

Overview of Research Opportunities

The Department of Medicine at the University of Colorado Health Science Center is one of the major research departments in the United States. With over \$290,000,000 in Department of Medicine research funding (FY2005), we rank among the top U.S. medical school departments of medicine. Our faculty are leaders in their research fields and continue to contribute significantly to practice changing research outcomes across the discipline of Internal Medicine.

The Department of Medicine is committed to offering every resident the opportunity for research training, to provide education and exposure for the research process, and to provide individually focused support for research careers.

To see the breadth and depth of research in the Department of Medicine, by Division or by individual research faculty, please visit our Website at <http://www.uchsc.edu>.

ABIM Research Pathway

The ABIM Research Pathway allows residents to substitute a year of clinical training in a subspecialty for the PGY3 year of the residency - in essence, to "short track" into fellowship training. Residents with an MD/PhD or equivalent advanced scientific training credentials will qualify for the Pathway. Credentials equivalent to an MD/PhD would ordinarily include at least two years of full-time research and one or more first-author publications, as well as strong support from previous research mentors.

Residents interested in the Pathway will meet with a member of the Resident Research Committee in the first month of residency to discuss their research and career plans. To qualify for the ABIM Research Pathway, they must "be rated as satisfactory in all components of clinical competence (clinical judgment, medical knowledge, clinical skills, humanistic qualities, professionalism and provision of medical care) and moral and ethical behavior in the clinical setting for both the PGY-1 and PGY-2 years of training." Residents identified as candidates for the Pathway will formally review their clinical progress with their Associate Program Director/Program Director mentor by November of their internship year, and if on track to achieving clinical competency will be encouraged to submit an application for subspecialty fellowship training with strong support from the Residency Program. They will have additional reviews of clinical progress at the end of the PGY1 year and the PGY2 year. The residency

program reserves the final determination of clinical competency to the end of the PGY2 year.

Residents who elect the ABIM Research Pathway will not be restricted to fellowship training at UCHSC but can expect to be strongly recruited to our fellowship programs.

The Residency Program adheres to the ABIM policies regarding the ABIM Research Pathway. They can be found at http://www.abim.org/cert/respath_pp.shtm

Research Electives for Residents

Residents are strongly encouraged to do research during their elective time. Most residents who elect to do research choose a mentor and project either at the end of the PGY1 year or the beginning of the PGY2 year. To help them find the right project, residents meet with a member of the Resident Research Committee and review a database of potential mentors. Residents will also be encouraged to enter the M3 – mentor-mentee match electronic database. Once a mentor is identified, residents prepare a formal proposal of elective research. These proposals are reviewed by the Resident Research Committee, and elective time is assigned based on the merit of the project and the nature of the research. Highly motivated residents who can identify a mentor and outline a project by January of PGY1 may take a research elective as their one month elective. More often, residents will establish their research plans and be ready to take up to a two month research block in the PGY2 and/or PGY3 years. In general, up to 3 months of research elective will be considered for meritorious and productive research candidates.

Research Curriculum

Many residents know they would like to consider research as part of their career future, but have not participated in significant research or have a full understanding of the broad array of research opportunities available. In order to provide an overview of research options a resident could consider and to provide education in the basics of research, a research curriculum is offered. Residents are encouraged to identify themselves as participants in the curriculum in their PGY1 year, but may elect in at any time during their residency. Didactics are held monthly covering topics such as clinical research ethics, biostatistics, and pharmacology. Four independent study assignments are also offered on additional topics. Twice a year, an “Academic

Affairs” night occurs offering an informal mingling of residents and faculty from all divisions within the Department of Medicine to discuss research careers, fellowship opportunities and applications, facilitate mentorship connections, and provide guidance and insight into the balance between academic life and personal life.

In addition to the Research Curriculum, there is considerable infrastructure available to support resident research. The Division of General Internal Medicine pays part salary of an expert biostatistician as a consultant to residents. The General Clinical Research Center is committed to supporting resident research with clinical, laboratory and statistical resources.

All residents in the Internal Medicine Residency are required to complete scholarly activity during their training. Residents may write up their ongoing research projects or choose a clinical vignette for their submission. Abstracts must be submitted to the local chapter of the American College of Physicians in years PGY2 and PGY3. Residents whose work is selected for regional or national presentation at either the ACP meetings or subspecialty meetings will receive support from the Internal Medicine Residency for their attendance and presentation with the following guidelines:

1. Resident must be first author on the work being presented.
2. Partial support from the mentor or subspecialty division if presentation is at a subspecialty oriented meeting will be expected.
3. Support for one presentation per year per resident maximum is anticipated. Exceptional situations will be reviewed by the Residency Research Committee and allocated according to merit and funding availability.

All residents are encouraged to also submit their work to the annual Department of Medicine Research Day. The DOM Research Day is an annual conference offering the opportunity for research conducted across all levels of the School of Medicine to be showcased. Competition and prizes for best poster at the resident level are offered.

Primary Care Track Research Curriculum

The University of Colorado offers a separate Primary Care track for residents who wish to pursue internal medicine training with a focus on primary care. The residency program strongly supports residents interested in research

careers within primary care/general internal medicine. In addition to the potential to participate in any of the above research opportunities, there is a primary care research curriculum built into the Primary Care Track. The curricular offerings have a stronger emphasis towards research skills and topics most commonly utilized by academic GIM researchers, such as outcomes and health services research. All residents, regardless of their designated track within the residency, may utilize this resource.

Advanced Research Training

Several programs are available to trainees with a serious commitment to a research career though graduate level training options available. Full details and application requirements for the programs can be found at <http://uchsc.edu/clinicalscience.htm> and <http://uchsc.edu/masters.htm>.

Both a Master's program option and a Clinical Research Training Program are offered to MD/DO candidates seeking higher education in the conduct of research. Degrees available include a Master's of Public Health, a Master's of Science in Clinical Science and a certificate program of Clinical Research Training Program.

Resident Research Curriculum

Educational Purpose and Goals:

- Observe and understand the principles of sound research design.
- Understand the various methodologies and techniques of research, including clinical, basic, and translational research.
- Clearly identify the research infrastructure that governs the conduct of research in the United States and the historical events that lead to its development.
- Understand the requirements of being a Principal Investigator, including their role in human subject's protection, appropriate management of conflicts of interest, oversight of research conduct, and primary responsibility for the accurate and timely completion of research projects.
- Understand and utilize the resources available to conduct research in the academic environment.

Learning Venues

Residents will have didactic sessions and also establish mentor-mentee relationships for the conduct of a research project(s). Venues for these projects may include, but are not limited to the mentor's laboratory and clinic space.

Principle Teaching Methods

Didactic sessions

1. Residents may opt to attend monthly lectures given by the research faculty of the University of Colorado Health Science Center or outside invited speakers.

Independent Study

1. Residents may opt to complete up to 4 independent study projects assigned quarterly by the Research Program Director. The case studies are designed to challenge the resident to investigate fundamental issues related to research conduct and answer real-world scenarios.
2. Residents are expected to investigate their disciplines of interest via literature review, conference attendance and informal discussions with faculty to help guide them to a potential project topic that they can design with their mentor that will both challenge and stimulate them.

Research Project

1. Residents, in conjunction with their Internal Medicine Program and/or Primary Care Track advisor, are expected to identify a research mentor with whom they will conduct a research project.

Any area of accepted research techniques is supported. Proposals for the project are to be submitted to the Residency Research Committee for review. In general, this review is designed to foster the feasibility of resident projects to ensure optimal success for completion.

2. Residents are to spend focused time on their research project during research elective rotations. They may continue research work between electives, provided that they are in good standing in the program, it does not interfere with their education or conduct requirements of other rotations and it does not have them working over required duty hours.
3. All residents involved in research electives and projects are expected to present their work for their ACP submission and present at the Department of Medicine Research day. Presentations at regional or national meetings are also encouraged for meritorious work.

Principle Ancillary Educational Materials

- A. All residents are provided with the Resident Research Curriculum and Learning Objectives prior to the start of each rotation.
- B. 24-hour access to on-line programs and literature is available through the link to the University of Colorado Health Science Center Dennison Library.
- C. Computer-based resources are available at the hospitals to facilitate research education and communication. The following are made available:
 1. E-mail services
 2. Internet access to medical sites on the World Wide Web
 3. Biostatistical support

Schedule and expectations of the research elective rotation

The elective resident research rotation begins on the first non-weekend day of the month and can extend for up to 8 contiguous weeks. Highly motivated and productive residents may elect up to a total of 4 months research/translational research blocks over their training. Residents are expected to meet with the mentors PRIOR to the start of their rotation to review project-specific goals and timelines for the rotation. Regular meetings during the rotation are expected to monitor the projects progress and troubleshoot any difficulties encountered. Residents are to prepare and abstract-style summary of the rotation for submission to the Research Committee at the conclusion of the rotation.

Outpatient Clinics

Residents will continue to participate in their outpatient clinics. Schedules for these clinics will be determined by the Department of Medicine/Continuity Clinic Leaders.

Research Curriculum Specific Competency Objectives

A. Research Fundamentals

1. Residents will be able to identify the principles of sound research design and ethical conduct of research.
 - a. PGY1 and 2 residents will have familiarity with the basics of the research regulatory process and its requirements in the United States.
 - b. PGY3 residents will have in depth understanding of the process of designing, implementing and completing a research project
2. Residents will be able to identify the various methods of research design and understand the categories of human subjects research.
 - a. PGY1 and 2 residents will be familiar with basic epidemiologic terms and principles, basic pharmacologic methods and principles, and basic biostatistics.
 - b. PGY3 residents will demonstrate the ability to design a mock research study in various methods of human research, and have completed human subject's protection training.
3. Residents will understand the requirements of being a Principal Investigator.
 - a. PGY1 and 2 residents will be familiar with the requirements of Good Clinical Practices.
 - b. PGY3 residents will recognize and understand the expectations and requirements of all members of a typical research team, as outlined by the National Institutes of Health.

B. Medical Knowledge

1. PGY-1-3 Residents will consistently apply current concepts in the basic sciences or known literature of a topic to the design of clinical research projects. They will use information from the literature and other sources including electronic databases.
2. PGY-1-3 residents in addition to the above will demonstrate appropriate habits to stay current with new medical knowledge as it pertains to their research project and the ethical conduct of research.

C. Interpersonal and Communication Skills

1. PGY-1-3 residents will develop and refine their individual style when communicating with research collaborators and, when applicable, research subjects.
2. PGY-1-3 residents will demonstrate the importance of protected health information and the protection thereof.

D. Professionalism

All residents will demonstrate integrity, accountability, respect, compassion, patient advocacy, and dedication to human subject's protection that supercedes self-interest. Residents will demonstrate a commitment to excellence and continuous professional development. Residents will demonstrate a commitment to ethical principles pertaining to the conduct of sound research, whether human or animal, confidentiality of protected health information and research data, and informed consent. Residents are expected to conduct research inclusive of all eligible subjects, regardless of patients' culture, age, gender and disabilities.

E. Practice Based Learning and Improvement

1. PGY 1 and 2 Residents will use the University library resources to critically appraise medical literature and apply evidence to their research proposals. They will use hand-held computers, desktop PC's and Internet electronic references to support hypothesis development, project development and self-education.
2. PGY 3 Residents will in addition consistently seek out and analyze data on practice experience, identify areas for improvement in knowledge of their research topic and make appropriate adjustments.
3. PGY-3 residents will begin to model independent learning and development.

F. Systems Based Practice

1. PGY-1-3 residents will be sensitive to research costs and the differential between standard of care and research testing
2. PGY-1-3 residents will consistently understand and adopt Good Clinical Practice guidelines and recognize the limitations of these guidelines.

RESIDENT RESEARCH DIRECTOR RESPONSIBILITIES

The Resident Research Director heads the Resident Research Committee and is responsible for the following:

1. Assisting the Program Director in identifying residents with an interest in research experience and potentially future research careers
2. Exposing all residents to the research opportunities available to them during their training
3. Meeting with residents designating themselves as interested in further subspecialty training and assisting in determining appropriate research goals for the IM training years
4. Coordination of the Resident Research Curriculum, including organization of didactic sessions, creation and review of the independent study series, organization of group events
5. Individual resident support for design, implementation and completion of research projects
6. Coordination of review of research proposals, travel support, elective time requests and other activities of the Residency Review Committee
7. Assistance to residents and mentors encountering logistical or programmatic difficulties with research electives

RESEARCH MENTOR RESPONSIBILITIES

The research mentor should work closely with the resident at each stage of developing the research question and carrying out the research plan. Mentors are expected to have regular meetings with the resident, and attend the “works-in-progress” meetings (2 each year) at which the resident is presenting.

A check-list of areas to be covered at each stage should include...

I. Developing the Research Question

- ◇ **Is the question clinically relevant?**
- ◇ **Is the project “do-able”?**
 - ◇ **Are data sources available and easily attainable?**
 - ◇ **Can the resident complete his/her tasks within their allotted time?**
- ◇ **What are the major hypotheses?**
- ◇ **What are the major and minor objectives?**

II. Developing the Research Protocol/Plan

- ◇ **identify data sources**
- ◇ **describe the population**
 - ◇ **identify inclusion/exclusion criteria**
- ◇ **identify predictor and outcome variables**
- ◇ **identify major analyses and appropriate statistical tests**
- ◇ **calculate sample size and power**
- ◇ **draft reasonable timeline**

III. Data Collection

- ◇ **Primary data collection**
 - ◇ **describe collection instruments (survey, chart abstraction, etc)**
 - ◇ **identify support staff**
- ◇ **Secondary data collection**
 - ◇ **finalize data extraction request**

IV. Statistical Analysis

- ◇ **what effect size can you detect with your final sample?**
- ◇ **assess internal validity**
- ◇ **assess external validity (generalizability)**

V. Publishing Results

- ◇ **abstract submission**
- ◇ **poster or podium presentation assistance**
- ◇ **manuscript writing**

Evaluations

Evaluation of the Residents by Faculty/Teaching Staff

Evaluation of the resident's research growth, professionalism, fund of knowledge and progress in these areas is conducted by the mentor throughout the research elective rotations. Constructive feedback is provided throughout the rotation to help them in their progress. At the end of the rotation, formal evaluation is conducted using the Department of Medicine standardized evaluation system. The content of these evaluations are made available to the residents in summary form at scheduled review time points during their internal medicine residency.

Evaluation of the Faculty/Teaching Staff by the Residents

Residents complete an evaluation of the elective at the end of each rotation. The evaluations are utilized as feedback on areas of strength and areas of needed improvement.

Schedule of the Research Curriculum

Research Curriculum Didactic Series and Events

- Oct 1 Clinical research ethics
- Nov 1 Research program "Academic Affairs" Night
- Dec 6 Basic Pharmacology

Jan 3	Basic biostatistics
February 7	Research – what it is, how to do it and how to figure out what you want to do when you grow up.
March 7	Basic epidemiology
April 4	Spring “Academic Affairs” Night
May 2	Regulatory process/ relationship with pharmaceuticals in research
June 6	Research Track Night Presentations and Celebration

Independent Study Assignments:

December	Conflicts of Interest
February	International Research Ethics
May	Clinical Trial Design

Primary Care Resident Research Curriculum

The Primary Care Program at the University of Colorado Health Sciences Center has a mission not only to train excellent primary care physicians, but also to prepare these physicians to assume leadership roles in their respective fields of interest. To help achieve these goals, we have developed a research program and curriculum for residents that can be tailored to each individual resident’s interests. For example, those residents who expect to be principally engaged in community practice will benefit from the exposure to techniques commonly used for evaluating and improving one’s medical practice such as utilization review, quality assurance and practice guideline development. Whereas those pursuing careers in academic medicine might be more inclined to research questions relating to decision analysis, medical education, clinical outcomes research or clinical epidemiology.

Research seminars will be held on selected Wednesday mornings during the Primary Care Curriculum rotations. Interns will be on block during August and March, while second- and third-year residents will be on block August, September, March and April.

First year residents will receive instruction in evidence-based medicine and clinical epidemiology, and will be expected to have selected a research project and mentor by the end of their internship. The Division of General Internal Medicine has assembled a list of over 50 projects and 20 mentors from which the residents can select, or the resident can design their own research project in conjunction with a mentor if they choose.

The research curriculum during the **second year** will focus on reviewing various primary care research areas, drafting a formal research proposal, and beginning data collection. The **final year** of the research curriculum will be devoted to analyzing and presenting the research findings at a local or national meeting, and will include didactic sessions on improving public speaking and research presentation skills.

1. Selecting a Research Project: The origins of many research projects in primary care seem to spawn from a critical appraisal of what we (as physicians) do, why we do it, and how well we do it. For example, “Do we have to send an electrolyte panel *every* day on this patient?”, or “How often are we sending patients for exercise treadmill testing appropriately and inappropriately?”. We hope to provide residents with some of the basic strategies for asking these types of questions. We recognize that there will be numerous competing time constraints related to residency training. Therefore, we strongly encourage either participating in projects that faculty members are conducting, or designing your own project using an established secondary database. Descriptions of faculty projects and established databases are included in the Appendix.

YEAR 1

August

- Session I:** Introduction to health services research
-Framing the research question
-Health services research in the “Real World”
- August II:** Evidence-based medicine (session 1)

March

Session I: Refining the research question; what data are available?

Session II: Evidence-based medicine (session 2)

Session III: Clinical epidemiology

2. Conducting the Research Project: The goals of our program are to provide physicians, *early* in their careers, exposure to health services research, instruction on how this research is performed, and insights into the advantages and limitations of various types of health services research. For example, using claims data, how valid are measures of disease incidence and prevalence in a capitated HMO? When is a self-administered questionnaire preferable to a telephone survey?

In light of these goals, the Division of General Internal Medicine will provide the necessary personnel support for compiling and analyzing your data. The resident will focus on framing the research question, deciding how to answer this question, and understanding the limitations of the final strategy. This process should begin with an intensive review of the literature relating to the proposed topic.

During the 2nd and 3rd years, residents will have the option to use elective months for research purposes (or “design-your-own” months, e.g. half treadmills, half research).

YEAR 2

August

Sessions I-III: Research Methodologies (3 x 2 hr. sessions)

September

Sessions I-V: Presentation of Research Proposals (5 x 2 hr.)

March

Sessions I-V: Works-In-Progress Presentations (5 x 2 hr.)

April

Sessions I-V: Flexible time

3. Presenting the Research Project: We hope by the beginning of the 3rd year, most residents have finished collecting and analyzing data, and are beginning to think about how and where to present their findings. We will include seminars on written, oral and poster presentations. Many local and national meetings (Mountain States or the National Society for General Internal Medicine Meetings, others) take place in the Spring of each year... meaning abstract deadlines are usually in December. The Department of Medicine will cover all expenses needed for travel, lodging and registration for any meetings in which a resident is presenting their findings.

Timeframe of Tasks to be Completed:

End of Year 1: Project and mentor selection

End of Year 2: Reviewing the literature

Data acquisition +/- analysis

End of Year 3: Project completion

Manuscript preparation

Present findings at local/national meeting

SUMMARY TIMELINE: Primary Care Research Program

	CURRICULUM	GOALS TO ACHIEVE
R-1 YEAR August	-Introduction to Health Services Research	-Begin thinking about research projects, mentors.
	-Evidence-Based Medicine I	
March	-Refining the research question	
	-Evidence-Based Medicine II	
	-Clinical Epidemiology	-Select Project & Mentor
R-2 YEAR August	-Health Services Research & Methodologies	
September	-Research Project Presentations	-Present Research Protocol
March	-Works-In-Progress	-Present Work-In-Progress
April	-Flexible	
R-3 YEAR August/September	-Presentation & Writing Skills Workshops	-Present Work-In-Progress
	-	-Abstract Submission
December	-	
March/April	-Grant Writing Skills (optional)	-Abstract Presentation

PRIMARY CARE RESEARCH AREAS & METHODOLOGIES

-Quality Assessment and Utilization Review: Evaluating your practice

-Questionnaire/Survey Research: Measuring attitudes, beliefs, satisfaction

-Qualitative Research:

-Secondary Database Analysis: Studying populations; generating hypotheses

-Meta-Analysis: Increasing power at what price?

-Statistics Introduction: “When to . . .”, not “How to . . .”

-Medical Education:

-Clinical Prediction Rules:

PRIMARY CARE RESEARCH MONTH ELECTIVE

Requirements

1. Identify Research Mentor
2. GIM Approval; Resident Research Committee Approval

Objectives

Specific Aims

1. Conduct complete literature review
bibliography

-*submit*

2. Develop research protocol/study plan

-read Hulley & Cummings
"Designing Clinical Research"
-meet with project mentor weekly
-*submit protocol*

3.

A. Research Question
B. Significance
C. Study Design
D. Study Subjects
• selection criteria
• sampling design
E. Measurements
• predictor variables
• outcome variables
F. Statistical Issues
• hypotheses

 Reliability

-identify/meet appropriate study personnel

-*submit timeline*

5. Develop COMIRB application
application

-*submit COMIRB*

PRIMARY CARE RESEARCH PROGRAM DIRECTORS RESPONSIBILITIES

Each resident, and subsequent research mentor, will be assigned to either Dr. Jean Kutner or Dr. Ralph Gonzales, for programmatic supervision and assistance. The major tasks to be accomplished include...

I. Project and mentor selection

- ◇ meet with each intern during the Winter to help in identifying a project area and mentor

II. Project facilitation and oversight

- ◇ meet with each resident/mentor pair to identify support areas (e.g. statistical analyses, chart reviewers, other faculty with specific expertise)... *prior to presenting research protocol at PCP conference.*
- ◇ approve final data extraction requests and statistical analyses conducted by Division staff.
- ◇ help resolve any research or programmatic issues arising for residents or mentors.

III. Coordinate didactic sessions for PCP conferences

IV. Moderate protocol and works-in-progress sessions

V. Participation in the Residency Research Committee

PRIMARY CARE RESEARCH SAMPLE SCHEDULE

	August	September	March
Year I	<u>Evidence Based Medicine</u> -6 total hrs avail. <u>Bayer Course</u> -4 total hrs (2x2) <u>Billing Module</u> -1 hr		<u>Clinical Epidemiology</u> (Steiner) -23 total hrs (13x1.75 hrs) <u>Leadership Course</u> (JUNE) -6 total hrs (3x2 hrs) Pick Project & Mentor
Year II	<u>Research Methodologies</u> -Case Control Studies -Survey Design/Studies -Cohort Studies -Meta-Analysis -Secondary Databases -6 total hrs (6x1) <u>Legal Medicine</u> -4 total hrs (2x2) Present Review/Proposal -12 total hrs (12x1)		<u>Legal Medicine</u> Conduct Research Work-in-Progress (?? b groups (based on research total hrs into 9 hrs) -18
Year III	<u>Presentation Skills</u> -How to organize and deliver a presentation		<u>Stanford Teaching Course</u> (Optional)

	<p>-Learning PowerPoint -3 total hrs (3x1)</p> <p>Work-in-Progress -18 total hrs (12x1.5)</p>	<p><u>Scientific Writing Workshops</u> -4</p> <p><u>Grant Writing Skills</u> <u>Invited Speakers: Job & Opportunities</u> (Foundations, HMO directors, Faculty)</p> <p><u>Job Negotiation Skills</u> Abstract Presentation</p>
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****Curriculum to be taught 9-12pm each Wednesday morning during Core Blocks... i.e. total 12 hours/month available**

****Steiner course to take place weekday mornings 7-8:45am during March.**