Resident Research Guidelines

Overview

The Department of Orthopaedic Surgery at the Wake Forest University School of Medicine is committed to excelling in: 1) clinical care, 2) education, and 3) research. Because research represents one third of the mission of the department, it receives a high priority and is an important component of the residency program. Residents actively participate in ongoing research within the department, or they pursue independent research projects with orthopaedic faculty mentors.

Dedicated research rotations

PGY-1: 1 month PGY 3: two, 2-month rotations

Mission: The purpose of the resident research rotations is to provide a structured introduction to core competencies in research, standard laboratory procedures, clinical research practices, general care of

orthopaedic patients, and basic surgical skills. The research component includes an overview of and experience in anatomy, ancillary clinical services, clinical laboratories, clinical outcomes studies, biomechanics, tissue engineering, physiology, basic science techniques, and research using animal models. At the completion of the residency program, all residents have conducted a focused basic science or clinical research project and have completed a manuscript describing their research project.

The department has a Research Advisory Panel. Members of this panel include Cynthia L.

Emory, MD, Cristin Ferguson, MD, Beth Paterson Smith, PhD, Thomas Smith, PhD, and L. Andrew Koman, MD. This panel provides the platform to promote and facilitate research within the department. The panel meets twice a year to monitor departmental research initiatives.

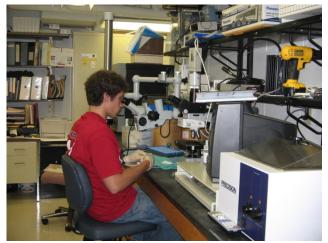
Yearly goals and requirements overview.

An overview of specific dates and requirements relating to resident research requirements during the five years of the orthopaedic residency program appears below.

SUMMARY OF RESEARCH ACTIVITIES BY YEAR

PGY-1

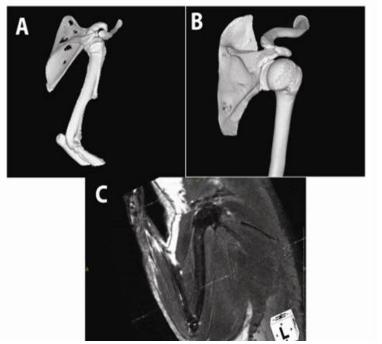
- 1. Complete core competencies in clinical and laboratory services, including introduction to microsurgery, electrophysiology, etc. during the one month research rotation
- 2. Become acquainted with departmental research projects and faculty research interests. A listing of research projects according to faculty member is provided to each PGY-1 resident.
- 3. Begin process of identifying a research project and faculty mentor.
- 4. Attend the weekly Wednesday morning departmental research meeting.





PGY-2

- 1. <u>Deadline October 1</u>. Submit a one to two page proposal summarizing the proposed research project. Include name of Research Mentor, Project Title, Background and Significance, Specific Aims, Hypothesis, Methods (Clinical projects include patient exclusion and inclusion criteria), Data Analysis Plan, and References. If the project is part of a larger/long-term project, the resident should outline the aims and objectives in terms of their specific role in that project.
- 2. Meet with members of the Research Advisory Panel to discuss project implementation. Residents are excused from clinical responsibility for this meeting, and the administrative chief will be informed of the meeting by Dr. Ferguson.
- 3. Resident Research Day: Present cases to the visiting professor



Terarecon image.CT of rat shoulder (A) & (B). MRI of rat shoulder. (C).

PGY-3

- 1. Complete the two month resident research rotation including attendance at weekly departmental research meetings, submission of weekly effort documentation, and preparation of project status reports.
- 2. Initiate the work required for completion of the research project.
- **3. Resident Research Day:** Provide an update of research project progress and preliminary findings in a presentation for the faculty, residents, and visiting professor.

PGY-4

- 1. Completion of research project during the two month resident research rotation.
- 2. Report any problems preventing or delaying project completion to the Research Advisory Panel.
- 3. Preparation of the manuscript for submission for publication.
- 4. Meeting with Research Advisory Panel in February.

5. **Resident Research Day**: Present case(s) to the visiting professor.

PGY-5

- 1. **Deadline:** <u>February 1</u>. Meeting with Research Advisory Panel and manuscript submission
- 2. **Resident Research Day**: Presentation of completed research project

All research proposals and manuscripts prepared by residents are submitted to Cristin M. Ferguson MD, (administrative



secretary: Kathy Prescott) following the previously described guidelines. *Residents who do not complete the yearly research requirements will have an academic report of deficiency forwarded to Jason E. Lang, MD, Residency Program Director.*

Research in the Department of Orthopaedic Surgery at the Wake Forest University School of Medicine

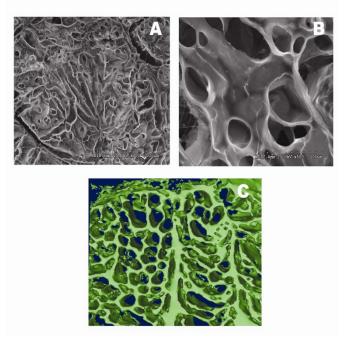
Orthopaedic research is coordinated by <u>Beth Paterson Smith</u>, PhD, and is facilitated by members of the research staff, research faculty, and Research Advisory Panel. Research within the department is divided into three main areas: 1) clinical retrospective/prospective studies, 2) biomedical engineering/tissue engineering studies, and 3) basic research studies.

Beth Paterson Smith, PhD, the Director or Research in the Department of Orthopaedic Surgery, supervises and directs the day-to-day operations of the Orthopaedic Research Laboratory by assisting faculty members and residents in planning and completing grant applications; developing experimental protocols and research models to address research questions; organizing data collection strategies; seeking collaborations with faculty in other departments to facilitate specific research goals, providing appropriate assistance with statistical analysis; and assisting with the preparation of manuscripts. Personnel (residents, medical students, and graduate students) involved in various research areas work under the direction of the various orthopaedic faculty members with Dr. Smith serving as a facilitator to expedite the completion of the various research initiatives. Dr. Smith has over 20 years of experience in designing and implementing clinical trials to study orthopaedic pathologies and possible interventions. Dr. Smith is an adjunct professor in the Wake Forest Institute of Regenerative Medicine, the Translational Science Institute, and the Center for Nanotechnology.

Thomas L. Smith, PhD: Dr. Smith serves as a basic science mentor to the residents in translational

studies in Orthopaedic Surgery. He provides advice experimental design, on project execution. interpretation of results, as well as selection of appropriate experimental models to address scientific hypotheses. In addition, he serves as a liaison with other scientists and departments within the university to facilitate and fulfill the residents' and fellows' research goals. Ongoing collaborations with the School of Biomedical Engineering and Sciences and the Wake Forest Institute for Regenerative Medicine offer several areas for research in these important fields. Dr. Smith's specific research interests include the application of nanotechnology to monitor compartment syndrome, the development of tissue-engineered tendons and ligaments, rotator cuff injury and repair, and the physiology and patho-physiology of peripheral nerve injury and repair. Dr. Smith also offers instruction in microsurgical techniques and experimental animal surgery. He has extensive experience in survival surgery techniques in rodents, rabbits, and dogs as well as expertise in nerve/muscle physiology and control of the circulation of the hands and feet.

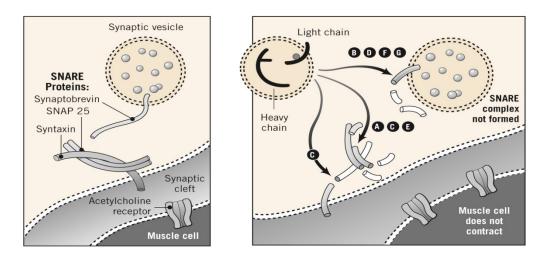
Tissue engineering technique developed in our department to produce scaffolds for tendon and meniscus repair. Tissue engineered meniscus scaffold: A) scanning electron micrograph of intact meniscus (150x), B) meniscus scaffold (2000x), C) meniscus scaffold (150x).



Overview of Support Provided by the Orthopaedic Research Laboratory

The faculty and staff of the Orthopaedic Research Laboratory provide research support for the residents and faculty in the Department of Orthopaedic Surgery. Specific areas of expertise available in the laboratory include development and use of animal models in research, cadaveric studies, tissue culture, molecular biology techniques, tissue engineering, basic statistical support, manuscript preparation/editing, and development of clinical research protocols. Technical support is provided by three laboratory technicians: **Martha Holden, Eileen Martin, and Jaiozhong Cai**. The laboratory staff is supervised by Martha Holden. Technicians are assigned to projects based on grant and abstract timelines and project funding levels. In addition, Martha Holden, a registered veterinary technician, serves as our liaison with the Animal Resources Program in the Department of Comparative Medicine. Eileen Martin has extensive experience in microsurgical techniques, chronic animal model studies, tissue culture, and histology. She is responsible for the oversight of the Animal Care and Use Protocols within the department. Jaiozhong Cai has extensive experience in immunohistochemistry, real time RT-PCR techniques, and other molecular biology techniques. All technicians assist with ordering research supplies and monitoring expenses on grant accounts.

Mechanism of Action of botulinum A toxin: The toxin prevents the release of acetylcholine at the neuromuscular junction. Our department has pioneered the use of intramuscular injections of botulinum A toxin for various orthopaedic indications.



Clinical Research Staff

Clinical research support is provided by clinical project managers, data collectors, and data management personnel.

Leticia Arnan, BS, MS facilitates research for the total joint surgeons. Ms. Arnan also prepares IRB applications and develops study protocols.

Debbie Bullard facilitates clinical research involving hand/shoulder and musculoskeletal oncology.

Brett Goodman, BA, MBA coordinates the Trauma Research initiative and is available to assist residents interested in trauma related research. He also oversees the ongoing Department of Defense studies within the department. Mr. Goodman also works with faculty and residents to develop research databases and to query the various patient databases within the medical center.

Lisa McCorkle, BA oversees study data entry, database design, and database maintenance. She works closely with the Department of Public Health Sciences to provide datasets to the biostatisticians that are compatible with SAS.

Regina Renegar, CNA, works with all members of the total joint replacement team. Her main focus is to collect outcomes information from all patients who undergo total joint arthroplasty.

Deanna Sizemore, Research Administrative Coordinator, oversees grant administration and oversight of the research funds. She also prepares budgets and facilitates the preparation of grant updates and final reports required by granting agencies. Ms. Sizemore interacts with the Office of Research to insure compliance with all medical school, state, and federal financial guidelines.

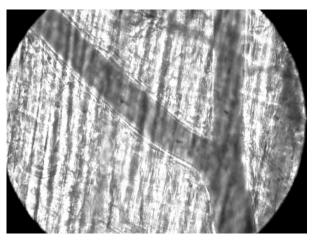
Sybil Snow, PTA works with the pediatric orthopaedic team and coordinates research involving scoliosis, cerebral palsy, and intrathecal baclofen pump therapy.

Wendy Williams is a data collector who facilitates data collection for studies for several different subspecialties within the department.

Assistance with health-related quality of life issues and development and selection of appropriate patient outcome questionnaires is provided by Michelle Naughton, Ph.D., Section on Social Sciences and Health Policy in the Department of Public Health Sciences.

Computers for Research

The department has a designated computer system to assist residents with statistical analysis, abstract and manuscript preparation, and power point presentations. The current computer is a Dell Optiplex 960 minitower with Intel CoreDuo processor (3.33 GHz, 4 GB SD RAM, 512 MB, NVIDIA Quadro NVS video adaptor, FIREWIRE Card, 320 GB hard drive at 3 GB/s speed with two 23 inch monitors and an external hard drive. The computer has the following software: Sigma Stat, Sigma Plot, Microsoft Office, Adobe Photo Pagemaker, Adobe Illustrator, Adobe Premier, Adobe Acrobat, Endnote, PASW Statistics, MatLab and GraphPad Prism.



The microvasculature of skeletal muscle viewed in rat cremaster experimental preparation. This preparation is used to study changes in the microcirculation of skeletal muscle under a variety of experimental conditions.

Human Performance and Biodynamics Laboratory (<u>www.biodynamicslab.org</u>)

This laboratory is a collaboration between Wake Forest School of Medicine's Department of Orthopaedic Surgery and Winston-Salem State University's Department of Physical Therapy. Physical therapists, physicians and biomedical engineers work with medical students, physical therapy students, orthopaedic residents, and patients in the laboratory to evaluate "people in motion" during a variety of activities. The state-if-the-art motion lab is equipped with 10 video cameras, four force plates embedded in the floor, and EMG equipment to analyze individuals walking, running, throwing, jumping, and swinging. Other equipment is available to measure pressure distribution of the foot during walking. A Biodex is available to measure muscle force and strength. A metabolic cart is available to assess oxygen consumption during exercise. An electronic "balance master" is available to evaluate all aspects of balance and balance control. The equipment can be used with a green (virtual reality) screen so that individuals involved in testing or rehabilitation activities can enjoy their testing sessions.

Collaboration with other Medical School Departments

The Department of Orthopaedic Surgery maintains strong collaborations with the **Wake Forest Institute for Regenerative Medicine**. These collaborations are focused on the development of tissue engineering solutions to orthopaedic conditions such as meniscus damage, tendon ruptures, and nerve injuries. Because of our collaborative ties, researchers in the Department of Orthopaedic Surgery have access to 20,000 square feet of dedicated laboratory space and the core facilities located within the Institute. The institute is equipped with micro CT, electron microscopy, Instrons, tissue culture facilities, histology equipment, and RT PCR technology.

The Department of Biomedical Engineering Sciences (BMES) is an engineering department within the medical school facilitating collaborations focusing on engineering research for relevant clinical and biomedical problems. The BMES department participates with the School of Engineering at Virginia Polytechnic Institute and State University and has developed a School of Biomedical Engineering and Sciences (SBES). Faculty and graduate students in SBES are available to facilitate studies research involving biomedical engineering. mathematical modeling motion analysis, and impact biomechanics. The campuses in Blacksburg (Virginia Tech) and Winston-Salem (Wake Forest) combine their resources for research and educational endeavors. As a result of this collaborative effort, the Virginia Tech Colleges of Engineering and Veterinary Medicine provide research opportunities for medical school faculty and residents.



Expertise from other basic science and clinical departments is available if specific needs for a project are identified. Research within the Department of Orthopaedic Surgery includes collaborative projects with Rheumatology, the Hypertension Center, Immunology and Microbiology, the Cancer Center, Neurobiology and Anatomy, Neurology, Plastic and Reconstructive Surgery, Public Health Sciences, Molecular Medicine, Neurosurgery, and Radiation Oncology/Biology.

The Department also collaborates with faculty from several departments at the main **Wake Forest University** campus, and faculty and students at the **Center for Nanotechnology.**

Adjunct Faculty

Luke Burnett, PhD is the senior research scientist for KeraNetics. He is a physiologist with experience in translational medicine and materials science. Various faculty have worked with Dr. Burnett during the past two years exploring the role of keratin hydrogel for the management of various orthopaedic pathologies.

Patricia E. Gallagher, PhD, associate professor in the Cancer Biology/Molecular Medicine and Translational Sciences and the Hypertension and Vascular Research Center focuses her research on the inhibition of cell growth by angiotensin-(1-7) in both cardiovascular cells/target organs and cancer cells/tumors. Dr. Gallagher is a biochemist/molecular biologist with an interest in carcinogenesis and cancer therapeutics who trained at St. Jude Children's Research Hospital. Her research has shown that Ang-(1-7) inhibited the growth of human lung cancer with a reduction in MAP kinases. Subsequent research demonstrated that MAS activation not only prevented the growth of human lung adenocarcinoma Xenografts but reduced tumor size in association with a decrease in COX-2. Dr. Gallagher collaborated with Ann Tallant, PhD to demonstrate that Ang-(1-7) inhibits breast tumor fibrosis suggesting a direct effect on the tumor microenvironment. Dr. Gallagher is collaborating with Cynthia Emory, MD on her studies using a mouse model to evaluate the histological and physiological effects of radiation on skeletal muscle in animals treated with or with Ang-(1-7).

Richard Loeser, MD is the chief of the section of Molecular Medicine has worked with orthopaedic faculty and residents on a variety of projects. He has worked with Drs. Ferguson, Smith, and Callahan to develop a mouse model of osteoarthritis in order to study changes in the meniscus associated with aging. Dr. Loeser's other interests include cellular and molecular mechanisms that

regulate cartilage destruction in osteoarthritis and the role of aging. Dr. Loeser also serves as a mentor for Dr. Ferguson on the research she is pursuing through the KO8 award.

Carol E. Milligan, PhD is a professor in the Department of Neurobiology and Anatomy has provided critical support for studies involving nerve regeneration and repair. Dr. Milligan generously shares resources within the Department of Neurobiology and Anatomy to support various research projects of our faculty and residents. Her interests include systems development; changes in muscle, neuromuscular junctions and spinal cord; and programmed cell death.

Katherine R. Saul, PhD is on the faculty of the Department of Mechanical and Aerospace Engineering at North Carolina State University. Dr. Saul developed a computer model of the upper extremity for simulating musculoskeletal surgery and analyzing neuromuscular control. Because of her expertise in upper extremity modeling, Dr. Saul has collaborated with several Wake Forest Orthopaedic faculty members and residents. Dr. Saul collaborates with Zhongyu Li, MD, PhD on a study funded by the Pediatric Orthopaedic Society of North America to identify muscular contributions to the development of shoulder deformity as a result of brachial plexus birth palsy. This study uses a rat model developed by Dr. Li that produces a brachial plexus injury in five-day-old Sprague Dawley rats. Dr. Saul has also collaborated with Christopher Tuohy, MD and Michael Freehill, MD on both basic science and clinical rotator cuff studies. Her basic science studies have evaluated neural tone in vivo passive-muscle-tendon unit biomechanical properties in the rat rotator cuff. The clinical research is designed to identify factors that contribute to rotator cuff rupture, improve the outcomes of repair, and the effect of tears on functional ability. Study participants are evaluated using magnetic resonance imaging of their shoulders, and clinical assessments by orthopaedic surgeons, patient questionnaires, and physical and functional shoulder assessments.

Joel Stitzel, PhD, associate professor in the Department of Biomedical Engineering has collaborated on a wide variety of faculty and resident projects involving biomedical engineering techniques. Dr. Stitzel's support is critical due to the wide overlap in the fields of orthopaedic surgery and biomedical engineering. Dr. Stitzel's research interests include crash injury research, biomechanics of trauma, human body finite element modeling, automotive safety, and sports and military biomechanics.

Ann Tallant, PhD, professor in the Department of Cancer Biology and in the Hypertension and Vascular Research Center is a biochemist/cell biologist with a long time interest in signal transduction mechanisms that inhibit cell growth in both cardiovascular and malignant cells and tissues. Dr. Tallant initially demonstrated the anti-proliferative properties of Angiotensin-(1-7) in vitro in vascular smooth muscle cells and in vivo in rats following vascular injury. She and Dr. Gallagher have shown that Ang-(1-7) inhibits tumor angiogenesis through a reduction in pro-angiogenic factors and an increase in anti-angiogenic factors as well as tumor fibrosis through effects on the tumor microenvironment. A Phase II clinical trial on the inhibition of sarcoma by Ang-(1-7) is ongoing at the Wake Forest Comprehensive Cancer Center. Dr. Tallant is collaborating with Cynthia Emory, MD on her studies using a mouse model to evaluate the histologic and physiologic effects of radiation on skeletal muscle in animals treated with or with Ang-(1-7).

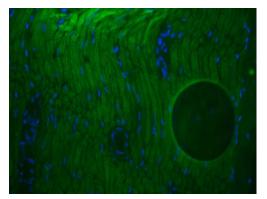
Mark Van Dyke, PhD is a chemical engineer with a Doctorate in Materials Sciences, who has more than 60 national and international patents and patents pending, most of these relating to keratin biomaterials. Dr. Van Dyke is an Associate Professor at Virginia Tech – Wake Forest School of Biomedical Engineering and Sciences at Virginia Polytechnical Institute and State University in Blacksburg, Virginia. Dr. Van Dyke is the leading expert in the use of keratin biomaterials for medical applications and has developed technologies using keratin hydrogel for fluid resuscitation, hemostasis, nerve and bone regeneration, and wound healing. He is co-founder, board member, and shareholder in KeraNetics LLC, a biotechnology startup focused on the commercialization of keratin biomaterials for medical and research applications. Dr. Van Dyke has collaborated with several faculty members in the Department of Orthopaedic Surgery and has served as a mentor for several of the physician scientists. The research endeavors in the department have been enhanced and our department is a serious participant in the development of tissue engineered technologies.

Jeffrey S. Willey, PhD, assistant professor in Translational Radiation Oncology studies radiation-induced injury to normal (noncancerous) musculoskeletal tissue following clinical and spaceflight radiation exposure. His research first documented that modeled cancer therapy and solar flares can cause acute musculoskeletal injury including quick bone loss, elevated osteoclast activity, muscle atrophy, weakened cartilage, and meniscal damage. Dr. Willey's research has shown that bone loss can be prevented following irradiation through the use of various radioprotectants. This work has been translated into a clinical trial that documented a similar pattern of acute bone loss following cancer radiotherapy. Dr. Willey has extensive experience in developing animal models of cancer radiation therapy.

Resident Research Expectations

During the course of training in the residency program, each resident completes at least one research project. The results of the project must be available in publishable form at the completion of the chief year. It is not necessary, however, for the paper to have been accepted for publication by PGY-5.

Residents choose their individual research topic(s), which can be either clinical or basic science in nature. Residents who have a strong interest in a particular research area are encouraged to pursue their interest. The department is supportive of efforts to obtain extramural funding for resident



research projects. Over the years, residents in our program have received funding from the Orthopaedic Research and Education Foundation, the Orthopaedic Trauma Association, the Arthroscopy Association of North America, and various industry sources.

Presentation by Residents at Orthopaedic Meetings

When a resident has a poster or podium presentation accepted at a national meeting, the resident is sponsored by the department to attend that meeting based on two

considerations. First, in order to attend meetings, residents must score in at least the 30^{th} percentile on their OITE. Second, the same presentation can be given at a maximum of two different meetings, *i.e.* regional and national meetings.

Documentation of Research Activities

PGY-1 residents complete a checklist to document the activities that are completed during their one-month rotation. Any activities that are not completed during the PGY-1 rotation are completed during the PGY-3 and PGY-4 research rotations. PGY-1, PGY-3, and PGY-4 residents complete weekly time sheets to document their research efforts during each week of their research rotation. Weekly research activities are collected using a REDCap database.

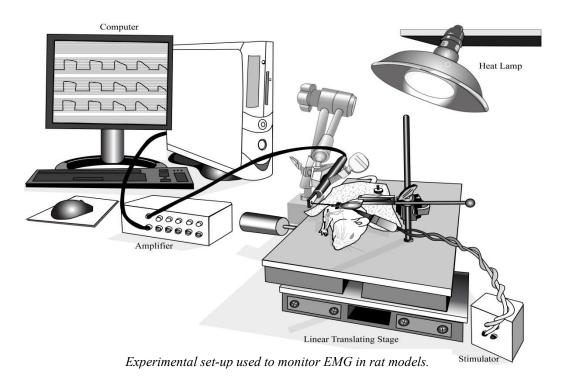
Documentation of Abstracts, Manuscripts, Grants, and Book Chapters

Each year, the department provides a report of its research-related activities to the Dean of the Medical School. Therefore, a list of all submitted abstracts, manuscripts, grants, and book chapters authored by the faculty and residents is maintained by the department to facilitate the preparation of the annual research summary.

Institutional Review Board (IRB), Animal Care and Use, and HIPAA Regulations

To ensure compliance with the medical school and federal rules governing research, it is imperative that residents understand and follow all research-related guidelines. HIPAA regulations are followed for every clinical research protocol within the department. Before working on clinical research projects, residents obtain certification through the Collaborative Institutional Training Initiative (CITI) by completing an online course. Because residents may participate in the enrollment of patients into various ongoing clinical studies within the department, they maintain their CITI certification by renewing it every two years. Similarly, residents working with animal models or who are completing the department microsurgery course receive certification through another online course, Laboratory Animal Training Associates (LATA). Information regarding the computer links to these websites is available from Martha Holden.

Anytime a resident is asked to prepare a clinical or basic science research proposal or to obtain patient follow-up, they first present the research question to be addressed to the Research Advisory Panel in order to ensure that all regulations and guidelines associated with the project have been addressed **before** work on the project is initiated. Because the medical school routinely audits clinical and basic science research, it is crucial that the Research Advisory Panel is aware of all research projects within the department. Martha Holden maintains the record of all IRB-approved protocols and Eileen Martin maintains the record of all animal studies (ACUC protocols).



Detailed Description of the Research Component of the Residency

PGY-1

- 1. All PGY-1 residents have access to a list of the ongoing orthopaedic research projects identified by faculty member. This list contains the titles of both basic science and clinical research projects. Residents at this level are encouraged to consider participation in ongoing research by specific faculty members, or alternatively, they may develop research projects of their own.
- 2. PGY-1 residents complete a one-month rotation in the Orthopaedic Research Laboratory during their internship year. During this time, they observe ongoing research activities to become acquainted with the techniques being utilized to address both clinical and basic science research questions. They attend the weekly departmental research meetings in order to learn about ongoing research projects within the department. Residents also have the opportunity to gain core competencies in clinical and laboratory services. Residents also learn about the general care of orthopaedic patients and basic surgical skills. Residents complete the specific activities described in the Resident Rotation Checklist during their rotation. This checklist is maintained as a part of each resident's research file.
- 3. The research rotation begins at 7:00 a.m. and continues until 5:00 p.m. The rotation is provided to offer "hands on" experience; therefore, working at home during this rotation is not an option. Residents must spend a minimum of 55 hours per week of in-house time during this rotation.

Goals and Objectives:

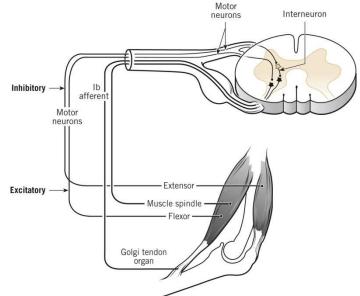
- 1. Learn techniques for research planning and project implementation.
- 2. Become familiar with ongoing research in the Department of Orthopaedic Surgery and the Orthopaedic Research Laboratory.

- 3. Become acquainted with the research resources available in the Department of Orthopaedic Surgery, Orthopaedic Research Laboratory, and collaborating departments.
- 4. Choose a tentative area of research interest and identify a mentor.
- 5. Learn general care techniques for orthopaedic patients and basic surgical skills.

PGY-1 – Resident Rotation Checklist

Use of the Computer in Research

Residents work with Cindy Livingston to learn the proper method to collect and organize data for the efficient collection and analysis of study data. Residents learn how to collect data using web-based data collection methods. Because computer technology is constantly evolving, Ms. Livingston provides computer instruction concerning the operation of new equipment and software as it is upgraded. All research data in the department is stored on the "R" research drive. This drive is monitored by Ms. Livingston.



Tissue engineering experience at the Wake Forest Institute for Regenerative Medicine

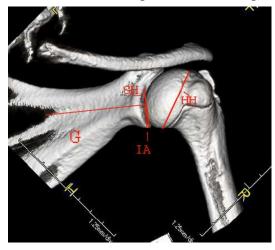
Residents shadow the physician scientists working on projects at the Wake Forest Institute for Regenerative Medicine (WFIRM) to become familiar with the ongoing tissue engineering projects and to understand the research collaborations between Orthopaedic Surgery and WFIRM.

Prosthetics/Orthotics

Residents attend two clinics with Tony Saia and/or Jim Butts to learn about the different types of prosthetics/orthotics used for diabetic foot patients, amputees, and pediatric cerebral palsy patients. They also learn how these devices are fabricated and fitted.

Electromyography Testing, Department of Neurology

Residents attend two clinics with neurology attendings to learn about the use of EMG and ultrasound in the diagnosis of neurological pathophysiology.



Terarecon image of the proximal humerus of a rat taken from a microimage of the rat shoulder.

Trauma Research

Residents meet with Brett Goodman, BA, MBA, to become familiar with the ongoing departmental trauma research projects.

Physical/Occupational Therapy

Residents spend three days at CompRehab working with therapists in the sports, hand, and spine therapy units. They become familiar with the different therapy protocols that have been developed for specific diagnoses and have the opportunity to observe patients involved in various rehabilitation programs. Residents spend one half day at the WFU Baptist Medical Center Inpatient PT/OT department to observe the therapy ordered for inpatients cared for by Orthopaedics.

The department maintains a collaborative relationship with the Department of Physical Therapy at Winston-Salem State University. The two institutions support the <u>Human Performance and</u> <u>Biodynamics Laboratory</u>. This laboratory supports research in musculoskeletal diseases, evaluation of orthopaedic implants and surgical techniques, rehabilitation approaches, and sports-related capabilities.

Microsurgery Course

Residents complete a Microsurgery course during their research rotation. The course usually takes 16-20 hours to complete but is tailored to meet each resident's learning rate. Instruction in microsurgery techniques are taught in a microsurgical suite housing several dual-headed operating microscopes located within the main orthopaedic research laboratory. Michael Callahan, PhD directs this course.

Orthopaedic Extremity Laboratory

Residents spend one day in the Orthopaedic Extremity Laboratory in order to learn how to perform an isolated cold stress test with laser Doppler fluxmetry, laser Doppler perfusion imaging, and vital capillaroscopy. These non-invasive techniques



allow for the quantitative analysis of extremity perfusion at the microvascular level. Residents learn how these tests are used for diagnostic purposes, how to evaluate microvascular perfusion before and after medical or surgical intervention, and how to interpret the test data. Derangements of microvascular blood flow are common in diverse conditions including Raynaud's disease/phenomenon, complex regional pain syndrome, and post-traumatic disorders.

Casting Techniques

Residents spend a day with the cast technicians at CompRehab to learn casting and splinting techniques. They also spend time working with the cast technicians in the hospital and learn how to apply traction.

Surgical Skills Simulator

The American Board of Orthopaedic Surgeons (ABOS) recently mandated that orthopaedic residency programs provide skills training for their residents. Unlike other surgical specialties, currently there is no widely used, cost effective surgical simulator designed to train and evaluate the surgical skills of residents. The Department of Orthopaedic Surgery at the University of California, Irvine has developed surgical simulators that use materials easily obtainable from national hardware chains at a low cost. The Department of Orthopaedics at Wake Forest is working with UC Irvine to test the feasibility of these simulators for resident skills training and evaluation of surgical skills. Two surgical simulators have been developed: 1) the fundamentals of orthopaedic surgery (FORS) simulator to simulate basic surgical skills required for orthopaedic procedures; and 2) the fundamentals of arthroscopic surgical techniques (FAST) simulator.

Orthopaedic Research Laboratory (Animal Model Studies)

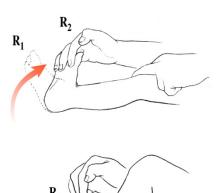
Residents spend a day with the technicians in the laboratory observing research involving the use of animal models. Our laboratory has developed several animal models to study orthopaedic pathophysiology. In addition, residents complete the Animal Care and Use Examination so that they can complete the microsurgery course and participate in animal model studies.

Outcome Studies

Residents complete the "on-line" program required to receive certification through the Collaborative Institutional Training Initiative (CITI). This program satisfies all Institutional Review Board and HIPAA guidelines and provides the certification necessary for residents to work with patients enrolled in study protocols and to have access to patient data. Residents spend two days observing and assisting the departmental study coordinators with their various clinical trials. This clinical study experience teaches residents how clinical outcomes data is collected and what happens to the data after it is collected. Residents learn how to conduct patient interviews; the strategies required to ensure that all required data is collected at each visit; and the guidelines for proper adherence to study protocols and federal guidelines.

Pediatric Physiatry

Residents spend one day in the clinic with Kat Kolaski, MD. Dr. Kolaski, a pediatric physiatrist, treats pediatric patients with cerebral palsy and other musculoskeletal disorders. She works closely with the pediatric orthopedic surgeons in the department to identify treatment plans to address each patients' individual needs.



Participation in Ongoing Research

In addition to their own research project, residents may assist with one project that is in progress during the time of their rotation. Participation in such a project allows the resident to participate as an author of an abstract or manuscript.

Case Reports

In addition to the other research activities, residents are encouraged to prepare at least one case report. The topic for the case report is chosen by the resident or their faculty mentor.

Anatomic Dissections

PGY-1 residents may be asked to assist with anatomic dissections that are scheduled during their research rotation.

Animal Care and Use Certification

Martha Holden supervises resident certification to participate in any research protocols involving animals. This certification is required before residents can begin the Microsurgery Course or participate in animal model studies.

<u>Checklist</u>

The progress of each resident in completing the Checklist activities is documented by noting on the checklist the date the activity was completed. All residents are expected to complete the items on the checklist by the end of their PGY-1 Research Rotation month. Any items not completed during this one-month rotation are completed during the PGY-3 research rotation. The checklist becomes a part of each resident's research file.

PGY-2

PGY-2 residents finalize the goals of their research project during this year to ensure the most efficient utilization of their time during their basic science/research rotations during their PGY-3 and PGY-4 years. Residents submit a one to two-page proposal of their research project to the Research Advisory Panel. The research proposal summary consists of the following elements: Name of Research Mentor, Project Title, Background and Significance, Specific Aims, Hypothesis, Methods (clinical projects include patient exclusion and inclusion criteria), Data Analysis Plan, and References. The deadline for submission of the research proposal summary to the Research Advisory Panel is **October 1** of the PGY-2 year. Preplanning of their research protocol during their PGY-2 year enables residents to begin work on their projects as soon as their research rotations begin during their PGY-3 year.

Meetings involving each PGY-2 resident and the Research Advisory Panel are scheduled during the PGY-2 year to clarify research goals and to discuss project implementation. These meetings provide an opportunity to finalize research plans and to identify the resources required for successful project completion.

Goals and Objectives:

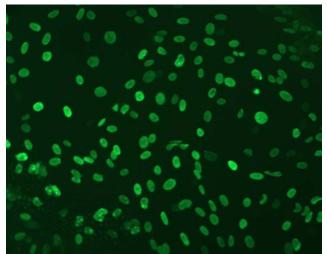
- 1. Finalize research plans with the goal of at least one publishable paper at the conclusion of the five year residency program.
- 2. Submission of a research proposal summary for approval by the Research Advisory Panel. This proposal summary becomes a part of each resident's research file.

PGY-3

BASIC STRUCTURE

The two-month research rotation provides each resident with dedicated, protected time to pursue their

research goals. During the Basic Science rotation, PGY-3 residents attend the weekly departmental research meeting and present progress reports on the status of their research at each meeting. Residents maintain a regular schedule to work on their research projects and document their activities during each week. The workweek is defined as Monday through Friday from 7:00 am to 5:00 pm. These hours represent the minimum requirement. Because this rotation is designed to provide "hands on" training experience, working from home is not an option. A summary of each resident's research



project status is submitted to the Research Advisory Panel at the end of the second research block.

Additional Duties

- Cover Outpatient Department surgical cases
- Assist with visiting professors and other visitors including hosting duties
- Attend weekly departmental research meetings scheduled every Wednesday morning following Grand Rounds

Goals and Objectives:

- Significant progress should be made on the individual resident's research project during the research rotation.
- A one-page progress report is due at the end of the rotation. This report becomes a part of each resident's research file.
- Resident Research Day: Provide a project progress update and any preliminary findings of their research project during the scientific session.

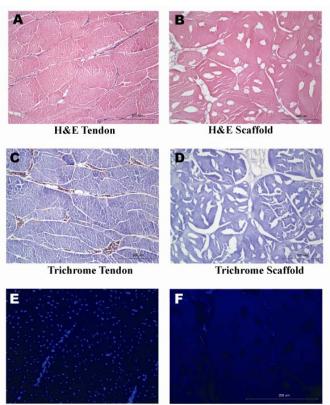
A designated desk and computer located in the research laboratory is available for use by the research resident. This designated study area provides an enhanced learning opportunity during the rotation by providing access to key research laboratory personnel and computer resources specifically developed to enhance the research experience.

PGY-4

Residents complete work on their research project during a two month research rotation and report any roadblocks to timely project completion to the Research Advisory Panel in order to develop a plan to facilitate their research. The manuscript describing the project should be under preparation during this year.

Goals and Objectives:

- 1. Finalize work on research project.
- 2. Report progress to the Research Advisory Panel.
- 3. Resident Research Day: Present cases to the visiting professor.



DAPI Tendon

DAPI Scaffold

Histological examples of native tendon and tissueengineered scaffold tendon showing the reduction in cellular material and increase in porosity.

PGY-5

Residents meet with the Research Advisory Panel one time during their PGY-5 year. Their manuscript is submitted to the members of the Research Advisory Panel for review no later than February 1st unless their manuscript has already been published. This submission deadline allows panel members to review the paper and offer editorial comments before Resident Research Day. Resident Research Day offers the opportunity for each PGY-5 resident to present their research project to the visiting professor, orthopaedic faculty, and orthopaedic residents.

Goals and Objectives

- 1. Completion of project and manuscript. The manuscript becomes a part of each residents' research file.
- 2. Resident Research Day: Presentation of completed research project

RESIDENT RESEARCH DAYS

Department of Orthopaedic Surgery Resident Research Day

Each spring, the Department of Orthopaedic Surgery sponsors a Resident Research Day. Residents (Physician Scientists and PGY-3 and PGY-5 residents) discuss the status of their research project during a Friday afternoon scientific session. By PGY-5, the results of each residents' research project are formatted for publication. Therefore, residents at this level present a comprehensive review of their research project. The PGY-2 and PGY-4 residents present cases to the visiting professor during a morning session. The residents and visiting professor are honored at a dinner at the end of the day. Since 2006, two prizes have been awarded at the dinner, one for the best clinical research presentation and one for the best basic science presentation.

Department of Orthopaedic Surgery Resident Research Day Agenda

Breakfast

Presentation by Visiting Professor

Case presentations by PGY-2 and PGY-4 residents for discussion with visiting professor

Lunch

Scientific Session - Includes second presentation by visiting professor, physician scientists, PGY-3, and PGY-5 residents

Dinner honoring visiting professor and residents

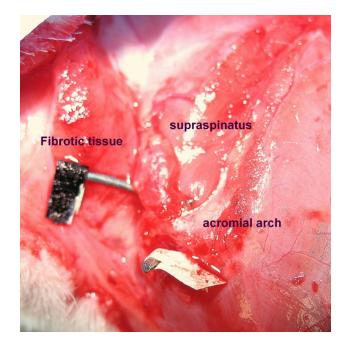
Resident Research Day Visiting Professors

1001	
1991	Lamar L. Fleming, MD; Emory University
1992	James H. Dobyns, MD; The Hand Clinic of San Antonio
1993	Eugene E. Bleck, MD; Stanford University
1994	William E. Garrett, MD; Duke University
1995	Greer Richardson, MD, PhD; Campbell Clinic
1996	James R. Kasser, MD; Harvard Medical School
1997	James Hughes, MD; University of Mississippi
1998	Andrew J. Weiland, MD; Hospital for Special Surgery
1999	James A. Rand, MD; Mayo Clinic (Scottsdale)
2000	Bert Mandelbaum, MD; Santa Monica Orthopaedic and Sports Medicine
2001	Peter J. Stern, MD; University of Cincinnati
2002	Regis O'Keefe, MD, PhD; University of Rochester School of Medicine and Dentistry
2003	Robert A. McGuire, Jr., MD; University of Mississippi
2004	Neil E. Green; Vanderbilt
2005	Michael J. Bosse, MD; Carolinas Medical Center
2006	Robert C. Schenck, Jr., MD; University of New Mexico
2007	Richard Buckley, MD; Foothills Medical Center, Calgary
2008	Thomas P. Vail, MD; University of California, San Francisco
2009	Robert M. Szabo, MD, MPII; University of California at Davis
2010	Mark T. Scarborough, MD; University of Florida
2011	Sanford Emery, MD; West Virginia University
2012	Hank Chambers, MD; University of California at San Diego
2013	David L. Helfet, MD; Hospital for Special Surgery

Division of Surgical Sciences Residents' and Fellows' Research Day

In the fall, the Division of Surgical Sciences sponsors a Residents' and Fellows' Research Day. Residents and fellows display posters and describe their research to a panel of judges. Prizes are awarded in several categories to acknowledge outstanding research efforts. Winners are announced at a dinner to honor the residents/fellows and their mentors. Our department has a history of winning prizes at this event.

Anatomy of the rat shoulder. A novel rat model was developed in our department to study rotator cuff injury and repair.



AUTHORSHIP GUIDELINES

A. General Principles and Right Conduct

One of the missions of the medical school is to foster the discovery and application of new knowledge through basic and clinical research in the biomedical and relevant social sciences. Coupled with this mission is the responsibility to communicate truthfully this new knowledge to the rest of the scientific community. When publishing results of biomedical research, authors should adhere to certain standards that will assure the quality and integrity of the publication. Specially, authors should:

- 1. If possible, report results and their verification in a peer-reviewed forum;
- 2. Report all relevant data including conflicting data if pertinent to the hypothesis in question;
- 3. Acknowledge the work of others that is relevant to the context of the study and its interpretation;
- 4. Refrain from redundant primary publications of the same data;
- 5. Take ultimate responsibility for the scholarly character, accuracy, and conduct of the research performed under their supervision;
- 6. Present research in appropriate scientific forums before reports are released to the press; and
- 7. Alert editors and readers of potential conflicts of interest that may affect how the article will be interpreted.

Fabricating data, falsifying data, and/or knowingly representing the work of others as one's own are serious violations of our mission and the public trust and constitute scientific misconduct.

B. Criteria for Authorship

Authorship refers to the listing of names of participants in all written communications of data and their interpretation to the scientific community. Authorship is the fulfillment of the responsibility to communicate scientific research to society and is the primary means for assigning credit for a scientist's contributions to the advancement of scientific knowledge.

Authorship should be given generously, but only to those who have contributed

significantly to the research, are prepared to stand behind their findings, and have reviewed the entire manuscript. All authors of a scholarly publication should meet the following four criteria:

- 1. Participate substantially in conception, design, and execution of the study, or in the analysis and interpretation of data;
- 2. Participate substantively in the drafting of the manuscript or in the subsequent editing of the manuscript;
- 3. Give final approval of the version of the manuscript to be published; and
- 4. Be able to explain and defend in public or scholarly settings that portion of the study for which he or she was directly responsible, including potential conflicts of interest.

A claim of authorship by, or assignment of authorship to, persons who may have been associated in some way with a study but do not meet the four criteria above is considered highly inappropriate. The referral of patients included in a clinical study does not in and of itself warrant co-authorship status. Individuals who have made lesser contributions such as providing advice, occasional analyses, subject/patient material, space, or who may have supported the research in other ways, should be acknowledged. The practice of permitting honorary authorship is unacceptable and should be actively discouraged.

C. Responsible Author

One author, designated as the Responsible Author must assume overall responsibility for each publication (e.g., primary research report, abstract, review article, book chapter) submitted from the medical school. The Responsible Author is typically the faculty member who leads the study and who assumes the responsibility for coordinating and completing the work, drafting of the manuscript, satisfying pertinent rules for submitting the manuscript and any required revisions, and coordinating responses of the group to inquiries or challenges. The Responsible Author should exercise due diligence in assuring the validity of the entire manuscript.

The selection of the Responsible Author, inclusion of collaborators as co-authors, and the order of authorship should ideally be determined by the research team as a whole. Decisions regarding authorship and its order should, when possible, be determined before the study begins and any disputes resolved at that time. A written memo attesting to this determination is valuable documentation if a dispute subsequently arises. Changes in authorship, which take place as a study proceeds, should similarly be documented in writing. The Responsible Author should assure that all collaborators are appropriately recognized and that study collaborators listed as co-authors meet the criteria for authorship described herein. The Responsible Author does not necessarily have to be the first author.

The Responsible Author should assure that all co-authors have had the opportunity to approve the final version of a manuscript or abstract, that each co-author has reviewed the portions of the manuscript or abstract representing his or her contribution, and each is willing to support that material.

Each co-author must consent to authorship prior to submission of any manuscript bearing his or her name. In addition, each co-author should practice due diligence to assure the validity of the manuscript.

D. Students, Fellows, and Research Associates

All persons designated as authors should qualify for authorship as defined herein.

Faculty should be aware of their responsibility to ensure that students, postdoctoral fellows, and other research associates participate in the preparation of manuscripts and are recognized as authors in publications covering the results of research in which they were active participants.

E. Multi-Authorship/Multi-Center Manuscripts

These criteria are considered important because there has been a gradual diffusion of responsibility for multi-authored or collaborative studies that has led to the publication of papers for which no single author was prepared to take full responsibility. Multi-authorship, including authorship on papers from multi-center studies, raises special issues, such as the ability of an author to evaluate all aspects of a study and the sequence of listing of authors. Authors should discuss these issues openly before initiating a multi-authored project and repeatedly during the course of such work. To promote this process in multi-center studies,

specially charged Publication Committees are often invaluable (see section on Disputes over Authorship). All authors should approve the final version of a manuscript and should be prepared to take public responsibility for the work. It is recognized, however, that medical studies often involve investigators from several specialties, and it may not always be possible for a single investigator to confirm each piece of data used in the written report. It is therefore the responsibility of each participating investigator to be actively involved in verifying the sections of a manuscript that discuss his or her specialty area, and to assure all co-authors that the sections are accurate and valid.

F. Disputes over Authorship

In general, authorship issues and related matters should be freely discussed and decided upon early during the research process and prior to writing of the manuscript. However, agreements relating to authorship may need to be changed during the collection of data and preparation of the manuscript. Possible disagreements include interpretation of the criteria for authorship, order of listing of authors, editorial control of content and focus of the manuscript, selection of journal or other publication media, and choice of Responsible Author.

1. A procedure for resolution of disputes over authorship is outlined along with a timetable for each step. It is recognized that extensions in the time to resolve a dispute may be necessary. When this occurs, the reason(s) for the delay in completion should be documented in the final report. All matters related to dissolution of authorship disputes should be held in a confidential manner as much as possible.

Disagreements between or among authors should be resolved in a collegial manner by the Responsible Author in consultation with the other authors, relevant research personnel, and any other individual who claims authorship. Generally, the Responsible Author has the primary responsibility for making decisions on authorship and other matters related to the publication of manuscripts.

When matters of authorship and related issues cannot be resolved in a satisfactory manner by the Responsible Author, other authors, research personnel, and other individuals who claim authorship, all should present their controversy in writing to the Department Chair. The manuscript in question should not be submitted for publication before these issues are resolved. The Department Chair should meet with the individuals involved in the dispute, collect and retain appropriate information, and make a recommendation in writing as to authorship within 60 days of receiving the complaint. When the authorship dispute involves the Chair, if the Chair has a major conflict of interest, or if the dispute involves more than one department, then a neutral mediator will be appointed by the Dean's designee. The mediator should hold the rank of tenured professor and make a recommendation to the Chair within 60 days. Normally, the Chair will notify the Dean of an impasse, but the individuals involved also can make this notification directly.

In the event that a satisfactory resolution still cannot be achieved by the

Departmental Chair or by a neutral mediator, then the Dean (or designee) will appoint three senior faculty members (one of whom will serve as Committee Chair from departments other than the involved departments) to a committee to investigate the dispute. The review group will not include individuals with personal responsibility for the research, but should include faculty members with unique qualifications relative to the dispute in question (i.e., research expertise, training of graduate students, experience with clinical trials, active peer-reviewed research, etc.). In the case of disputes involving faculty member from other schools within Wake Forest University, a member of the committee should be from the faculty of the affected school. In addition, a representative from the Office of Research will serve as Executive Secretary. Within 75 days, the committee will make a recommendation in writing to the Dean who will evaluate this recommendation and render a decision within 10 days. The decision of the Dean is final.

2. Disputes Over Authorship in Multi-Center Studies

Publication, presentation, and authorship policies should be determined and accepted by all participating investigators at the beginning of any multi-center study. Specifically, it is recommended that a Publication Subcommittee representing all Investigators should be established at the beginning of any multi-center study for the purposes of expediting, coordinating, and monitoring the paper-writing processes. Inherent in these charges is the responsibility to adjudicate disputes over authorship. As with single-center studies, difficulties for a particular paper can be avoided if the identification and sequence of authors is agreed upon by all participants in advance. If a dispute between investigators from separate centers does arise, the solution to the dispute should arise from within the organizational structure of the multi-center study. If a dispute cannot be resolved, the principle of academic freedom generally indicates that an investigator has the right to present those data for which he/she is contract custodian. However, this right should be tempered by the concept of collegial collaboration. It is unacceptable for an investigator to publish or present a study's finding before the total group of study investigators has had a reasonable opportunity to do so.