Clinical Research: Tools and Techniques
2010-2011 Draft Agenda

Course Director: Karl E. Anderson, M.D.
Module Directors: Jason E. Glenn, Ph.D.
Christine M. Arcari, Ph.D., M.P.H.

1. Resources and Training for Clinical and Translational Research at UTMB
Karl E. Anderson, M.D. 08/16/10

2. Methods of Assessing Nutrition and Body Composition
Harold H. Sandstead, M.D. 08/23/10

3. Medical Effectiveness Research
James Goodwin, M.D. 08/30/10

4. Molecular Methods in Clinical Research (Part 1)
Adrian Recinos, Ph.D. 09/13/10

5. Molecular Methods in Clinical Research (Part 2)
Adrian Recinos, Ph.D. 09/20/10

6. Tracer Methodologies in Clinical Research
Elena Volpi, M.D., Ph.D. 09/27/10

7. Bioinformatics Tools in the Transomics Era
Bruce A. Luxon, Ph.D. 10/04/10

Clinical Research: Tools and Techniques

Regulations & Ethics in Clinical Research
(Director: Jason E. Glenn, Ph.D., Institute for Medical Humanities)

8. Why Research became Regulated
Jason E. Glenn, Ph.D. 10/11/10

9. Roles and Responsibilities of the PI
Toni D’Agostino 10/18/10

Amy McGuire, J.D., Ph.D. 10/25/10

Michele A. Carter, Ph.D. 11/01/10

12. Three Principles of the Belmont Report – “Justice, Subject Recruitment, and Perspectives from an IRB Community Representative”
Rabbi James L. Kessler 11/08/10

13. Oversight at the Federal Level – Most Common PI Pitfalls and Mistakes
Sukreti L. Bhagi 11/15/10

14. Legal Perspectives – Focused Case Study
Laura D. Hermer, J.D., L.L.M. 11/22/10

15. Research in Foreign Countries
Alexandra (Lexi) Nolen, M.P.H., Ph.D. 11/29/10

16. Conflicts of Interest in Pharmaceuticals Research
Howard Brody, M.D., Ph.D. 12/06/10

17. Hot Topics in Human Subject Research – “Ethics of Research on Prisoners”
Jason E. Glenn, Ph.D. 12/13/10

Risk Management Education (✓) credit is required for all UTMB faculty, fellows, and housestaff under the Medical Liability requirements. (✓) Sessions are approved by UTMB Risk Management to meet the annual requirement of up to 5.0 hours of Risk Management Education.

Graduate School This course is offered for credit as a seminar course for students enrolled in the Graduate School of Biomedical Sciences (Course ID - PMCH 6135).

GME Designated sessions are under review by the UTMB GME Committee for the following general categories of graduate medical education:
1. Medical Knowledge
2. Practice-Based Learning & Improvement
3. Interpersonal & Communication Skills
4. Professionalism
5. Systems-Based Practice

Look for other TRANSLATIONAL RESEARCH COURSES such as Topics in Translational Science (offered monthly) and Scientific Writing (to be offered this spring).

Clinical Research: Tools and Techniques

18. Proteomics and its clinical application
Alexander Kurosky, Ph.D. 01/10/11

19. Gene therapy
Reuben Matalon, M.D., Ph.D. 01/24/11

20. Teaching Skills
Vicki Freeman, Ph.D. 01/31/11

21. Pharmacokinetics in Clinical Research
Wayne R. Snodgrass, M.D., Ph.D. 02/07/11

22. Writing Successful Research Articles
TBD

Epidemiological & Statistical Methods in Clinical Investigation (Director: Christine M. Arcari, Ph.D., M.P.H. Preventive Medicine and Community Health)

23. Descriptive Epidemiology & Measures of Morbidity & Mortality
Christine M. Arcari, Ph.D., M.P.H. 02/21/11

24. Validity and Reliability of Diagnostic and Screening Tests (Part 1)
Christine M. Arcari, Ph.D., M.P.H. 02/28/11

25. Validity and Reliability of Diagnostic and Screening Tests (Part 2)
Christine M. Arcari, Ph.D., M.P.H. 03/07/11

26. Healthcare Epidemiology
C. Glenn Mayhall, M.D. 03/14/11

27. Introduction to Study Design and Causality
Christine M. Arcari, Ph.D., M.P.H. 03/21/11

28. Case and Cross-Sectional Studies
Michael Malloy, M.D., M.S. 03/28/11

29. Case-control Studies
Christine M. Arcari, Ph.D., M.P.H. 04/04/11

30. Cohort studies
Christine M. Arcari, Ph.D., M.P.H. 04/11/11

31. Clinical trials
Christine M. Arcari, Ph.D., M.P.H. 04/18/11

32. Descriptive Statistics & Data Visualization
Heidi Spratt, Ph.D. 04/25/11

33. Estimation and Hypothesis Testing
Heidi Spratt, Ph.D. 05/02/11

34. Regression
Heidi Spratt, Ph.D. 05/09/11

35. Confidence Intervals, Sample Size and power
Heidi Spratt, Ph.D. 05/17/10

Draft Dated 7/15/2010
**Course Information**

This course, presented by the Institute for Translational Sciences – Education Office (ITS-EO), consists of one-hour presentations held on **Monday Evenings at 5:15 PM, Children’s Hospital, Room 2.312.** UTMB faculty, fellows, residents and others interested in patient-oriented research may attend. Upon completion of this course, participants will be able to discuss the methods and ethical issues involved in the conduct of research involving human subjects. Upon request, participant attendance and self-assessment results may be reported to training program directors.

**Schedule**

The enclosed schedule of lectures is subject to change. Additional sessions may also be added, based upon registration. Optional discussion sessions may also be added, based upon interest. The LATEST INFORMATION is available on the ITS web page, HTTP://WWW.ITS.UTMB.EDU

**Two Modules** in this Course, *Regulations & Ethics in Clinical Research and Epidemiological & Statistical Methods in Clinical Investigation,* may be attended as individual courses, as described in more detail in separate brochures.

**Acknowledgement**

This course is part of the Institute for Translational Sciences Educational Program, which is partially supported by a grant from the National Institutes of Health (UL1RR029876).

**Registration**

Complete and submit the registration form located on this brochure and on www.its.utmb.edu/, call the Institute for Translational Sciences - Education Office (ITS-EO) (formerly CREO) at 409-772-1484, or email b@utmb.edu. Graduate students must also register through the GSBS during regular fall and/or spring registration (Course ID - PMCH 6135).

The registration fee of $50 includes refreshments and lecture handouts.

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## Clinical Research: Tools & Techniques 2010-2011

### Registration Form

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COURSE FEE: $50  TOTAL $______

Method of payment:

[ ] Check enclosed, made payable to:
  “UTMB – ITS-EO”

[ ] Interdepartmental Transfer:
  FRS Account Number
  Billing Contact Name
  Billing Contact Extension

**Fax or Mail Registration Form To:**

Institute for Translational Sciences – Education Office
ITS-EO
UTMB Route 0266
301 University Blvd.; Galveston, TX 77555-0266
Fax (409) 772-8097 E-Mail CTSA@utmb.edu

PHONE (409) 772-1484