Symposium Addresses Challenges in Research

The annual Research Symposium at the UT College of Medicine Chattanooga once again proved to be a lively platform for “town and gown” research networking, point/counterpoint debate, and a jump-start for residents and investigators interested in clinical trials.

Attendees were welcomed by B W. Ruffner, MD (Dean, UT COMC), and Jim Brexler, (Erlanger Health System CEO and President). Leonard “Rusty” Johnson, PhD (UT HSC Vice-Chancellor for Research), moderated a lively debate entitled, “Pharmaceutical Support: Tainted or Trusted?” Billy Arant, MD presented an overview of institutional tenure and promotion procedures. Break-out sessions covered abstract writing, data and discovery, research from an employer prospective, and an update on UT HSC research. Stephen Teutsch, MD, MPH (Merck & Co., Inc.) discussed evidence-based medicine and its implications for coverage, practice and translational research.

The keynote speaker, Drummond Rennie, MD, FRCP, MACP (Professor, UCSF and JAMA Deputy Editor) presented a very compelling talk on the current challenges in the credibility and publication of clinical trials, entitled “Ain’t Misbehavin’.”

In addition there was a ninety-minute “round-robin” session where attendees could meet with faculty and representatives from the UT COMC, the Medical Library, the UT-Chattanooga campus, graphics and design, BlueCross BlueShield of Tennessee, and UnumProvident to discuss collaborative research and explore opportunities for shared resources.

This Symposium provides contacts and training for faculty as well as residents. It will be followed by Research Week in May 2007 (see pp 6-7) when the UT COMC residents present their research to a panel of judges at walking poster rounds and at oral presentations. The culminating awards event is one of the highlights of the year for UT COMC faculty and residents.

Comments, articles, and announcements for the COMmunicator can be submitted in publishable format to Sylvia Friedl, Office of Human Subject Protections, Sylvia.Friedl@erlanger.org, 423.778.3899.
Welcome

Stuart I. Myers, MD, FACS, joined the UT COMC in September 2006 as a Professor. He is currently a member of the Department of Surgery with specialization in Vascular and Endovascular Surgery. He attended Washington University School of Medicine in St. Louis, MO on a Danforth Scholarship and obtained his MD in 1976. While in medical school, he received the Dr. Robert M. Carter Medical School Prize and other honors. He completed his General Surgery training at Washington University School of Medicine, then completed a fellowship in vascular surgery at the University of Texas Southwestern Medical School in Dallas. He completed advanced training in endovascular surgery at Eastern Virginia Medical School in 2004.

Prior to coming to Chattanooga, Dr. Myers was Professor of Surgery (with tenure) at Virginia Commonwealth University. He has also served as Professor and Chair of the Department of Surgery (Temple University School of Medicine, with tenure), Vice Chair of the Department of Surgery at the University of Texas Southwestern Medical Center, and Chief of Surgical Services, Department of Veterans Affairs, Dallas, Texas.

Dr. Myers has a very active career in surgical research as principal investigator with current funding of a VA Merit Grant entitled, “Surgical studies on renal blood flow and function after distant injury.” Dr. Myers is very committed to the publishing of academic research and is currently on the Editorial Board of the Journal of Vascular Surgery and has various peer-reviewed papers, abstracts, book chapters, and book reviews to his credit. He is the Associate Editor of the 3rd edition of the book Modern Surgical Care: Physiologic Foundations and Clinical Applications.

He and his wife, Patricia Ann Lowry, MD, are the proud parents of two children, Daniel (who is currently attending Johns Hopkins University) and a daughter, Sarah (who is a student at GPS). Patricia Lowry, MD is a Pediatric Radiologist at TC Thompson Children’s Hospital.

Local Physicians Provide Care in Panama

A twelve person medical team traveled to the Republic of Panama from September 9-16, 2006. The program named “Project Happy Faces” was led by Larry Sargent, MD. This was the third time a team from the Tennessee Craniofacial Center at Erlanger Medical Center and TC Thompson Children’s Hospital traveled to Panama to provide free medical treatment to children with facial deformities. These patients, the majority with cleft lip and cleft palate, lack the medical resources for treatment or the funds necessary to pay for surgery.

Project Happy Faces is a collaborative effort between the Oxford International School and the Hospital del Nino in Panama City and the Tennessee Craniofacial Center and the Craniofacial Foundation. This year, the team evaluated 27 patients and performed 23 operations during their week in Panama. The physicians from the Hospital del Nino provide follow-up care for all of the patients who were treated.

Members of the team were: Dr. and Mrs. Larry Sargent, Dr. and Mrs. Louis Carter, Dr. and Mrs. Thom Peterson, Dr. David Steckler, Dr. Phillip Lackey, Mr. and Mrs. Tom Farmer, Ms. Eloise Wolfe, and Ms. Tricia Davies.
Publications and Presentations

The Department of Medicine at the UT COMC was very well represented at the Tennessee Chapter of the American College of Physicians Scientific Meeting in Nashville, September 14-16, 2006.

Mukta Panda, MD was the chair for the scientific meeting. The theme of the meeting was Confronting America’s Epidemics. Dr. Panda did an excellent job in organizing the meeting and providing a proper balance between knowledge, professional interactions and perspectives on clinical, social economic and humanism issues in health care.

The associates program was one of the highlights of the meeting. Laura Cooley, MD did an outstanding job trying to “Stump the Professor.” It was a very interactive session with Faith Fitzgerald, MD from California. Supriya Mannepalli, MD received the 3rd place award for her poster presentation on “Coexisting Human Papilloma Virus and Cytomegalovirus Infection in an AIDS Patient: Relation to Severe Gastrointestinal Bleeding.” Umesh Yalavarthy, MD was the winner in the oral presentation and will be representing the Chattanooga Unit at the National ACP meeting in 4/07 at San Diego. Asma Khan, MD presented an update on the epidemic of Venothromboembolic Disease at the Chief Resident’s update. Dr. Panda was the faculty mentor for all four residents. The Chattanooga team won 2nd place in Internal Medicine jeopardy. The faculty presentations by Drs. Jones, Staton, M. Anderson, and Tim Holden were also rated very highly. Congratulations to all the Chattanooga participants.

The Department of Orthopaedic Surgery had three papers accepted for presentation at the Tennessee Orthopaedic Society Annual Meeting, October 26-28, 2006 in Sandestin, Florida. They are:

“Biomechanical Testing of a Novel Proximal Femur Plate for Treatment of Vertical Shear Pauwel’s Type C Unstable Femoral Neck Fractures,” to be presented by Brian Weatherby, MD. Co-authors are Jonathan Pettit, MD, Peter Nowotarski, MD, Paul Stafford, MD, Bain Ervin, BSE, and Ronald Goulet, PhD.

“The Effect of Resident Work Hours Regulations on Orthopaedic Surgical Education,” to be presented by Brian Weatehrby, MD. Co-authors are Joseph Rudd, PhD, Bain Ervin, BSE, and Brent Norris, MD.

“How We Communicate”
Ed Smith, PhD
Noon, December 12, 2006

IRB Conference Room
Whitehall Building

“Simple Prospective Guidelines for Reducing Blood Transfusions in Total Joint Replacement Patients,” to be presented by Terry Arrington, MD. Co-authors are Paul Apyan, MD, Thomas Currey, MD, and Joseph Rudd, PhD.

Brian Weatherby, MD will be presenting a poster on “The Reamer Irrigator Aspirator (RIA) as a Device for Harvesting Bone Graft in Non-Union and Segmental Defect Repair” at the American Academy of Orthopaedic Surgeons Annual Meeting, February 14-18, 2007 in San Diego, CA. Co-authors are Brent Norris, MD, Peter Nowotarski, MD, Paul Stafford, MD, Bain Ervin, BSE, and Joseph Rudd, PhD.
Publications and Presentations—continued

Gregory Heath, DHSc, MPH, has been invited to moderate a plenary session at the Institute of Medicine (IOM) Workshop on the Adequacy of Evidence for Physical Activity Guidelines Development to be held on October 23-24, 2006 at the National Academy of Sciences in Washington, DC.

The workshop will engage expert research scientists and physical activity practitioners from government and academia to explore whether there is sufficient evidence base for the U.S. Department of Health and Human Services (HHS) to proceed in a more systematic way to develop a comprehensive set of physical activity guidelines for Americans. The invited workshop moderators, speakers, and discussants will be asked to consider the available evidence related to physical activity and the general population, and special population subgroups including children, adolescents, young adults, pregnant and post-partum women, older adults, and persons with disabilities.

Additionally, the workshop will consider specific issues of relevance in assessing the quality and breadth of the available evidence. Dr. Heath’s session will cover Special Considerations for Persons with Disabilities.

CME Program

Hypertensive Emergencies in Acute Ischemic Stroke: Pathophysiology and Management
November 14, 6:00 pm

November 14 is set for a special Continuing Medical Education program featuring Elias A. Giraldo, MD, Assistant Professor of Neurology and Neurosurgery and Director of the Stroke, Neurological Critical Care and Headache Medicine Programs at the UT Health Science Center in Memphis. Dr. Giraldo will speak on Hypertensive Emergencies in Acute Ischemic Stroke: Pathophysiology and Management. His clinical research has focused on the study of stroke genetics, stroke epidemiology, secondary stroke prevention and thrombolytic therapy.

The program will take place in the Probasco Auditorium at the Erlanger Medical Mall and begins at 6:00 PM.

This program is part of a new CME initiative in cooperation with the Chattanooga State Technical Community College Community Health Institute and the UT College of Pharmacy to provide continuing education for both physicians and pharmacists. A light dinner will be served.

Please call Larry Miller at 423-778-3821 to register for the program in advance.
Frequently Asked Questions about Expedited Review

The IRB often receives questions from both experienced and new investigators about exempt or expedited review of their proposed research. Exempt review means that the research is of minimal risk to the subject and does not require the full board to review. It is always better to check with the IRB before you start your research if you think it qualifies as exempt.

When is expedited review permitted?

There are two requirements for expedited review. First, the IRB office must determine that the study meets the definition of minimal risk. Second, the research must fall within one of the categories of research defined by OHRP for expedited review. The most common expedited review types are:

- Minimal collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (amounts defined in the regulations)
- Prospective collection of biological specimens for research purposes by noninvasive means (e.g., hair and nail clippings, baby teeth, teeth extracted in routine care, placenta removed at delivery)
- Collection of data through noninvasive procedures (routinely employed in clinical practice (e.g., EKG, height, weight, MRIs, x-rays)
- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected for non-research purposes (such as medical treatment or diagnosis)

Can the IRB expand on the list of expedited review categories?

No. If the research doesn’t fit in the categories as defined by the OHRP, it must be reviewed by the full Board, regardless of the risk level.

Is informed consent necessary for expedited-reviewed research?

Yes. Requirements for informed consent (or waiver or alteration of informed consent) apply regardless of whether research is reviewed by full board or expedited procedures.

Who can conduct expedited review?

The IRB chair and/or one or more experienced IRB members designated by the Chair. The reviewer may approve the study or make recommendations, but may not disapprove the research. Additionally, the reviewer may refer the application to the full Board for a standard review.

Does the full IRB stay informed about studies receiving expedited review?

Yes. In our IRB these reviews are summarized in a monthly activity report.
CALL FOR ABSTRACTS

The UT College of Medicine Chattanooga and the Erlanger Health System announce the 25th Annual Research Week, Monday - Friday, May 7-11, 2007.

The purpose of this event is to provide residents with an opportunity to develop and present a research project or scholarly case report. Residents may submit multiple abstracts for consideration by the Research Abstract Selection Committee. The week culminates with an Awards Dinner at an outside venue on Friday evening, 5/11/07.

All residents, faculty, and spouses are invited to attend both the oral presentations and the dinner, sponsored and funded by Erlanger. Cash awards and plaques will be given at the end of the evening to the oral presenters as well as to the authors of the best posters. Please mark your calendar!

- Each resident should check with the appropriate chair to determine whether an abstract submission is included as a Scholarly Activity Requirement for his/her department/program
- The abstract submission form is available from departments/programs or at http://www.utcomchatt.org/Docs/F-RWAbs07.doc
- Indicate if the submission is for a Poster Presentation and/or Oral Presentation
- Font should be Times New Roman, 12 pitch; check grammar and spelling
- Abstract narrative is limited to the one-page form

- A Research Project must be a prospective or retrospective study accomplished while in training in Chattanooga. Abstracts should include:
  - Statement of purpose
  - Method used
  - Significant results
  - Conclusion
  - Signature of chair, indicating approval
  - Documentation of IRB review (approval number or exemption confirmation)

- A Case Report must be a scholarly analysis of an uncommon disease or uncommon presentation of a common disease encountered while training in Chattanooga. Abstracts should include:
  - Brief review of case, reviewing cogent points of history, physical exam, data
  - Brief summary of literature
  - Importance of case in the context of literature
  - Signature of chair, indicating approval
  - Documentation of IRB review (approval number or exemption confirmation)

See timeline on following page for submission details and deadlines

- The Research Abstract Selection Committee will review all abstracts and select those to be presented
- Exceptions to submissions encountered “while in training in Chattanooga” will be considered on a case-by-case basis by the Research Abstract Selection Committee

- Selections (for oral and poster presentations) will be announced by Friday, 3/23/07
- 20-30 posters will be selected for display in the Erlanger Medical Mall Atrium
  - Posters must be 3’ x 7’ mounted in 4’ x 8’ poster board and displayed the entire week
  - Posters will be judged at morning & afternoon “Poster Walking Rounds” on 5/11/07
- The best 4-6 abstracts will be orally presented prior to the Awards Dinner.
  - Oral presentations will be approximately 10 minutes each (including questions)
  - The authors of abstracts selected for oral presentations will also need to prepare posters for display, however, their posters will not be judged during the Walking Poster Rounds.
2007 Annual Research Week Deadlines

Department/Program submission deadline: Check with your Residency Coordinator.

Mon, 2/5/07: Electronically submit a completed abstract form (see pp 8-9) and a paper copy of the IRB Form H (see pp 10-14) to department/program chair. Forms are also available on the UT COMC website (http://www.utcomchatt.org/Research/Research.asp?dpage=irb).

Mon, 2/19/07: Department electronically submits the approved Abstract Form and a paper copy of Form H (both with Department/Program Chair signature) to Stacey.Hendricks@erlanger.org. The IRB will then review the Form H (if not previously reviewed by the IRB).

Wed, 2/28/2007: All abstract forms will be electronically submitted from the IRB office, given approval or exemption, to GME@erlanger.org.

Tues, 3/6/2007: Blinded abstracts and score sheets will be distributed to the Research Abstract Selection Committee.

Mon, 3/19/2007: Selection Committee members return scored abstract spreadsheet to the GME Office for tabulation.

Thurs, 3/22/2007: Selection Committee meets at 5:30 PM to make final selections for posters and oral presentations.

Fri, 3/23/2007: Departments and presenters notified of the Selection Committee’s decisions.

Thurs, 3/29/2007: Poster presenters meet with John Stroud and Dr. Heath regarding poster guidelines and appointment scheduling with Mr. Stroud for poster design and printing.

Fri, 3/30/2007 through Mon, 4/16/2007: Presenters meet by appointment with Mr. Stroud to submit all text and graphic files for layout of posters, proofing, etc.

Mon, 4/30/2007: Final proof approvals from authors/departments so printing can begin.

Fri, 5/4/2007: All poster authors and/or residency and research coordinators will bring their posters and presentation boards to the Medical Mall at 1:30 PM to assist Mr. Stroud and the GME staff in setting up the poster displays.

Mon, 5/7 through Fri, 5/11/2007: Posters on display in the Medical Mall.


Did you know ...
Jim Brexler, Erlanger Health System President and CEO, presented new strategic imperatives to the Board of Trustees including collaboration with the UT COMC to strengthen our education & training and position EHS as the region’s Academic Medical Center?
2007 ANNUAL RESEARCH WEEK
ABSTRACT FORM

TITLE: ____________________________________________________________

Check the appropriate spaces (Research or Case Report)
Research Topic ____  Case Report ____  Poster Only ____ Oral Presentation or Poster ____

Submission is limited to this page (the space below) using Times New Roman 12 pitch font.
FORM H

UT College of Medicine Chattanooga Unit IRB
REQUEST FOR THE RESEARCH USE AND DISCLOSURE
OF PROTECTED HEALTH INFORMATION (PHI)
WITHOUT SUBJECT AUTHORIZATION

IRB # ________ Date: __________

STUDY TITLE:

PRINCIPAL INVESTIGATOR:

DEPARTMENT __________ PHONE #: ______ FAX #: ______

ADDRESS _______________________________________________________

E-MAIL ADDRESS ___________________________________________________

STUDY COORDINATOR __________ PHONE #: ______ FAX #: ______

STATUS OF STUDY: NEW ____ PREVIOUSLY APPROVED ____

COMPLETE SECTION A AND EITHER SECTION B, C, D, E, OR F. PROVIDE APPROPRIATE SIGNATURES AT THE BOTTOM OF THE FORM. YOU MUST ALSO COMPLETE THE DATA BASE QUERY REQUEST FORM (ATTACHED) IF MEDICAL RECORDS WILL BE NEEDED FROM ERLANGER HEALTH SYSTEM.

SECTION A: GENERAL INFORMATION ABOUT THE REQUEST

1. Check the regulatory category under which the request is being made to use PHI without subject authorization: (check only one).
   a. IRB waiver or alteration of authorization is being requested. (Complete only sections A and B of this form.)
   b. All PHI to be used is from deceased individuals. (Complete only sections A and C of this form.)
   c. PHI to be used in the study is a “limited data set”. (Complete only sections A and D of this form.)
   d. The health information to be used involves “de-identified data”. (Complete only sections A and E of this form.)
   e. The PHI will be used for a review preparatory to research. (Complete only sections A and F of this form.)

2. Describe the PHI to be used in the research activity.
3. If PHI will be disclosed to the investigator by another covered entity or entities, briefly describe these entities.

4. Explain who will receive and use the PHI and where it will be stored.

SECTION B: REQUEST FOR WAIVER OR ALTERATION OF SUBJECT AUTHORIZATION

1. Check the activity for which the waiver or alteration of subject authorization is being requested:
   - Use of PHI for the conduct of the study itself
   - Use of PHI to identify potential subjects for recruitment
   - Use of PHI to contact potential subjects regarding study participation

2. If an alteration of authorization is being requested, describe the proposed alteration of the authorization and attach a copy of the altered authorization section of the consent form. If a waiver is being requested, skip to (3).

3. Explain how there is no more than minimal risk to the privacy interests of subjects whose PHI will be used by addressing each of the following points:
   a. Describe the plan to protect the identifiers from improper use and disclosure.

   b. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. (If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, this should be explained.)

   c. Is it true that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI is approved by the IRB? Yes____ No____
4. Explain why the research activity could not practicably be conducted without the waiver or alteration of the authorization requirements.

5. Explain why the research activity could not practicably be conducted without the access to and use of protected health information.

SECTION C: REQUEST TO USE PHI FROM DECEDENTS IN RESEARCH

1. Are all subjects whose PHI will be used in the study deceased?
   Yes____ No____

2. Does adequate documentation exist that all subjects are deceased?
   Yes____ No____

3. Explain why the PHI being sought is necessary for the research study.

SECTION D: REQUEST TO USE A LIMITED DATA SET IN RESEARCH

1. Will the PHI used in the research study exclude the 16 categories of direct identifiers necessary for the creation of a limited data set?
   Yes____ No____

2. Has a data use agreement been reached with the covered entity for the use of the PHI in the research study?
   Yes____ No____

3. If a data use agreement has been completed, attach a copy. If not, it must be submitted prior to final IRB approval of the Form 8 request.

SECTION E: REQUEST TO USE DE-IDENTIFIED DATA IN RESEARCH

1. Check the basis on which the health information to be used has been determined to be de-identified?
   An appropriate expert has made the determination
   (Attach a copy of this determination.)
   The health information excludes all 18 categories of direct identifiers
2. Will the entity that maintains the health information utilize a code or other means to re-identify the records?
   Yes____ No____
   (If “yes”, then answer questions #3 and #4.)

3. Is it true that the code or other means used to re-identify the records is not derived from or related to the individuals, or otherwise capable of being translated to identify the individual subjects?
   Yes____ No____

4. Is it true that the entity maintaining the records will not disclose the means for re-identifying the records?
   Yes____ No____

SECTION F: REQUEST TO USE PHI PREPARATORY TO RESEARCH

1. Is the use or disclosure being sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research?
   Yes____ No____

2. Is it true that no PHI will be copied or removed from the entity maintaining the PHI by the investigator in the course of the review?
   Yes____ No____

3. Briefly explain why the use of the PHI is necessary for purposes preparatory to research:

SECTION G: SIGNATURES

Signature of Investigator ___________________________ Date ___________

Signature of Department or Program Chair ___________________________ Date ___________

DO NOT WRITE BELOW THIS LINE

IRB ACTION: Approved Exempt ______ Approved Expedited ______ Approved w/provision(s) ________
Referred For Board Review ______

Comments: ________________________________________________________________

Signature of IRB Chair ____________________________________________ Date: _________________________
Certification by IRB That Waiver or Alteration Has Been Granted
For Use Only with Section B.

The IRB is the University of Tennessee College of Medicine/Erlanger Medical Center IRB.
The application has been reviewed and approved by: Normal full board
procedure __________ Expedited __________
The PHI is described in Section A.2 above.
The IRB has determined that the alteration or waiver authorization, in whole or in part, satisfies the following three criteria:

1. The research could not practicably be conducted without the waiver or alteration. (Section B.4 above).
2. The research could not practicably be conducted without access to and use of the protected health information. (Section B.5 above).
3. The use or disclosure of protected health information involves no more that a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   A. An adequate plan to protect the identifiers from improper use and disclosure (Section B.3.a above).
   B. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law(Section B.3.b. above).
   C. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorization oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart (Section B.3.c. above).

Signature of IRB Chairman ____________________________ Date ______________________

For New Applications:

If Form H accompanies an application requiring full board review, submit the original and 2 copies.

If Form H accompanies an application for expedited review, submit the original and the original

If Form H accompanies an application for exempt status, submit the original only.

For Previously Approved Studies:

Submit the original only.