital capture system is available to capture digital photographs and video clips of arthroscopic surgical procedures.
- 18) 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
- 19) Four Stryker TPS power sets and two large Stryker power sets
- 20) 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
- 21) Space for preparation of, and training with, anatomic specimens obtained through the Maryland State Anatomy Board. Surgical equipment and all types of orthopaedic devices and equipment are available
- 22) Walk-in freezer for anatomic specimen storage, and two, two-body morgue refrigerators for temporary specimen storage
- 23) 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
- 24) Two refrigerators for thawing and overnight storage of anatomic specimens
- 25) Vertical milling machine that provides a rigid platform with x, y, z movements for experimental setups and minor modifications to test fixtures
- 26) Small horizontal lathe
- 27) Ability to design and have fabricated custom testing devices as needed

II. 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
 - c. An up-right Olympus BII microscope with digital camera
 - d. A polarizing Olympus BII microscope
- 5) Animal study equipment:
 - a. 5-lane mouse/rat treadmill with adjustable pace and inclination
 - b. Mouse/rat digital gait analyzer
- 6) 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
- 7) Other facilities:
 - a. Two pH meters
 - b. Two chemical hoods
 - c. Two benchtop autoclaves
 - d. Two benchtop incubators
 - e. One water purifier
- 8) Office area is equipped with desktop computers, printers, and a fax machine

III. New Laboratory under Construction

MUMH is in the process of constructing a 3,500 square foot laboratory dedicated to spine research. The laboratory will include the following core areas of research: biomechanics, histology and histomorphometry, 3-dimensional printing, radiography, and in vivo biological modeling. For further information please contact Bryan Cunningham at bryan.w.cunningham@medstar.net or 410-554-4368.

1. Biomechanics: Six-Degree-of-Freedom Musculoskeletal Simulator

The biomechanical testing laboratory consists of a six-degree-of-freedom (6DOF) musculoskeletal simulator, which is designed to apply controlled multidirectional motions in flexion/extension, lateral bending, and axial rotations to musculoskeletal structures. Biomechanical testing platforms are configured with highly accurate optoelectronic motion analysis systems that permit quantification and comparison of segmental kinematics

following destabilization or reconstruction techniques to musculoskeletal structures. The testing platforms are interfaced with LabVIEW software so that a variety of transducers can be incorporated to measure parameters such as intervertebral disc pressure, strain within osseous structures or orthopaedic instrumentation. The laboratory is also equipped with a servo controlled MTS Bionix unit for static and fatigue testing of specimens.

2. Histology and Histomorphometry

The histology laboratory is capable of processing a wide variety of tissue samples including operative fusion segments, osseous defects, metallic and polymeric implant devices using un-decalcified and decalcified techniques. The laboratory is uniquely equipped for examination of oversized osseous specimens using EXAKT Micro Grinding technology, Buehler diamond cutting blades and a Leica Sliding Microtome, the last of which can produce histologic slides of 10 micron thicknesses that permit accurate assessment of bone remodeling, wear debris, inflammatory reactions, degenerative changes, and osseointegration at the implant-interface. Immunohistochemical macrophage and cytokine assays can also be performed to further delineate cellular mediators in inflammatory reactions. Using Image and MATLAB programs, histomorphometric image analysis permits quantitative calculations of multiple osseous and soft tissue parameters.

3. 3-Dimensional Printing (Additive Manufacturing)

Two 3D printers are available for computer aided design (CAD) prototype modeling. The Makerbot Replicator (filament extruder system) and Formlabs SLA Ecosystem (UV curable photoresin) provide two different 3D printing platforms for prototyping of implants and osseous structures limited to a 10 inch cube dimension.

4. Radiography

A comprehensive suite with software systems (MATLAB, 3D Slicer and Image J) are dedicated to visualization and quantitative assessment of radiographic plain films, high-resolution microradiographs (Faxitron BioVision system), fluoroscopic images and dual-energy x-ray (DEXA) scanner for quantification of bone mineral density.

5. In Vivo Biological Modeling

A wide variety of pre-clinical in-vivo models are available to assess safety and efficacy of implant materials and devices. Strict adherence to all applicable guidelines as outlined by the Code of Federal Regulations (CFR, Title 21, part 58) and the USDA Animal Welfare Act is of paramount importance in these studies. All research facilities are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), compliant with the National Institutes of Health [Office of Laboratory Animal Welfare](#) (OLAW), licensed by the US Department of Agriculture (USDA), and inspected by the Food and Drug Administration (FDA). Research projects will be approved and closely monitored by the Institutional Animal Care and Use Committee (IACUC), and strictly adhere to all applicable stipulations of the most recent version of the USDA Animal Welfare Act and Good Laboratory Practices (GLP). Staff investigators have extensive experience with in-vivo biological modeling for arthrodesis, bone graft substitutes, motion preservation-based surgical reconstruction techniques, osteoarthritis and neurotoxicity models.

IV. Other Research Resources

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 orthopaedic 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 orthopaedic 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 Orthopaedic Research for more information.

MHRI has its own animal research facilities housed at the MedStar Washington Hospital Center. For more information please contact Monique Richburg at Monique.L.Richburg@medstar.net, 202-877-0603.

Orthopaedic Research Laboratory

The original orthopaedic 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 orthopaedic problems and a variety of pharmaceutical and medical device company sponsored studies. Equipment available in this laboratory includes:

1. Two -80° freezers
2. One -40° freezer
3. One -20° 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
11. Bioquant image analysis system for quantitative histomorphometry

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.

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 12. For further information contact the Histology Supervisor Deb Duckworth at 410-554-2757.

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 orthopaedic 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 Wilk, 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, gowns, and scalpels. A bag is located in the prep room with these items. Fees for anatomical specimens are located in Appendix 11.

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 13 for additional information regarding tissue disposal.

Sharps Containers

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

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.

Sports Medicine Center

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 four computers and other electronic resources.

Other Presentation/Publication Resources

The following pieces of equipment/software can be accessed by contacting the Research Coordinator x2970:

1. Digital projector
2. Projection screen
3. Laptop computer (1)
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. MedStar Union Memorial Orthopaedics has implemented a series of specialty specific outcomes measures using a robust electronic platform called OBERD (Outcomes Based Electronic Research Database). Through OBERD, we created and launched a web-based clinical outcomes program that is used by each of our sub-specialties which include: spine, total joint, shoulder, foot and ankle, and sports medicine.

Patients scheduled for specific orthopaedic procedures receive validated instruments which they can complete on their home computers. Patients can also complete the questionnaires via text message if they verbally opt-in to this service. 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 after receiving IRB approval. In addition, OBERD can currently be used for designing customized prospective studies in addition to the ongoing routine outcomes data collection protocols. Please contact the Outcomes Research Coordinator, Chuck Amos charles.s.amos@medstar.net, for assistance in setting up a protocol in OBERD.

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 6). 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 at MedStar UMH has a full-time editor and an assistant editor to help with the writing and publication process. The editor provides editing, paper submission, and publications management support to the program. This service covers research papers, abstracts, and posters.

ROGER H. MICHAEL ANNUAL RESEARCH AWARD

Background

In 1995, Dr. Leslie S. Matthews, current Chairman of Orthopaedic 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 orthopaedic 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 14 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 Orthopaedic Library.

Choosing the Recipients

All current residents and ACGME-accredited clinical fellows may apply. The award decision will be made by members of the Orthopaedic 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 orthopaedic 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.

APPENDIX 1: RESIDENT RESEARCH ROTATION OBJECTIVES AND ASSESSMENT CRITERIA

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 orthopaedic 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 Orthopaedic 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 Orthopaedic 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.

APPENDIX 2: INSTITUTIONAL REVIEW BOARD GUIDELINES

MedStar Union Memorial Hospital is under the jurisdiction of the MedStar Health Research Institute's Institutional Review Board (IRB). You may not conduct any research activities involving human subjects (e.g., including case and/or chart reviews) until your research protocol has been reviewed and approved by the IRB. ORC approval is not a substitute or the same as IRB approval.

All IRB submissions must be submitted electronically via the InfoEd Web Portal with all required forms attached. Log on to: <http://www.medstarhealth.org/mhri/research-support/office-of-research-integrity-and-irb-information/institutional-review-board/>. You should allow 45-60 days for IRB review and approval.

Help with IRB submissions can be obtained by contacting the Clinical Research Coordinator in Orthopaedics at casey.fisher@medstar.net or 410-554-2893.

Online Training

The Collaborative Institutional Training Initiative

All investigators and research staff must successfully complete CITI training prior to participating/conducting any research that involves human subjects including case and/or chart reviews. For training information see: https://ct1.medstarhealth.org/content/uploads/sites/116/2015/01/Website.Frequently-Asked-Questions.Training-final-2.28.18.pdf?_ga=2.99799769.637741283.1529509239-1283023663.1529341835.

The time it takes to complete this training will vary based on your familiarity with human subject protections and the CITI training Good Clinical Practice (GCP) research guidelines. It is recommended that you allow up to 4 hours to complete this training.

Conflict of Interest Disclosure

The Research COI committee aims to assure that relationships with industry are ethical, do not impair professional judgment, and do not create conflicts of interest (or conflicts of commitment, as applicable) that could endanger patient safety, impair objectivity or data integrity, or damage the reputation of MedStar Health its affiliated entities or its representatives. In order to create your COI account and complete your disclosures please contact Kate Cohen, Research Compliance Director, at Katherine.B.Cohen@medstar.net with the following information:

- Full Name
- Email Address
- MedStar entity you are with
- How long you anticipate your research lasting
- Indicate if you have any of the following roles at MedStar:
 - Full or Part Time Associate/Employee (Management Level)
 - Employed or Contracted Physician
 - Purchasing Committee Member
 - Faculty or Teaching Staff
 - Non Physician Practitioner (NP, PA, CRNA)

Once your account has been created go to <https://medstar.coi-smart.com/login.php> to complete your disclosures.

APPENDIX 3: 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 prior to IACUC submission. The PI must provide a copy of the IACUC proposal and final approval letter to the Hand Center's Research Coordinator, Ike Fleming (ike.c.fleming@medstar.net). A pre-study meeting is also required prior to study start-up and can be coordinated through Ike Fleming. **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 receive 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 Ike Fleming, CCRC at 410-554-2486. The form is to be printed out, filled in and faxed directly to Ike Fleming, CCRC at 410-554-2486. 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.
1. **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>). 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.

- Overview of the care and use of animals in research: AALAS Learning Library training modules including: “Common Compliance Issues”, “Working with the IACUC: Non-VA version”, “Pain Recognition and Alleviation in Laboratory Animals”, “Euthanasia of Research Animals: AVMA Guidelines”, “Occupational Health and Safety in the Care and Use of Research Animals”, and “Introduction to Ergonomics”.
- 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/>
- 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
- 4) 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

- 5) 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 Diamond Tompkins at Diamond.Tompkins@MedStar.net. Please contact the IACUC coordinator at 301-560-7337 with any questions.

APPENDIX 4: PROPOSALS FOR ORTHOPAEDIC RESEARCH PROJECTS

Non-clinical Research proposal

rev. June 2018

| | |
|---|-------------------------|
| Date submitted: | Total Amount Requested: |
| Project Title: | |
| Primary Investigator: | Phone/Pager |
| PI E-mail: | |
| If Fellow/Resident, PGY? – Current Rotation | Phone/Pager: |
| Faculty Advisor: | |
| 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.

| ITEM | Cost/unit | Subtotal |
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| Total | | |

Please answer the following questions

Sample size required _____
(Contact Janet Yu-Yahiro for sample size calculation)

Indicate the specimen type
___ Animal Model Which animal _____
___ Human Cadavers
___ Other Please specify _____

If using animals or humans, what age, sex, weight and species animal will you use? Why? What is the source of the specimen animals? 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)_____

If appropriate please identify up to three (3) possible sources of outside funding (grants) for this project.

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

| From | To | Location |
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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 policies 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, MedStar Union Memorial Hospital, the Department of Orthopaedic Surgery, and the Orthopaedic Research Committee.

Signature: Primary Investigator

Date

Signature: Faculty Advisor

Date

Clinical Research Proposal

rev. June 2018

| | |
|---|-------------------------|
| Date submitted to ORC: | Total Amount Requested: |
| Project Title: | |
| Protocol version: | Revision date: |
| Primary Investigator (PI)*: | Phone/Pager: |
| PI E-mail: | |
| If Fellow/Resident, PGY? – Current Rotation | Phone/Pager: |
| Faculty Advisor: | |
| Co Investigators: | |

*Residents and Fellows cannot be PIs on interventional clinical studies.

Research may not begin until IRB approval has been received. ORC Approval is not IRB Approval.

Checklist for Clinical Research Projects

Have you:

- Discussed Project with Clinical Research Coordinator(e.g., what type of IRB review is required: full board, expedited, exempt, etc)
- Registered for an InfoEd Account(Required to make IRB submissions as PI)
- Completed Online Conflict of Interest
- Completed/Active CITI Training for PI and all co-investigators
- Provided updated CV for PI, Sub-Investigators

**If you need assistance with any of the above contact the Clinical Research Coordinator (CRC),
Casey Fisher at 410-554-2893 or casey.fisher@medstar.net.**

-
1. Introduction - Write a synopsis of the research project. State the problem, why this problem exists, is there any current/other solutions to the issue? Why haven't they been successful? Provide 2 or 3 key references with citations pertaining to the proposed project. Limit your response to no more than one page.
 2. Objectives and Hypothesis (es)– The purpose of the study should be clearly and concisely stated (research questions and/or study objectives). In experimental designs, objectives will be stated as hypotheses to be tested.

3. **Study Design-** Describe the type of research proposed (experimental, correlative, survey, qualitative) and specific study design that will be used (Retrospective, prospective, chart review, random, blind, etc.) State how long the study will take. *Contact CRC, Casey Fisher if you need help with designing your study.*
4. **Device/Drug Description (if applicable)-**Describe the study device/drug (pictures are great).
5. **Recruitment-** Describe the sampling approach. For experimental designs, include justification for sample size determination. Identify the procedures that will be used to recruit, screen, and follow study volunteers. Specifically define the study sample (number of subjects to be enrolled). *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. See Appendix 7 of Research Manual for sample size calculation and/or contact Dr. Janet Yu-Yahiro if you need help.*
6. **Eligibility Criteria-** Patients will meet all of inclusion criteria and none of the exclusion criteria. Patients who do not meet the study eligibility criteria will not be enrolled.
 - 6.1. **Inclusion Criteria-** Patient **MUST** meet all of the following criteria:
[Numbered list of all the inclusion criteria]
 - 6.2. **Exclusion Criteria-** Patients **MUST NOT** meet all of the following criteria:
[Numbered list of all the exclusion criteria]
7. **Study Procedures-** Describe in detail on how you will conduct your study and gather information. What surveys will you use? Put a time line for follow up assessment if applicable. Example is shown below in Table 7-1.

Table 7-1: This is an **example** of a study assessment. **Not all studies will use this (i.e. Chart Review).** Use your best judgment.

| Study Evaluation | Baseline | Procedure | 2 weeks | 3 months | 1 year |
|------------------|---------------------------|---------------------------|----------|-----------|-----------|
| | Within 30 days of surgery | Within 30 days of surgery | ± 5 days | ± 15 days | ± 90 days |
| Informed consent | ✓ | | | | |
| Physical Exam | ✓ | | | | |
| X-ray | ✓ | | ✓ | ✓ | ✓ |
| Questionnaire | | ✓ | ✓ | ✓ | ✓ |

8. **Statistical Analysis-** Explain your data analysis and statistical approach. Contact Dr. Janet Yu-Yahiro if you need help.*

*MedStar Health Research Institute (MHRI) Biostatistics and Biomedical Informatics department can assist with database mining and statistical analysis. After consultation with Dr Yu-Yahiro, residents and fellows may use statistical support provided through the MHRI Biostatistics and Bioinformatics Department (301-560-2981). Forty hours of support per project are provided at no cost. Copies of any analyses performed through MHRI must be given to Dr Yu-Yahiro. To request statistical support a Biostatistic and Biomedical Informatics Request Form should be filled out at <https://researchdata.medstar.net/redcap/surveys/?s=JUh345>.

9. Adverse Event Definition and Reporting (If applicable) - Describe what is considered an adverse event/serious adverse events (AE/SAE) in your study and provide a plan for documenting AEs/SAEs.

10. Potential Risks and Benefits- Explain the potential risks and benefits of the study.

11. Data Management and Monitoring- Explain how you will manage and monitor the data. If you are collaborating with another site, make sure you include how they will store and protect the data. Indicate how long personal data will be stored once the study is completed. Provide data collection forms and/or data collection sheet (e.g., excel spreadsheet) to be used for data collection. The IRB will want to see how you plan to collect your data and in what form.

12. Delegation of Study Duties- Provide an outline of which investigators and/or staff are responsible for executing each portion of the project (e.g., informed consent, data collection, IRB correspondence, etc.) **This is required per the CITI training Good Clinical Practice (GCP) research.**

13. Materials and Supplies - Estimate what equipment/supplies (large and small) will be required for the project. Prepare a budget if equipment, supplies, parking vouchers, radiographs, procedures, etc

| ITEM | Cost/un it | Subtotal |
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14. Data Analysis- What is the expected time needed for data collection and study completion?

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

15. 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.

16. Conflict of Interest- Do you, your mentor, or any other investigator on this study has a conflict of interest to disclose concerning this project?

____Yes ____No

(If yes, please list)_____

17. If appropriate please identify up to three (3) possible sources of outside funding (grants) for this project

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

| From | To | Location |
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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 policies 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, MedStar Union Memorial Hospital, the Department of Orthopaedic Surgery, and the Orthopaedic Research Committee.

Signature: Primary Investigator

Date

Signature: Faculty Advisor

Date

APPENDIX 5: INFORMED CONSENT

The informed consent template can be found on the MHRI website at <http://www.medstarhealth.org/mhri/research-support/office-of-research-integrity-and-irb-information/institutional-review-board/irb-forms/> Forms are subject to change. You **must** use the latest versions 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
3. A statement that the participation is voluntary
4. A statement 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.
5. A description of the procedures to be followed and identification of any procedures that are experimental
6. An explanation of the expected duration of the subject's participation
7. A description of any reasonably foreseeable risks or discomforts to the subjects
8. A description of any benefits to the subject or others that may reasonably be expected from the research
9. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
10. 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
11. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatment is available if injury occurs and, if so, what it encompasses, or where further information may be obtained
12. 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

Additional elements of informed consent that may be included are:

2. 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
3. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
4. Any additional costs to the subject that may result from participation in the research and the anticipated prorated payment, if any, to the subject for participating in the trial
5. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
6. 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
7. The approximate number of subjects involved in the study
8. If the research involves children (minors), neonates, or fetuses, appropriate parental signature(s) are included and assent is included when appropriate

The documentation of informed consent:

1. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subjects legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability of negligence
2. Shall be documented by the use of written consent form approved by the IRB and signed and dated by the subject, subjects legally authorized representative. A copy shall be given to the person signing the form.
3. The information given to a subject or the representative shall be in language understandable to the subject or representative (i.e., lay terms)

APPENDIX 6: 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 7: DETERMINING SAMPLE SIZE FOR STUDY

Four factors affect whether the data will be significant:

1. α level (=Type 1 error = p value)
2. β level (or Power = $1-\beta$)
3. n = number of subjects in the study (or per group)
4. σ = 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 (α , β , σ).

1. α 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 α 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 α 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 α of 0.01 or even 0.001.

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

2. β level = false negative = the chance of saying a treatment is not significant when it really is. By medical convention, the largest β level accepted is usually 0.10, i.e., a 10% chance that you will fail to detect significance when it actually exists. β is also something you select and there may be situations in which a β 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 β 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 α , the lower the β or the more stringent the criteria for the smaller n in a study, the larger the existing β 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)

$$\text{Power} = (1-\beta) \cdot 100$$

$$(1-.10), 100 = 90\%$$

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

3. σ = 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.

σ 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/cm^2 . Because I had 1000 subjects per group, or a large enough n , I obtained statistical significance. However, does a 0.01 g/cm^2 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 $\mu_1 = 1$.

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.

APPENDIX 8: RESEARCH /BIOMECHANICAL LAB EVALUATION



Please evaluate the trainee's performance of each component of clinical competence. It is anticipated that few individuals will merit a rating of either 1 or 5; most will receive ratings between these graduations. Identify the major strengths and weaknesses you have observed in the trainer's performance under the "comments" portion at the end of this evaluation.

I. Patient Care

General Competency: Fellows must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.

1. Manual dexterity

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. Uses proper sterile techniques.

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3. Has knowledge of pertinent anatomy

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

4. Uses instruments and sutures appropriately

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. Uses surgical assistants effectively

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

6. Is attentive to coworkers discomfort and risks

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

II. Medical Knowledge

General Competency: Fellow/Resident must demonstrate knowledge about established evolving biomedical, clinical, and cognate (e.g. epidemiological and social-behavioral) sciences and the application of this knowledge to patient care.

7. Possesses knowledge and cites literature accurately

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

8. Investigates topics needed for clinical assignments

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

III. Interpersonal and Communications Skills

General Competency: Fellow/Resident must be able to demonstrate interpersonal and communication skills that result in effective information

9. Listens to information provided by other members of the health care team.

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

10. Records information accurately and competently

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

IV. Practice Based Learning and Improvement General Competency

Fellow /Resident must be able to investigate and evaluate his or her patient care practices, appraise, and assimilate scientific evidence, and improve patient care practices.

11. Takes into consideration scientific evidence for care of patient's problems.

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

12. Is aware of study design and statistical methods necessary to evaluate scientific studies.

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

13. Analyzes effectiveness of own practice

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

14. Improves own practice based on appropriately gathered data and feedback.

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

15. Uses available information technology to obtain and manage information

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

16. Educates other health care professionals

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

17. Functions independently with little need for faculty supervision

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

V. Professionalism

General competency: Fellow/Resident must demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population.

18. Exhibits unselfish regard for the welfare of others.

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

19. Demonstrates firm adherence to a code of moral and ethical values

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

20. Respects other members of the health care team

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

21. Provides prompt consultations upon request

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

22. Is accountable for own actions

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

23. Is reliable

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

24. Performs to the best standard

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fair | Good | Very Good | Excellent | N/A |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

APPENDIX 9: LIST OF VENDORS FOR POSTER PRODUCTION

1. PhD Posters
www.phdposters.com
2. FedEx Office (formerly Kinko's)
www.FedExOffice.com
1-800-463-3339
3. MakeSigns.com by Graphicsland, Inc.
<http://www.makesigns.com/>
1-800-347-2744
4. Bay Imagery
<http://bayimagery.com>
8922 Yellow Brick Rd
Baltimore, MD 21237
410-687-7703
5. Severn Graphics
<http://www.severngraphics.com/>
7590 Ritchie Highway
Glen Burnie, MD 21061
410-768-6118
6. SciFor Inc.
The Science Forum
<http://www.scifor.com/>
4 New King St.
White Plains, NY 10604
1-800-446-4966

Poster costs can range from \$30 to \$600. The ORC will only reimburse up to \$200 per poster. 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 and in the STAT Laboratory. After a poster has been presented at a meeting it may be displayed in the laboratory hallways.

The editor is available to review posters.

APPENDIX 10: INSTITUTIONAL REVIEW BOARD FEES

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.

MedStar Health Research Institute
Institutional Review Board Services Fee Schedule
 (Effective as of January 31, 2017)

| | |
|--|---------|
| Full Board Review (Effective as of July 1, 2015) | |
| Initial IRB Review | |
| Reviewed at Regularly Scheduled IRB | \$2,500 |
| Out of Cycle or Emergency Meeting | \$3,500 |
| Amendments | \$500 |
| Continuing Review | \$1,500 |
| Closure Fee (Includes maintenance of file) | \$500 |
| Expedited Review | |
| Initial Review | \$1,500 |
| Amendments | \$350 |
| Continuing Review | \$7500 |
| Closure Fee (Includes maintenance of file) | \$500 |
| Other Review Items | |
| Advertisement and Promotional Materials | \$200 |
| Official Determination of "Engagement in Research" | \$200 |
| HIPAA (Independent Review) | \$200 |
| Institutional Requirements Compliance review (for outside IRB) | \$750 |
| Chart Reviews/preparatory to Research Review | \$250 |

APPENDIX 11: 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.

| Item | Cost/Fee |
|-------------------------------|--|
| General lab fee | \$600/day |
| MTS Bionix load frames | \$150/hr or \$750/day |
| Tekscan ISCAN equipment | \$100/hr (\$500/day) |
| Tekscan ISCAN sensors | \$200 each (\$150 for in-house studies) |
| Research assistant | \$65/hr |
| Cadaver tissue | \$650/sample (\$215/sample for in-house studies). \$1300.00 for upper/lower torso (\$352 for in-house studies). Full spine\$1300.00 (\$430 for in-house studies) |
| Complete cadaver | \$705 for orthopaedic resident training |
| Special equipment or fixtures | Cost + (depends on type of equipment or fixture) |
| Lab supplies | \$200/project or 5% of budget whichever is greater |
| Mini Fluoroscopy Unit | \$700/day |
| Large Fluoroscopy Unit | \$1300/day |

APPENDIX 12: HISTOLOGY FEE SCHEDULE

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

| Process | Fee |
|--|--------------------|
| Process, embed in paraffin and section 1 block (includes 1st H&E slide) | \$9.00 |
| Each additional level or recut (2 nd H&E slide on same tissue block) | \$2.00 |
| Special stains SSI (microorganisms) SSII | \$81.27 \$71.87 |
| Immunohistochemistry Stains | \$68.00 |
| Estrogen/Progesterone Antibodies | \$76.47 |

APPENDIX 13: 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 14: ROGER H. MICHAEL RESEARCH AWARD APPLICATION FORM

Applications are available from the Department of Orthopaedic 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 amelia.e.stierstorfer@medstar.net and to Janet.Yu.Yahiro@Medstar.net.