

Training Undergraduates in Clinical Research: The Furman Oncology Research Team (FORT)

Introduction

Furman University is the oldest, largest, and most selective private institution in South Carolina. Founded in 1826, Furman is one of the leading liberal-arts colleges in the United States and is an exemplar of a new type of liberal-arts institution that is grounded in the humanities, arts, and sciences and that promotes development of professionalism in its students through engaged learning: a problem-solving, project-oriented, experience-based approach to the liberal arts. Engaged learning encourages students to develop creative ways to put classroom theory into practice and to take a more active role in their education through internships and research (Proudman, 1992).

This emphasis on engaged learning led to the establishment of the Furman Oncology Research Team (FORT) in March 2007, a cooperative effort between Furman University and a local regional teaching and research hospital. The initiative opened opportunities for participation in instruction by the hospital physicians and for learning by undergraduate university students.

Furman is dedicated to equipping students with the tools and experiences needed to gain access to graduate and professional schools, including those involved with the medical profession. Students who wish to pursue a career in allied health following their undergraduate experience must show exceptional ability in five areas: academics (grade point average and professional school exams; Koenig et al., 1998), humanitarianism, leadership, knowledge of the medical profession (Ferguson, 2002) and research. Students are able to build their knowledge of the medical field by observing medical professionals, and they gain research experience by performing medically related research in a laboratory as well as a clinical setting.

While knowledge of medicine and research may sound straightforward, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) has become problematic for students seeking access to medical facilities and pre-health advisors who manage these activities (Annas, 2003). To circumvent this obstruction, Furman University developed an affiliation with a local medical center to give undergraduate students a variety of medically related experiences. Initially, these experiences

were observation-based. As the program began to expand, we developed a clinical research program that focused on student involvement in retrospective clinical research coupled with stimulating, informative, and research-relevant observations of medical and surgical procedures. In this article we examine the steps that were taken to educate undergraduate students from a variety of disciplines in retrospective clinical research.

Research, an increasingly important criterion for admission into health-related professional schools, chiefly exists in two forms: basic science research and clinical research. Basic science research examines the fundamentals behind disease and typically involves intensive laboratory experimentation in a variety of scientific disciplines. Clinical research is focused on the disease process and patient outcomes, using observed correlates with the goal of improving direct patient care. Historically, undergraduate students have had access to basic science research, primarily through their home academic institutions or through various national summer-research programs, such as those funded by the National Science Foundation (Seymour, 2004). With an increased emphasis on research as a criterion for admission to medical school or other professional programs in health care, undergraduate institutions have steadily increased the opportunities they provide for their students to participate in basic science research. However, it is not typical for undergraduate students to participate in clinical research, and yet clinical research is a primary aspect of medical training. Furthermore, the National Institutes of Health, the agency that funds the vast majority of clinical research in the United States, lacks university-based summer clinical research experiences comparable to the National Science Foundation's Research Experience for Undergraduates (REU). Yet, clinical research helps undergraduates integrate basic science knowledge with the application of medical treatment of disease. Our combination of integrating basic science with medical treatment is a good example of the university's underlying commitment to engaged learning.



FORT students observe oncologic surgery with Dr. Steven Trocha. From left: Brian Greenwell, Jodi Schneidewind, Kaylee Nuckolls, Paige Zdybel, Amanda Byrd, Dr. Trocha, Sarah Asman, Brent Schoen and Simon Lehtinen.

Steps Toward Establishing a Clinical Research Program at an Undergraduate Institution

1. The Clinical Research Partnership—Physicians, Faculty, and Students

Partnership

The first step in the development of a clinical research program is establishing a partnership between university faculty and hospital physicians, both of whom must have the common goal of educating undergraduate students. This is essential to the development of a relevant and successful research program because the educational outcomes for the students and the success of each project is proportional to the dedication and time commitment of all supervisors and mentors. Three physicians within the hospital system—two surgical oncologists and one pathologist—and three Furman faculty members comprised the FORT Leadership Team that committed to work with undergraduate students for an intensive 10-week summer period. The leadership team identified the research projects, planned the training of the students, selected the students, set the research schedule, and determined the goals and deadlines for preparation of conference abstracts and journal manuscripts. As communication is vital for the success of the program, the leadership team met weekly to discuss data, the progress of students and the projects, modifications to hypotheses, as well as successes and challenges.

Identification of Students and Mentors

Students interested in pursuing a health-related career were identified throughout the academic year. The program was open to any student who was interested in pursuing such a career (MD, DO, PA, PT, nursing). Selection of participants was based on several criteria: maturity, ability to work with others, interest in clinical research, and competitiveness in their intended professional program. Five informational sessions preceded the summer research program, during which clinical research procedures and hypotheses were discussed and commitment to the program and expectations were explained. With this knowledge, the eligible students were able to determine whether to participate in FORT. During the summer of 2007, 10 students chose to participate.

The physicians in the FORT leadership group identified four surgical residents who were required to complete clinical research as part of their residency program and who were willing to act as project mentors (Nathan, 1998). These residents were assigned to specific research projects based on their interests and were required to assist in directing the projects. Their duties included attending daily FORT progress meetings and weekly journal clubs and regularly meeting with the students to answer questions, assist in data collection, and assure progress of the project. The students found the resident-mentors invaluable, since they gained insights into the inner workings of the medical profession from the perspective of recent medical-school graduates. The residents, in turn, found the students essential to data collection and analysis.

Establishment of Research Teams

Each research project was assigned a team consisting of two students and one resident. Each team member was responsible for his team's performance, thus ensuring accountability. This design encouraged maximum student involvement in the project while allowing for optimal coordination of scheduling and focused interactions with the resident. These focused interactions allowed for additional surgical observations and intense mentoring. The residents provided an increased level of knowledge and experience with the research project's subject matter, but most had not participated in clinical research prior to this experience. Thus, the residents and students interacted as colleagues in many arenas. Furthermore, faculty supervision of each student research group was critical for quick identification and resolution of unforeseen challenges. This also allowed for weekly assessment of students' development of clinical research skills and appropriate progress of the projects.



FORT students in the pheresis unit of the Cancer Treatment Center. FORT students observe patient/physician interactions with Drs. McKinley and Trocha.
 From left: Sarah Asman, Kaylee Nuckolls, Simon Lehtinen, Dr. McKinley, Brian Greenwell, Brent Schoen, Paige Zdybel, Dr. Trocha, Amanda Byrd, and Jodi Schiedewind.



Learning about the pathology of cancer with Dr. Schammel. Dr. Schammel explains the intricacies of the histologic features of pancreatic cancer.
 From left: Simon Lehtinen and Dr. David Schammel.

2. Preclinical Research Preparation

Project Design

During initial planning sessions, physicians identified potential clinical research projects. Because of time constraints imposed by the 10-week summer research period, five projects were selected that were of manageable size, had well-defined hypotheses, and circumscribed data-collection boundaries. Clearly defined research goals helped focus the daily activities of students, residents, faculty, and physicians.

Preparation of Participants in Clinical Research

Students' participation in hospital-based clinical research programs required completion of extensive paperwork as well as training required by the regional medical center and mandated by federal guidelines that govern access to medical information.

According to the affiliation agreement between Furman University and the regional medical center, all participants of the FORT program were required to obtain or provide the following: immunization records, health history, TB test results, a felony background check, a Hepatitis B declination form, a HIPAA confidentiality form (Annas, 2003), and the hospital's orientation form. The students were able to obtain the immunization records, health history, and TB tests from the Furman University Student Health Service. The investigative background

check was completed through Furman, utilizing the agency designated by the medical center. Results were processed through Furman's Department of Public Safety and received by the Pre-Health Internship Director in a sealed envelope. The Hepatitis B declination form, HIPAA confidentiality form, and hospital orientation form were obtained from the medical center. The forms were filled out following students' completion of an on-campus orientation session approved by officials from the hospital. The Pre-Health Internship Director forwarded all completed student paperwork packets to the Academic Services Student Office at the hospital. The hospital agreed to retain all information, except those items requiring yearly renewal, for three years after each student entered the project. Each student who completed the prescribed training and orientation received a hospital-specific 'STUDENT' badge that was to be worn in conjunction with his or her Furman University identification. All nominal fees for tests and processing of background checks were the responsibility of the student.

Prior to involvement in FORT, each student completed training to guarantee ethical treatment of patient information. The CITI Human Subjects Research Educational Program, a 17-module Web-based education program designed by experts from Institutional Research Boards (IRBs), educates biomedical investigators conducting research involving human subjects about established national research guidelines to ensure standards for ethical practice. Verification of successful completion of this

program was forwarded to the medical center electronically and was part of the researcher's record of training and standards' compliance. CITI training is required every two years for all individuals participating in clinical research (Braunschweiger and Goodman, 2007).

3. Training Undergraduate Students for Clinical Research

The undergraduate students needed to be proficient in understanding their research topic and working with patient records, pathology reports, and surgical notes. Thus, the FORT Leadership Team organized a series of journal club discussions and informational meetings for the students to address these issues. Additionally, the students were required to compile reference material and terminology lists relating to their area of research.

Journal Club

The physicians identified key research articles that exemplified current clinical practices for each of the proposed projects. Five club meetings were held before the beginning of the summer research program to provide an introduction to each project. During the first three of these two-hour meetings, the physicians presented the research papers and described the pertinent anatomy, physiology, and statistical analysis associated with each project. During the final journal club meeting, the students were assigned to present research papers on their proposed projects. Student presentations addressed key learning objectives, requiring students to critically analyze the research papers and present an unbiased summary of conclusions. The FORT leaders used this opportunity to identify and address inadequacies in students' preparation.

Background and Terminology

Medical terminology, acronyms, abbreviations, and procedures, as well as pharmaceutical names, are unique within the medical field and new to the students and university faculty. To ensure mastery of this new vocabulary, the students were required to keep lists of all terms, abbreviations, and protocols encountered during their clinical research experience. For example, students were required to develop familiarity with the staging criteria for the different cancers studied (Lyman *et al.*, 2006).

Prior to the summer research period, each student was required to conduct an extensive search of the scientific and medical literature to identify research articles that pertained to their specific research project. Each research team was required to maintain a reference list that was also used during the writing of their abstracts and research manuscripts for journal submission.

Extraction of relevant information from medical records was seen as a daunting task for the undergraduate student researchers. Presentations were given on such topics as taking and recording a patient history, understanding the format of a pathology report, and the organization of a surgical report. Since much of the data collected by the students was found in primary patient records, understanding how these reports were generated and the type of information that they contained was essential for accurate and expeditious data collection.

4. The Clinical Research Projects

Institutional Review Board (IRB) Proposals

Institutional Review Board (IRB) approval of a research project is essential to assure that appropriate steps are taken to protect the rights and welfare of humans involved in research. Approval is required by the Food and Drug Administration and is essential for research to be presented at meetings or published in journals (Markin, 2005). IRB approval is required prior to any clinical research, whether a clinical trial or a retrospective review of patient charts. The process of IRB approval can take several weeks, so approval for the summer research projects was obtained during the spring. The students were involved in writing the IRB proposals for expedited review, since the proposed projects dealt with retrospective patient-data analysis as opposed to actual patient contact. Each student was designated as a co-investigator, and in compliance with IRB procedure, was required to complete a *curriculum vitae* for submission with the IRB proposals.

All IRB documentation was collected by FORT leaders and stored in a central, secured location in the hospital. All forms and records related to the research projects were readily accessible, to comply with IRB verification requests from various hospital departments. (Markin, 2005).

Identification of Research Projects

In medicine, retrospective clinical research facilitates the optimization of medical practice and assessment of new procedures. Relevant data, including demographic information (age, race, sex, height, weight, etc.), pathological information (staging and grading of tumors), treatment history (radiation, chemotherapies, surgeries), and information regarding medical procedures must be culled from a variety of sources, including patient charts, pathology reports, and surgical notes. To do this efficiently, the retrospective clinical studies were designed to have clearly defined goals. Similarly, database schemas had to be robust enough to encompass project hypotheses and any potential challenges associated with data collection and assessment (Hulley *et al.*, 2006). Therefore, before embarking on the complete patient review that could involve thousands of patient records, students completed pilot studies using medical data from 30 patients. The pilot study also identified general features of the patient population that met the criteria for inclusion in a particular study. In addition, given the 10-week summer time constraint, the patient population needed to be of manageable size and amenable to statistical analyses. The pilot study allowed for reevaluation of the hypotheses if the patient populations were inadequate (Wittes and Brittain, 1990).

Establishing a Multifaceted and Multi-Use Database

The key to the success of a clinical research initiative is breadth, depth, and flexibility of its data schema and the suitability of the database for extracting information relevant to specific hypotheses (Hulley, 2006). FORT faculty and students collaborated in a number of conference sessions to establish a data schema appropriate for a multi-user relational database capable of warehousing clinical data for thousands of patients. Data fields were designed to incorporate general demographic data (age, gender, etc.) as well as specific patient outcomes (recurrence, morbidity, etc.) related to the different types of cancer. Additionally, the students identified previously published research papers within their field of research for use as templates for data collection. Thus, as students became immersed in the literature associated with their particular study, they were able to identify all important parameters for data collection. Ultimately, all projects used a common database schema with hypothesis-specific fields that could also be adapted and modified for future clinical research.

The database software selected for the project was Filemaker Pro™D version 8.5 Pro (Filemaker, Inc., Santa Clara, CA) running under Mac OS™ 10.48 (Apple, Inc., Cupertino, CA). Selection criteria included ease of use, SQL standards compliance, ability to easily edit data, and flexibility in creation of database schemas.

Procurement of Data

An initial screen of patient records contained in the hospital's cancer registry was done to identify patients for inclusion in the various studies (see Adams *et al.*, 2006 for information on the use of a tumor registry in breast-cancer epidemiological research). Students identified study-specific parameters, including the type of cancer and the extent of the tumor or procedure used, to facilitate this search. Once the patients were identified, paper-based, electronic-based, or microfiche-based records were retrieved by the hospital's medical records department. Depending on the project, additional data was obtained from pathological or surgical records, often to confirm original diagnoses and American Joint Committee on Cancer (AJCC) stage. Daily meetings with the FORT Leadership Team were used to assess progress with data collection and assessment.

Statistical Analyses

Statistical tests were identified in the pilot studies, and JMP™ statistical software version 7.0 for Mac OS™ 10.48 (SAS Institute, Cary NC) was used in all analyses. Tests performed included t-tests, survivorship, and other non-parametric analyses. The medical center's biostatistician evaluated all raw and statistically analyzed data. Once datasets were completed and analyzed, the students began writing the project abstract.

5. Outcomes: Publications, Credit and Assessment of the Instructional Model

Abstracts and Manuscripts

FORT physicians identified potential national and international clinical cancer-research symposia to which project abstracts could be submitted. The students were given guidelines for creation of abstracts and produced drafts that were then evaluated, edited, and submitted by the FORT leaders. Students whose abstracts were accepted obtained travel funds to attend meetings from Furman's Undergraduate Research Office, the biology department's Townes Funds, as well as the Dean's office.

Perspectives on the FORT experience

“The exposure of students to the many aspects of the medical career through this program was amazing. Additionally, the availability of the faculty to the students and their eagerness to educate and assist us was essential to the experience.”—FORT student

“I particularly enjoyed receiving instruction from the surgeons and accompanying them into the OR.”—FORT student

“This was a phenomenal experience overall. I have high praise for FORT! I would like to return next summer to fine-tune my clinical research skills.”—FORT student

“I am confident that the FORT students have at least the same, if not, a greater knowledge about their topics than many of my surgical residents.”—Dr. Steven Trocha

“I have heard good reports from students who were surprised by the professionalism of the experience. They were engaged more as colleagues than as undergraduates.”—Furman Biology faculty member not involved with FORT

With the successful completion of data analyses and presentation of a paper at a national or international meeting, the FORT leadership worked with students to prepare manuscripts for publication in peer-reviewed clinical oncology journals. This process is ongoing and is facilitated by parallel preparation of student-authored research papers for course credit at Furman. Three students participating in the inaugural year of FORT were juniors. Two of these students are returning to FORT for a second year, and the third is participating in summer research at another facility. Four of the seven seniors who participated in the program have been accepted to medical school, two are continuing other forms of education beyond their bachelor's degree, and one will be doing research at the National Institutes of Health.

Course Credit

Course credit was awarded on the basis of the student's participation in the research project and an individually authored research paper and seminar presentation. The Furman Biology

Department's seminar committee—a committee of three faculty who oversee senior research and internship courses— independently assessed each student's paper and seminar presentation.

The Research Community

The FORT Leadership Team knew early in the process that clinical research involving retrospective data analyses would mean primarily office work for the students. To enrich the clinical research experience, students were allowed to attend medical conferences in which physicians from various disciplines discussed patients and their disease-management strategies. This occurred three mornings per week. Each week the physicians also reviewed their scheduled surgical cases with the students and allowed the students to function as observers in the operating room. These sessions within the operating room became very powerful teaching tools for the physicians and learning experiences for the students. The students were able to observe the surgical procedures pertaining to their clinical research projects, which provided a tangible illustration of procedures they knew only from reading the medical literature. Projects thus acquired real meaning for the students since they were able to observe genuine medical procedures, patients, and deal with the implications for improvement of medical practices.

Outcomes

Of the five projects begun by 10 students in June 2007, four were completed by December 2007. Due to compelling statistics, the fifth was expanded to include 1,000 more patients and was to be completed by May 2008. The four completed project databases have produced five abstract submissions to meetings, of which three have been accepted as posters to date. Sites for poster presentations include: The Sentinel Node Symposium, Sydney, Australia (February, 2008), The American Society of Colon and Rectal Surgeons, Boston (June, 2008), and The American Society of Clinical Oncology, Chicago (ASCO; June, 2008). The abstract for ASCO also was honored by being scheduled for discussion during the president's forum. Acceptance of two abstracts was pending. Manuscripts are being prepared for all projects. Students' experiences were assessed using a questionnaire that evaluated expectations, skills, and perceived outcomes. The students assisted in writing the abstracts submitted to national conferences (Sentinal Node Society, American Society of Clinical Oncology, etc.) and of manuscripts submitted to journals. If an abstract was accepted

to a professional meeting, the student assisted in the creation of the poster for that meeting. In addition, each student was required to write a 20-page paper and to give both a 15-minute oral and a poster presentation at Furman for credit.

The Next Step

The success of FORT has attracted much attention. Additional physicians have agreed to participate as mentors, seven projects have been proposed, and 14 students are prepared to work full-time during the summer of 2008. Additional students desire to participate on a part-time basis, and the hospital is adopting this model to facilitate research to include medical students. Over the course of the program, the students involved in FORT have had the opportunity to grow and mature in not only their knowledge of clinical research and medicine, but also in character. The students' maturity and experience have been recognized by the admissions committees of professional schools, such that all students are pursuing graduate experiences in the health professions. This exceptional experience has also shaped how each of these students interprets medicine within their profession. This new generation of health professionals will be shifting the paradigm of medical research as they realize that their research lab has the ability to be the bedside, and that significant research can be done from bedside to bench.

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A typical day for the research teams was:

7 a.m.—Meeting with Drs. Trocha, Schammel, Schisler, Thompson, other involved physicians, residents and all FORT students. The meeting consisted of updates on each project and training in data procurement, warehousing, and analysis. (This would occur at 8 a.m. on days that the students attended a medical conference.)

9 a.m.—Students broke into their research teams to work on their data.

12 noon—Students met for lunch to discuss their projects.

1 p.m.—On a rotating schedule, the students observed surgical procedures that related directly to their research project. Students would often “scrub in” to have a direct view of the surgery. Students not in surgery would continue to process data.

To keep group morale high and facilitate the establishment of community, weekend events were scheduled on several occasions for all participants in the research projects. These events included a pool party, a dance/game night, and paintball.

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Christine M.G. Schammel, PhD

Pre-Health Internship Director
Furman University
3300 Poinsett Highway
Greenville, SC 29613
864-294-2084
EM: Christine.Schammel@furman.edu

Christine M.G. Schammel received an MS in Molecular, Cellular and Structural Biology from the University of New Mexico and her PhD in Microbiology and Immunology from Georgetown University. She is currently the Pre-Health Internship Director at Furman University, where she also directs the FORT program and FUMMO, a medical-mission program for undergraduate students.

Nicholas Schisler received his PhD from the University of Western Ontario. His research interests include genetics, molecular biology, and bioinformatics. He currently is an assistant professor at Furman University, where he is active in teaching and research and is part of the FORT leadership team. Email: Nicholas.Schisler@furman.edu.

Laura K. Thompson received her PhD from Virginia Tech. Her research interests center around molecular genetics, cloning, and gene structure. She currently is the Pre-Health Advisor at Furman University and is part of the FORT leadership team. Email: Laura.Thompson@furman.edu.

A. Joseph Pollard received his PhD in botany from the University of Cambridge. His interests are ecology, plant-herbivore interactions, and plant taxonomy. He currently is the chair of the Department of Biology at Furman University. Email: Joe.Pollard@furman.edu.

David P. Schammel is a board certified anatomic and clinical pathologist, with interests in gynecologic and breast pathology. He received his MD from the University of Minnesota and completed his residency at the University of New Mexico and a surgical pathology fellowship at the University of Minnesota. He was the vice-chair of the Breast and Gynecologic Division at the Armed Forces Institute of Pathology in Washington, DC. He is currently in private practice with Pathology Associates in Greenville, SC. Email: dschammel@ghs.org.

Brian McKinley is board certified by the American Board of Surgery and holds memberships in the Society of Surgical Oncology and the American Society of Clinical Oncology. He received his MD from Jefferson Medical College, completed his residency in General Surgery at Geisinger Medical Center, and completed a surgical oncology fellowship at Roswell Park Cancer Institute. He is currently part of the University Medical Group of Greenville Hospital System, where he is a member of the Surgical Oncology Division. Email: bmckinley@ghs.org.

Steven D. Trocha is a board certified by the American Board of Surgery and holds memberships in the Society of Surgical Oncology, American Society of Clinical Oncology, and the American College of Surgeons. He received his MD from the Medical College of Wisconsin, completed his residency in General Surgery at Louisiana State University Medical Center, and completed a surgical oncology fellowship at the John Wayne Cancer Center. He is currently part of the University Medical Group of the Greenville Hospital System, where he is a member of the Surgical Oncology Division. Email: strocha@ghs.org.