

Post-Doctoral Fellowship in Psychology and Women's Health

Program Focus

This newly-established fellowship program focuses on psychological and interdisciplinary research in women's health. The research curriculum provides training in theory and methods as they pertain to the clinical research setting. The clinical curriculum provides supervised training hours in the clinical assessment and care of inpatient and outpatient populations and fulfills the requirement for licensure in the state of Texas.

Program Structure

A two-year commitment to the program is recommended and encouraged. All fellows will be initially appointed for one year and re-appointed for a second year following annual evaluation. During the first year, fellows from clinical psychology will devote 50% of their time to research and 50% to clinical training and supervision. In Year 2, 100% time will be devoted to research. Non-clinical fellows will devote 100% time to research in Years 1 and 2. The overall structure of the program is designed to achieve independence in research and clinical practice. To enable fellows to become proficient, independent clinical investigators, a structured core curriculum is offered that includes didactic, small group interaction, and experiential learning activities. Specifically the curriculum includes:

- needs assessment and development of an individualized development plan with a primary mentor
- mentored research activities
- completion of core didactic experiences in clinical research methods (including research ethics), statistics and epidemiology, and scientific writing
- individualized support of fellows' writing, quantitative skills and career development
- monthly small group learning and discussion with fellows from pediatric psychology and aging
- guided grant writing experience
- clinical experience in a variety of settings focused on clinical health psychology and clinical supervision to achieve licensure in the state of Texas

Program Objectives: Research Curriculum

| Fellowship Training Objectives |
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| At the conclusion of the program, fellows will be expected to: |
| 1) Demonstrate skills and habits consistent with professionalism in science, including creativity, open-mindedness, critical thinking, ethical sensitivity, and the ability to exchange constructive criticisms and develop collaborations with colleagues. |
| 2) Identify appropriate issues for investigation, develop them into testable research questions, and design projects that are valid, ethical, focused, feasible, and methodologically as precise and reliable as available technology will allow. |
| 3) Develop or adapt scientific methods that will allow application of innovative concepts and approaches to women's health research. |
| 4) Manage a research project, including (a) efficient fiscal management, (b) development and maintenance of research resources, (c) training and supervision of personnel, (d) design and conduct of an experimental protocol, (e) adherence to standards for ethical conduct of research, and (f) accurate recording of methods and results. |
| 5) Critically analyze and interpret experimental results with an understanding of their technical complexities, statistical basis, and clinical importance. |

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| 6) Effectively communicate research results in discussions with colleagues, oral presentations, posters, papers, and grant proposals. |
| 7) Strategically develop a research program and career plan to optimize productivity in publications and grant proposals, obtain consistent funding, and advance professionally. |

Program Objectives: Clinical Health Psychology Track

The Clinical Health Psychology Track will have several options for clinical experiences in a medical setting. This track offers a variety of settings including but not limited to: inpatients, outpatients, oncology, surgery, student wellness, and pain management. Fifty percent (50%) of the fellows' time during the first year will be dedicated to clinical work (patient assessment, treatment, consultation, and report writing).

Program Objectives: Women's Health Research Track

The Women's Health Research Track offers several options for research mentoring with regard to the expertise of the mentors and the topics of the ongoing funded projects in the Division of Pediatric and Adolescent Gynecology. Current federally-funded projects address bone mineral density in premenopausal women, stress and substance abuse, use of hormonal contraceptives among adolescent females, and cervical cancer prevention.

Campus Environment

UTMB is the third oldest medical school in the U.S. Established in 1891 UTMB is a major academic medical center with 77 main buildings, covering 99 acres. The campus includes four schools (Medicine, Nursing, Allied Health Sciences, and Graduate School of Biomedical Sciences) and two institutes for advanced study. There are 1147 full-time faculty members, 934 within in the School of Medicine. Resources include a major medical library, a network of hospitals and clinics that provide a full range of primary and specialized medical care, an affiliated Shriners Burns Hospital, numerous dedicated research facilities, and several recognized centers, including the Center of Interdisciplinary Research in Women's Health. The university is located on beautiful, historic Galveston Island. Galveston boasts over 32 miles of beaches, 13 museums and historic homes, and The Strand National Historic Landmark District with over 95 shops, antique stores, restaurants and art galleries.

Faculty

There are 4 core faculty in the fellowship program in addition to a number of affiliated faculty including psychologists, psychiatrists, epidemiologists, biostatisticians, and obstetricians/gynecologists. Fellows will be expected to align with a primary mentor among the core faculty, but also with other core and affiliated faculty.

| Faculty Member | Contact Information |
|--|---------------------|
| Jeffrey M. Baker, PhD Associate Professor, Orthopaedic Surgery and Rehabilitation Chief Psychologist and Director of Psychology Resident Training | Ph: (409) 772-9576 |
| Abbey B. Berenson, MD Professor, Obstetrics & Gynecology and Pediatrics Director, Center of Interdisciplinary Research in Women's Health (CIRWH) | Ph: (409) 772-2417 |
| Carmen Radecki Breitkopf, PhD Assistant Professor, Obstetrics & Gynecology | Ph: (409) 747-4982 |
| Z. Helen Wu, PhD Assistant Professor, Obstetrics & Gynecology | Ph: (409) 772-1021 |

Jeffrey M. Baker, PhD joined the UTMB faculty in 1984. He is chief psychologist and director of psychology resident training. He has published in *Journal of Allied Health*, *Archives of Clinical Neuropsychology*, *Journal of Bone and Joint Surgery*, and *International Journal of Clinical and Experimental Hypnosis*. Dr. Baker's interests include: psychological assessment, sexuality counseling, eating disorders, crisis intervention, and pain management.

Abbey Berenson, MD joined the UTMB faculty in 1989 with a dual appointment in the Departments of Pediatrics and Obstetrics and Gynecology. She has secured federal grant funding from the Department of Defense and the National Institutes of Health (NIMH, NICHD) and has built a strong national reputation for her research programs in hymenal development, sexual abuse, contraception, and most recently, bone health. Dr. Berenson has published 54 peer-reviewed, patient-oriented research articles. Of these 54 papers, 23 address pregnancy or contraceptive issues, 13 concern sexual abuse, six are about domestic violence, and nine discuss health risk behaviors associated with substance abuse including tobacco, alcohol, and illicit drugs. Three publications address psychosocial issues such as depression. She also has published five qualitative review papers in the areas of adolescent gynecology. Her research has been published in *Obstetrics & Gynecology*, *Pediatrics*, *Journal of Adolescent Health*, *Journal of Clinical Psychiatry*, *American Journal of Psychiatry*, *American Journal of Obstetrics & Gynecology*, *International Journal of the Addictions*, *Family Planning Perspectives*, and *Journal of Reproductive Medicine*. Dr. Berenson is the Director of the Center of Interdisciplinary Research in Women's Health on the UTMB campus.

Carmen Radecki Breitkopf, PhD joined the UTMB faculty in 1999 after completing a postdoctoral fellowship at the University of California, San Francisco, in Health Psychology. She has published in *Health Psychology*, *Journal of Experimental Psychology*, *Journal of Applied Psychology*, *Academic Psychiatry*, *Herpes*, and *Obstetrics & Gynecology*. In 2001, Dr. Radecki Breitkopf was awarded a small grant from the National Cancer Institute to study cognitive, affective, and behavioral determinants of adherence to follow-up of abnormal Papanicolaou (Pap) smears. In 2006 she has been awarded a major grant (R01) as principal investigator of a 5-year, multi-site, randomized clinical trial examining a theory-based clinic intervention to improve adherence to follow-up among women receiving abnormal Pap test results. Her theoretical and applied interests include: body image, attitude formation and change, organ donation, health maintenance, decision making, and cancer prevention.

Z. Helen Wu, PhD joined the faculty in November 2000 after completing a postdoctoral fellowship in epidemiology at UTMB. She has published in *Annals of Epidemiology*, *American Journal of Epidemiology*, *Preventive Medicine*, *European Journal of Cancer Care*, *Ethnicity and Disease*, and *Gerontologist*. In 2001, Dr.

Wu was awarded a small grant from the National Institute of Drug and Alcohol Abuse to study club drug use in young, low-income women. In 2006 Dr. Wu received R01 funding as principal investigator of a longitudinal study addressing the relationship between stressors and drug use in low-income women. In addition to her interest in substance abuse, Dr. Wu is also interested in the following areas: health outcome and services research, minority health, combined quantitative and qualitative methods, cancer epidemiology, smoking cessation, and health and society.

Stipend

Stipend levels depend of years of related experience.

Application Procedure

The program is designed to strengthen and extend research training for individuals who have obtained a doctorate in clinical or experimental (social, cognitive, health) psychology. Applicants must be U.S. citizens or must be authorized to work in the U.S. Preference will be given to individuals who seek a two-year appointment. To apply to the fellowship program, the following materials are requested from each applicant: (1) current curriculum vitae; (2) a list of three references with contact information (three letters of support should be sent under separate cover); (3) written description of research training background and current research interests; and (4) representative reprints if available. Applicants may be asked at a later date to provide an academic transcript from graduate/undergraduate institutions. Application materials and all correspondence may be addressed to:

Clinical Health Psychology Track:

Jeff Baker, Ph.D.
University of Texas Medical Branch
301 University Boulevard
Galveston, Texas 77555-1152

Women's Health Research Track:

Carmen Radecki Breitkopf, Ph.D.
University of Texas Medical Branch
301 University Boulevard
Galveston, Texas 77555-0587

The deadline for application materials is rolling. We will initiate telephone interviews with selected applicants. Upon identifying the most competitive candidates, we may conduct in-person interviews to assist core faculty in making final decisions. At this time, candidates may be expected to have prepared a research talk to be delivered to core and affiliated faculty in a colloquium-style presentation. Final decisions will consider the overall strength and promise of the applicant, fit with the program objectives, and overlap of research interests with core faculty. Fellows should expect to begin the program on or about September 1.

Overview of Didactic Experiences

The following table summarizes the fellowship training activities. As noted, some activities will be required and others offered on an “optional/as needed” basis. A detailed description of these activities is included on the pages that follow. The course schedules reflect the topics and speakers for the present year and are intended to reflect the breadth and structure of the program. They are subject to change by those organizing the curriculum for the 2006-2007 academic year.

| SUMMARY OF TRAINING ACTIVITIES | | |
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| Required Activities | | |
| Component | Description | When Offered |
| Needs assessment | To determine training needs | First 30 days |
| Development of career plan | Developed with mentor based on needs assessment, level of experience, and personal goals | First 30 days |
| Guided grant writing | Tailored program for grant development | Ongoing |
| Responsible conduct of research | Certificate obtained online | Within first 90 days, 1 hour only |
| GCRC lectures | Formal lecture series on research methods and ethical issues | 37 sessions, 1 hour per week |
| Navigating the Institutional Review Board & Investigator Responsibilities | Formal lectures describing IRB process | 4 sessions, 2 hours each |
| Grants-for-lunch | Informal lunches to develop grantsmanship skills | Monthly |
| Scientific writing | Formal interactive lectures to improve writing skills | 5 seminars, 2-3 hours each |
| Small group sessions | Informal sessions with other fellows in psychology | 1 seminar per month |
| Optional/As Needed Activities | | |
| Component | Description | When Offered |
| Grant management skills | Formal sessions on budgeting, contracts, and financial management | 4 sessions, 2 hours each |
| Statistics, epidemiology, and prevention and public health courses | Formal courses offered by graduate school | Each semester |
| Departmental activities | Grand rounds, didactic | As scheduled |

Summary of Program for Guided Grant Writing

The goal of this program is to assist fellows in developing their own grant proposal using the NIH application as the foundation of the training. This schedule will be tailored to the individual needs of each fellow based on prior training.

| Year 1 | Year 2 | Mentoring Objective | Instruction/Activity |
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| X | | Become familiar with bone density grant | Self-study-read grant and supporting literature |
| X | | Select area of interest | Self study, literature searches Moody Medical Library courses on database usage |
| X | | Locate and select potential funding sources | OVPR seminars/Division training/self-study |
| X | | Preliminary contact with program director | Informal guidance by Dr. Berenson and/or core faculty mentor |
| X | | Select and design clinical research proposal | Weekly meeting with core faculty mentor |
| X | | Evaluation of existing knowledge base | Moody Medical Library courses Self study/meeting with core faculty mentor |
| X | X | Grant writing/application process | Self-study of online documents from NIH, local IRB OVPR lunch seminars on grantsmanship Begin 37-session GCRC course 8-hour scientific writing course Four sessions by OCR on clinical trial management |
| | X | Recruitment, consenting, tracking and retention of study subjects | UTMB course on human subject protection/certification OVPR workshop on protecting human subjects Self-study CDC document—Guide for writing consent documents |
| | X | Data collection | Weekly meetings with core faculty mentor/literature review |
| | X | Data analysis | Statistics coursework SPSS/SAS basic training |
| | X | Manuscript preparation and submission | Self-study/meetings with core faculty mentor Department publication office |
| | X | Research presentation | Self study/ meetings with core faculty mentor Department publication office Present research at national conference |
| X | X | Monitoring mentee's progress | Informal meetings with core faculty mentor Formal annual review by core fellowship faculty members |

OVPR = Office of the Vice President for Research.

OCR = Office of Clinical Research.

Clinical Research: Tools and Techniques and Responsible Conduct of Research

This course, presented by the General Clinical Research Center (GCRC) and Clinical Research Education Office (CREO), consists of 37 presentations held once per week, each approximately one hour in length.

| GCRC Course Schedule and Topics | | |
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| Session Title | Presenter | Department |
| Module: General Research Methods and Skills | | |
| General Clinical Research Centers | Walter J. Meyer, III, MD | Department of Psychiatry and Behavioral Sciences |
| Fundamentals of Experimental Design & Analysis | Samuel Baron, MD | Department of Microbiology |
| Presentation skills | Glennnda M. Rassin, LMSW, ACP | Department of Pediatrics |
| Evaluation of the medical literature | James A. Hokanson, PhD | Department of Preventive Medicine & Community Health |
| Pharmacokinetics in clinical Research | Wayne R. Snodgrass, MD, PhD | Department of Pharmacology |
| Health services and Outcomes research | James S. Goodwin, M.D. | Department of Internal Medicine |
| Methods of assessing nutrition and body composition | Harold H. Sandstead, MD | Department of Preventive Medicine & Community Health |
| Research Issues and Risk Management | Ann Smith | Office of Risk Management and Quality Assurance |
| Research grants: Writing the proposal | Constance D. Baldwin, PhD | Departments of Pediatrics and Family Medicine |
| Writing successful research articles | Constance D. Baldwin, PhD | Departments of Pediatrics and Family Medicine |
| Teaching Skills | Rodger Marion, PhD | School of Allied Health |
| Tracer methodologies in clinical research | Kevin Tipton, PhD | Department of General Surgery |
| Molecular methods in clinical research I | Randall J. Urban, MD | Department of Internal Medicine |
| Molecular methods in clinical research II | Randall J. Urban, MD | Department of Internal Medicine |
| Gene therapy | Reuben Matalon, MD, PhD | Department of Pediatrics |
| Module: Regulation and Ethics in Clinical Research | | |
| Why research became regulated | Harold Y. Vanderpool, PhD | Institute for the Medical Humanities |
| Connecting federal regulations to conducting your research | Cheryl M. Chanaud, PhD | Office of Clinical Trials |
| Monitoring and oversight at the federal level | Cheryl M. Chanaud, PhD | Office of Clinical Trials |

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| The Belmont report: Ethical principles and their applications | Harold Y. Vanderpool, PhD | Institute for the Medical Humanities |
| Session Title | Presenter | Department |
| Roles and responsibilities of institutional review boards | Frank C. Schmalstieg, MD, PhD | Department of Pediatrics |
| Ethical Issues in Data Monitoring and Safety | Michele A. Carter, PhD | Institute for the Medical Humanities |
| Legal issues in clinical research | Jennifer S. Bard, JD, MPH | Institute for the Medical Humanities |
| Special issues related to research with prisoners | Jennifer S. Bard, JD, MPH | Institute for the Medical Humanities |
| Special issues related to Research with Children | Harold Y. Vanderpool, PhD | Institute for the Medical Humanities |
| Ethics of Paying Subjects to Participate in Research | Harold Y. Vanderpool, PhD | Institute for the Medical Humanities |
| Module: Epidemiological and Statistical Methods in Clinical Investigation | | |
| Measures of morbidity and mortality | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Measures of disease-exposure association | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Cross-sectional and case studies | Michael H. Malloy, MD, MS | Department of Pediatrics |
| Case-control studies I | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Case-control studies II | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Cohort studies I | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Cohort studies II | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Clinical trials: Methodological issues I | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Clinical trials: Methodological issues II | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| Hospital epidemiology | C. Glen Mayhall, MD | Department of Preventive Medicine & Community Health |
| Bayesian statistics in medicine | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |
| P-Value, power, & sample size issues | Hari H. Dayal, PhD | Department of Preventive Medicine & Community Health |

Navigating the IRB and Investigator Responsibilities

This course, presented by the UTMB Office of Research Education, consists four two-hour sessions.

| NAVIGATING THE IRB AND INVESTIGATOR RESPONSIBILITIES | |
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| Discussion Topics | Speakers |
| Part 1. Overview of the UTMB Institutional Review Board | |
| <ul style="list-style-type: none"> • Organization • Purpose • Regulatory Governance | <ul style="list-style-type: none"> • Wayne Patterson, Director, Office of Research Subject Protections |
| Part 2. Getting Started—Initial Submission | |
| <ul style="list-style-type: none"> • Submission and Review Process • Form #1 with Examples of Information Required by the IRB • Requirements for Expedited Review • Requirements for Waiver of Informed Consent • Sample Consent Form With Attention to Critical Areas • Form #2 with Examples of Information Required by the IRB • Forms for Vulnerable Populations • Sample Research Protocol Format | <ul style="list-style-type: none"> • April Vanderslice, IRB Manager, Office of Research Subject Protections • Malcolm Moore, Coordinator II, Office of Research Subject Protections • Helen Kurusz, Manager, Clinical Trials Program, Office of Clinical Research |
| Part 3. Obtaining Informed Consent | |
| <ul style="list-style-type: none"> • Review Requirements for Informed Consent Process • Acceptable Methods for Retention of Signed Consents • Video Presentation: "The Consent Zone" (30 minutes - Optional) | <ul style="list-style-type: none"> • April Vanderslice, IRB Manager, Office of Research Subject Protections • Malcolm Moore, Coordinator II, Office of Research Subject Protections • Helen Kurusz, Manager, Clinical Trials Program, Office of Clinical Research |
| Part 4. Ongoing Research Review | |
| <ul style="list-style-type: none"> • Continuing Review Process and IRB Form #3 • IRB Form #4 and Amended Request Submission Process • IRB Form #6 and Submission Process • Adverse Event Reporting Requirements and Submission of Reports Using IRB Form #7 | <ul style="list-style-type: none"> • April Vanderslice, IRB Manager, Office of Research Subject Protections • Dominique Ware, Coordinator II, Office of Research Subject Protections • Helen Kurusz, Manager, Clinical Trials Program, Office of Clinical Research |

Scientific Writing for Clinical Research

This course, conducted by Constance Baldwin, PhD, consists of 5 interactive seminars of 2–3 hours each. This course will teach the fellow how to prepare high quality scientific papers and grant proposals.

| SCIENTIFIC WRITING FOR CLINICAL RESEARCH |
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| Part 1. Developing an Effective Writing Style |
| <ul style="list-style-type: none">• Controlling word choice and sentence structure Using extracts from the participants' own writings as examples for discussion, the group learns how to choose words with precision, avoid overused and ill-used phrases, and compose clear and concise sentences. Participants are given practice exercises to sharpen their self-editing skills. |
| <ul style="list-style-type: none">• Writing paragraphs and extended arguments Building on skills practiced in the previous session, the participants learn how to construct clear and readable paragraphs and develop sound arguments that persuade the reader. Practice exercises include unscrambling poorly ordered paragraphs and reorganizing longer passages to heighten their clarity and persuasive impact. |
| Part 2. Writing Research Articles and Grant Proposals |
| <ul style="list-style-type: none">• Writing productivity and responsible authorship Participants discuss the obstacles to writing productivity and strategies for overcoming these barriers. The group learns and talks about 10 tips to writing efficiency and 7 tips for avoiding procrastination. The discussion covers how to protect one's time for writing, creating a productive and supportive environment, using the computer effectively, recycling old work, multi-tasking, and overcoming psychological barriers to productivity. In addition, the rules of responsible authorship and peer review will be presented and discussed. |
| <ul style="list-style-type: none">• Writing successful research articles In a session focused on the research article, the class discusses the importance of choosing a focused, significant subject and developing it in keeping with the conventions of a scientific report. The group evaluates selections from their own articles in preparation and discusses the content and strategy of the introduction, methods, results and discussion. Finding an appropriate balance between "big picture" issues and scientific details is also considered. |
| <ul style="list-style-type: none">• Writing successful research grant proposals This session addresses the basic principles of successful proposal writing: selling the "big picture," providing essential details efficiently, and making proposals as easy to read and navigate as possible. Pre-planning steps to enhance writing efficiency are also discussed. The group then focuses on appropriate content and winning strategies for each section of the NIH application: Specific Aims, Background/Significance, Preliminary Studies, and Experimental Design and Methods, plus supporting documentation. This information is useful for preparation of research grants targeting any foundation or agency. |

Grants-for-Lunch Program

This is an informal, 18-month, noon-hour program to develop grantsmanship skills and promote networking.

| Grants-For-Lunch: Topics and Speakers |
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| Welcome to NIH-An Overview of the National Institutes of Health Ralph M. Metzger, Director, Sponsored Programs |
| Developing & Using Your NIH Contacts Cheryl M. Chanaud, Director, Clinical Trials |
| Tips for Beginning Grant Writers: Common Mistakes and Solutions that Work James Halpert, Professor & Chair, Pharmacology & Toxicology Edward Postlethwait, Assoc. Professor, Internal Medicine |
| Confessions of an NIH Grant Reviewer Ricardo Saban, Assistant Professor, Internal Medicine Miles Cloyd, Professor, Microbiology |
| Pre-Planning Before Writing a Proposal Constance Baldwin, Associate Professor, Pediatrics and Family Medicine |
| Tips for Defining Specific Aims Robin Froman, Associate Dean, School of Nursing |
| Tips for Writing the Background Constance Baldwin, Associate Professor, Pediatrics and Family Medicine |
| Tips for Presentation of Preliminary Data (New Grant vs. Competitive Renewals) Robert Wolfe, Professor, Surgery |
| Tips for Writing the Research Design Constance Baldwin, Associate Professor, Pediatrics and Family Medicine Hari Dayal, Professor, PM&CH |
| Tips for Writing the Methods Constance Baldwin, Associate Professor, Pediatrics and Family Medicine Hari Dayal, Professor, PM&CH |
| Tips for Getting the Most out of Letters of Support Randy Goldblum, Professor, Pediatric Child Health Research |
| Budget Development (Including the NIH Modular Grant) James F. Leary, Professor, Internal Medicine |
| Recycling Your Grant Proposal: Tips for Revising and Resubmitting Randall Urban, Professor, Internal Medicine |
| Importance of Progress Reports Randall Urban, Professor, Internal Medicine |
| Planning & Coordinating Multi-Site Projects Toni D'Agostino, Management Resources Specialist, Office of Clinical Trials |
| Preparing for a Sponsor Site Visit Sarah Toombs, Director, Institutional Research Development J. Regino Perez-Polo, Professor, HBC&G |
| Your Proposal is Approved for Funding: Now What? Barbara DeHaven, Associate Director, Sponsored Programs |
| Managing Your Award Budget Patricia Delgado, Sponsored Programs Specialist Susanne Johnston, Clinical Trials Specialist |
| Successful Management of Research Teams: What to Expect Rodger Marion, Professor, School of Allied Health Sciences |
| Intellectual Property: What Is It? How Do I Protect It? What Are the Rules Governing It? James C. Arie, Interim Director, Technology Management Office |
| Special Considerations in Award Management: Cost Sharing and Time and Effort Reporting Terry Behrends, Assistant Director, Office of Sponsored Programs |
| Advice for Continued Research Funding Spanning 15+ Years |

Grant Management Skills Program

This course, sponsored by the Office of Clinical Trials, consists of four, 2-hour training sessions.

| Grant Management Skills Program | |
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| Session 1: Clinical Trial Budgets | Session 2: Clinical Trial Contracts |
| UTMB Standard Budget Language <ul style="list-style-type: none"> • Discuss basic elements • UTMB overhead • Review negotiation process The UTMB Study Budget <ul style="list-style-type: none"> • Review budget template • Explain use of the template • UTMB policy on consistent treatment of costs statement • Importance of the study protocol in the budget process The Sponsor Study Budget <ul style="list-style-type: none"> • Review typical sponsor budgets • Review payment terms • Look for missing items Federal Grant Budgets <ul style="list-style-type: none"> • Review PHS 398 budget pages | Confidentiality Agreements <ul style="list-style-type: none"> • Use and abuse • Procedure Other Preliminary Contracts <ul style="list-style-type: none"> • Investigator brochure • 1572 • Financial disclosure • W-9 • Protocol The Clinical Trial Contract <ul style="list-style-type: none"> • The Process of Negotiation • Review of UT System Compliance Issues • Review of the UTMB Standard Clinical Trial Contract Amendments • Meaning of end date • Change in PI |
| Session 3: Account Maintenance | Session 4: Financial Management |
| Reading the Ledger <ul style="list-style-type: none"> • Balance Posting Expenses <ul style="list-style-type: none"> • Allowables; unallowables • Budget transfers • Expense transfers • HRMS approvals • End date notice • Deficit notice Study End Date <ul style="list-style-type: none"> • Study extended period • Account closeout • Clinical trial residuals | Setting up Clinical Trial Accounts <ul style="list-style-type: none"> • Required forms/signatures • Final IRB approval • Budget load • Signature load Sponsor Payments <ul style="list-style-type: none"> • Study start up invoices • Account receivable adjustments • Milestone payments • Study extras • Billings Payment Template <ul style="list-style-type: none"> • Keeping track of procedures and milestones |

Graduate School Courses

Courses in quantitative methods, epidemiology, and prevention and public health are available to fellows. These courses are offered on campus each semester and are optional.

| Description of Courses |
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| Statistical Methodology I (PMCH 6443) |
| <p>This course provides the student with a basic understanding of the use and interpretation of certain classical and state-of-the-art statistical techniques and in the study of health and biomedical problems. Topics to be covered are basic probability, sensitivity and specificity, Bayes Rule, population measures of location and dispersion, Gaussian distributions, point estimation, confidence intervals, classical and practical hypothesis testing, simple analysis of variance with mean separation tests, nonparametric procedures for one- and two-way classifications, least squares regression and correlation, including lack of fit tests, simple categorical data analysis including goodness of fit, and homogeneity of proportions.</p> |
| Introduction to Epidemiology (PMCH 6330) |
| <p>This course provides an introduction to the theory and practice of epidemiology. The historical development of epidemiologic research, theories of disease causation, epidemics and their prevention, measures of disease frequency, epidemiologic research, theories of disease causation, epidemics and their prevention, measures of disease frequency, risk and other measures of effect, point and interval estimation, various epidemiologic study designs, confounding and effect modification, and an introduction to stratified analysis are covered in the lectures. Case studies that illustrate the application of epidemiologic principles to substantive issues of health and illness are discussed during the class.</p> |
| Prevention and Public Health (PMCH 6401) |
| <p>This course provides students the opportunity to acquire an applicable knowledge and general appreciation of the concepts, theories, issues and trends basic to an understanding of the physical, biological and social interdependencies that orient work and research in preventive medicine and community health. Organized in a seminar format, the course will focus on fundamental perspectives from history and philosophy, basic themes in governmental involvement with health needs, important issues in health behavior, and social policy, and concepts of environmental management.</p> |