APPENDIX A.

PHS POLICY ON INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH (RCR)
December 1, 2000 (suspended)

I. Background and Introduction

The Public Health Service (PHS) has been addressing for more than a decade recommendations from the research community to further a joint commitment to education in the responsible conduct of research. In 1989, the Institute of Medicine (IOM) stated that "instruction in the standards and ethics of research is essential to the proper education of scientists," and recommended that "[u]niversities ... provide formal instruction in good research practices."**(1)** In that same year, the PHS published misconduct regulations that state that research "[i]nstitutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested."**(2)** In 1990, the National Institutes of Health required all applications for National Research Service Award Institutional Training Grants to include a description of a program to provide instruction in the responsible conduct of research. In 1992, the National Academy of Sciences expanded and repeated IOM's earlier recommendation by stating that "[s]cientists and research institutions should integrate into their curricula educational programs that foster faculty and student awareness of concerns related to the integrity of the research process."**(3)** The Commission on Research Integrity recommended in 1995 that the Department of Health and Human Services add a new assurance " that the institution has an educational program on the responsible conduct of research ... [that] applied to all individuals supported by PHS research funds."**(4)**

These actions by the PHS and research community over the past decade have produced substantial strides by research institutions, scientific societies and associations, individual scientists, and government agencies in providing increased awareness of and formal instruction in the responsible conduct of research. However, more can be done at the Federal and institutional levels to promote responsible research practices in protecting human subjects, monitoring potential conflicts of interest, and in other areas. Accordingly, the PHS announces adoption of this policy to recognize accomplishments to date and to stimulate greater efforts and cooperation between the PHS and the research community in providing instruction in the responsible conduct of research. A similar policy will cover PHS intramural staff engaged in research or research training.

II. General Policy and Scope

A. It is the policy of the PHS that research staff (as defined below) at extramural institutions shall complete a basic program of instruction in the responsible conduct of research, as set forth in this document. Research staff who are working on the PHS-supported project at entities other than the institution that received the PHS research grant, cooperative agreement, or contract, are also covered by the policy. The institution may make reasonable determinations as to which research staff fall within the policy. The policy pertains to all research, including animal, human, and basic research, or research training, conducted with grant, contract, or cooperative agreement support from any agency, or office, of the PHS.

B. The PHS also recommends, but does not require, that the institution consider the need for providing RCR instruction to (1) non PHS-supported research staff at the institution, including those supported by institutional, private, and other governmental sources of support and (2) departmental and sponsored research/administrative staff and other support staff, with instruction relevant to their jobs and roles in the research enterprise (as determined by the institution). This policy does not limit the authority of the institution to expand the policy's scope or to impose broader requirements for RCR education.

III. Definitions

"Institution" means the public or private entity or organization that is applying for, or is a recipient of, financial support from the PHS, including grants, contracts, or cooperative agreements.

"Instruction/Program of Instruction" means completion of an educational activity, such as reading a self-study guide; attending a lecture, formal course, workshop, or seminar; making a presentation; working through a CD-ROM or Internet program; leading or participating in a discussion of case studies; or participating in any other educational activity that is consistent with the terms of the policy.

"RCR" means the responsible conduct of research.

"Research staff" means staff at the institution who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training supported by PHS funds or who otherwise work on the PHS-supported research project even if the individual does not receive PHS support. The institution may make reasonable determinations regarding which research staff fall within this definition.

IV. Purpose and Basic Principles

A. This document explains the PHS policy on education in the responsible conduct of research for staff engaged in PHS supported research. PHS agencies and research institutions strongly believe in promoting the responsible conduct of research and discouraging research misconduct and questionable research practices through education and awareness. With this policy, PHS extends the existing NIH educational requirement for research trainees to all research staff at extramural institutions who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, supported by PHS funds or who otherwise work on PHS-supported research projects even if the individual does not receive PHS support.

B. This policy reflects the following underlying principles.

1. The PHS and research institutions recognize the importance of providing instruction in the responsible conduct of research to PHS-supported researchers. While this policy only requires basic instruction, the long-term goal of providing high quality, relevant instruction appropriate to the needs of the individual researcher may involve more detailed and specific instruction that can be phased-in over time as new curricula materials and methods of instruction are developed and as the needs of the research institution dictate.
2. Institutions are given flexibility to determine the exact content, length, level, and method of instruction consistent with this policy. They may use available resources, develop their own resources, and determine whether or not to require a demonstration of competency by recipients of the instruction. The PHS will make available educational resources that will assist institutions to meet the policy as described in Section VI.
3. The institution may reasonably determine which "research staff" fall within the scope of this policy.
4. Instruction in the core areas is required to the extent that the core areas are applicable to the institution's research programs and the particular research projects and staff involved. The institution may exercise reasonable discretion in determining which core areas are applicable to its research staff.
5. The institution may determine the method of documenting that instruction has occurred.

C. The policy reflects the importance that the PHS places on fundamental and continuing education in conducting research responsibly, and it provides a basic foundation from which more detailed or focused programs may develop. Through this policy, PHS seeks to join with research institutions and researchers to pursue the following long-term goals:

- Increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research.

- Improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research.
- Develop appreciation for the range of accepted scientific practices for conducting research.
- Provide information about the regulations, policies, statutes, and guidelines that govern the conduct of PHS-funded research.
- Develop positive attitudes toward life-long learning in matters involving the responsible conduct of research.

Moreover, the PHS is committed to providing educational resources that meet the requirements of this policy and financial resources to further the development of educational products in the responsible conduct of research.

V. Core Instructional Areas

A. The policy includes instruction in nine core areas determined by the PHS to be significant in conducting responsible research and ensuring integrity of the research record. Some institutions may decide that all research staff covered by the policy should receive some exposure to each of the core areas, even if at a very basic level, such as reading an overview or attending a brief presentation, in order to ensure that all research staff have received a well-rounded RCR education. However, the PHS recognizes that not all of the core areas are applicable to the research programs at every institution. Therefore, the institution may exercise reasonable discretion in determining which core areas are applicable to the research staff receiving instruction at the institution. The core instructional areas are:

1. Data acquisition, management, sharing, and ownership
2. Mentor/trainee responsibilities
3. Publication practices and responsible authorship
4. Peer review
5. Collaborative science
6. Human subjects**(5)**
7. Research involving animals**(6)**
8. Research misconduct
9. Conflict of interest and commitment

B. For each of the nine core areas, information about compliance with related PHS and institutional policies should be included in the instruction provided. The Appendix to this policy contains descriptions and possible topics for the core instructional areas. It is intended as guidance material only and is not a detailed list of prescribed topics for each core area. Responsibility for determining whether to require a demonstration of competency in any of the core areas rests with the institution.

VI. RCR Instructional Resources

This policy does not establish exact content or minimum length, level, or format of instruction. The determination of the content, length, level, and format of instruction rests with the institution. However, in order to provide assistance to research institutions, PHS is committed to providing RCR educational resources that meet the policy, providing financial resources for broader development of RCR materials, and encouraging the sharing and centralization of existing RCR educational resources. For current information on available RCR resources, check the Office of Research Integrity (ORI) web site at **http://ori.hhs.gov.**

VII. Phase-in Period and Implementation

A. A phase-in period has been established for program implementation to allow current research staff to receive the program of instruction. By October 1, 2003, all research staff at the institution, as specified in the policy and reasonably determined by the institution, shall have received a program of instruction in RCR, as described.

B. New research staff beginning work after October 1, 2003, shall receive instruction in RCR prior to working on a research project, or as soon thereafter as practicable, but no later than one year after beginning work on the research project.**(7)** In the event that a newly-hired individual has previously completed timely instruction in any of the core instructional areas described in the policy, that person may receive credit for that portion of the program of instruction that was completed. In addition, persons who have completed timely instruction that meets the requirement for any of the core instructional areas, prior to the implementation of the policy, will not be required to repeat that portion of the instruction that was completed.

C. It is recommended that all research staff covered by the policy receive periodic, continuing education, e.g., videos, group discussion, short seminar, newsletters, etc., in RCR to refresh and extend knowledge of RCR issues, keep current on updates and new policies, and maintain sensitivity to the issues.

VIII. Assurances

A. Each institution that applies for or receives PHS funds for research or research training must assure by October 1, 2001, that:

1. The institution has a program of instruction that complies with this policy and has a written description documenting the program. The written description must address the provisions of this policy, its applicability to all research staff at the institution, and how the institution plans to document completion of RCR instruction by its research staff. The institution may include in its written plan a description of the role it expects the principal investigator to play in assisting the institution to implement the policy. Defined roles of principal investigators in this context will augment, but not supplant, the responsibility of the institution to provide RCR instruction as required. ORI may ask an institution to submit the written description of its RCR program of instruction at any time.
2. The institution will publish, or otherwise make accessible, the written description of the program of instruction to research staff at the institution and to others who work on the PHS-supported research project.
3. The institution will carry out its program of instruction.
4. Implementation of the institution's program of instruction for existing staff will be completed by October 1, 2003.

B. The RCR instruction assurance will be provided in conjunction with the Assurances/Certifications on the grant application, Form PHS 398, and in conjunction with the submission of the Annual Report on Possible Research Misconduct (Form 6349) by institutions, to the Office of Research Integrity. Compliance for work conducted under contracts will be assured under a different mechanism.

APPENDIX: Description of Core Instructional Areas

PHS provides as guidance the following description of the Core Instructional Areas:

1. Data acquisition, management, sharing, and ownership - Accepted practices for acquiring and maintaining research data. Proper methods for record keeping and electronic data collection and storage in scientific research. Includes defining what constitutes data; keeping data notebooks or electronic files; data privacy and confidentiality; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws.

2. Mentor/trainee relationships - The responsibilities of mentors and trainees in predoctoral and postdoctoral research programs. Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abusing the mentor/trainee relationship.

3. Publication practices and responsible authorship - The purpose and importance of scientific publication, and the responsibilities of the authors. Includes topics such as collaborative work and assigning appropriate credit, acknowledgments, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, author responsibilities, and the pressure to publish.

4. Peer review - The purpose of peer review in determining merit for research funding and publications. Includes topics such as, the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality.

5. Collaborative science - Research collaborations and issues that may arise from such collaborations. Includes topics such as setting ground rules early in the collaboration, avoiding authorship disputes, and the sharing of materials and information with internal and external collaborating scientists.

6. Human subjects - Issues important in conducting research involving human subjects. Includes topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and special protections for targeted populations, e.g., children, minorities, and the elderly.

7. Research Involving Animals - Issues important to conducting research involving animals. Includes topics such as definition of research involving animals, ethical principles for conducting research on animals, Federal regulations governing animal research, institutional animal care and use committees, and treatment of animals.

8. Research misconduct - The meaning of research misconduct and the regulations, policies, and guidelines that govern research misconduct in PHS-funded institutions. Includes topics such as fabrication, falsification, and plagiarism; error vs. intentional misconduct; institutional misconduct policies; identifying misconduct; procedures for reporting misconduct; protection of whistleblowers; and outcomes of investigations, including institutional and Federal actions.

9. Conflict of Interest and Commitment - The definition of conflicts of interest and how to handle conflicts of interest. Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts.

1. The Responsible Conduct of Research in the Health Sciences, p. 30 (IOM 1989).
2. 42 CFR 50.105.
3. Responsible Science: Ensuring the Integrity of the Research Process, p. 13 (NAS 1992).
4. Integrity and Misconduct in Research, p.18 (HHS 1995).
5. On June 5, 2000, NIH announced in the NIH Guide for Grants and Contracts new requirements for education in the protection of human subjects, beginning on October 1, 2000. Once the PHS Policy on Instruction in the Responsible Conduct of Research is fully implemented (See Section VII), it will supersede the NIH policy for purposes of this core requirement. There will be a subsequent announcement when this occurs. In addition, the Office of Human Research Protections (OHRP) plans to provide further guidance on instruction for responsible research in human subjects in the next several months. Individuals who receive instruction in compliance with this OHRP guidance will also be deemed in compliance with core element 6 (human subjects) of this policy.
6. The PHS policy on Instruction in the Responsible Conduct of Research complements, but does not supersede, the existing instructional requirements of the PHS Policy on Humane Care and Use of Laboratory Animals and the NIH Office of Laboratory Animal Welfare. Individuals who receive instruction in compliance with these latter requirements will also be deemed in compliance with core element 7 (Research Involving Animals) of this policy.

7. Researchers involved in human subject or animal research may be subject to separate educational provisions which require that instruction be received prior to working on projects involving human or animal subjects.

APPENDIX B.
UTHSCH TASK FORCE ON EDUCATION ON THE RESPONSIBLE CONDUCT OF RESEARCH
Membership Roster

Chair

Melissa Proll, Ph.D., M.B.A., Office of Research Affairs

Members

Eugene Boisaubin, M.D., Professor, Internal Medicine, Medical School

Peter Davies, M.D., Ph.D., Assistant Vice President Research Affairs and Professor, Integrative Biology and Pharmacology, Medical School

Robert Emery, Ph.D., Assistant Vice President Research Administration

Cheryl Erwin, J.D., Associate Director, Research Support Committees

Claire Gonzales, J.D., Assistant Vice President and Chief Compliance Officer

Paula Knudson, Executive Coordinator, Research Support Committees

Sue McPherson, Ph.D., Associate Professor Epidemiology and Associate Dean for Research, School of Public Health

Stanley Reiser, M.D., Ph.D., Griff T. Ross Professor in Humanities and Technology in Health Care, Director, Program on Humanities and Technology in Health Care, School of Public Health

Larry Scott, M.D., M.A., Professor, Internal Medicine, Medical School

Jacquelyn Slomka, Ph.D., R.N., Assistant Professor Behavioral Sciences, School of Public Health

George Stancel, Ph.D., Dean, Graduate School of Biomedical Sciences and Executive Vice President for Research Affairs

APPENDIX C.
FEDERAL REGULATIONS REQUIRING RESPONSIBLE CONDUCT IN RESEARCH TRAINING AT UTHSCH

	Regulations	Individuals Covered	Instruction	Implementation Details
Humane Use of Animals	• *Health Research Extension Act (Public Law 99-158)* – provides statutory mandate for PHS Policy on Humane Care and Use of Laboratory Animals and applies specifically to vertebrate species used in PHS funded research; PHS policy also incorporates U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training	• *Personnel involved with animal care, treatment and use* - scientists, animal technicians, and other personnel	• *Required topics on use of animals* - humane practice of animal maintenance and experimentation; concept, availability, and use of research or testing methods that limit the use animals or limit animal distress and pain • *Required topics on occupational risks* – zoonoses, chemical safety, microbiologic and physical hazards, unusual conditions/agents that might be used in experimental procedures, handling of waste materials, personal hygiene, other workplace risks	• Compliance assured in Institutional Assurance negotiated every 5 years with the NIH Office of Laboratory Animal Welfare
	• *Animal Welfare Act (9 CFR, Chapter 1, Subchapter A, Part 2)* - implemented through the USDA, it applies to all warm-blooded mammals	• *Personnel involved in animal care, treatment, and use* - scientists, research technicians, animal technicians, and other personnel	• *Required topics* - humane methods of animal maintenance and experimentation; concept, availability, and use of research or testing methods that limit use of animals or minimize animal distress; proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by facility; methods whereby deficiencies in animal care and treatment are reported; utilization of services available to provide relevant information	• Training and instruction must be made available and qualifications of personnel reviewed with sufficient frequency to fulfill research facility's responsibilities

APPENDIX C. (CONTINUED)
FEDERAL REGULATIONS REQUIRING RESPONSIBLE CONDUCT IN RESEARCH TRAINING AT UTHSCH

	Regulations	Individuals Covered	Instruction	Implementation Details
Human Subjects Protection	• *Education in Protection of Human Subjects (NIH Grants Policy Statement, Part II)*– implemented through Office for Human Research Protections	• *Key personnel in NIH applications with human subjects research* - new or non-competing awards	• *Issues important in conducting research involving human subjects* – e.g. ethical principles, informed consent, confidentiality/privacy of data/patient records, risks/benefits, preparation of research protocol, institutional review boards, adherence protocols, proper conduct, special protections for targeted populations	• *Required* – complete initial training prior to submitting application and refresher training every 3 years • *Required* – PI submits description of education for all key personnel in cover letter to NIH prior to awarding of funds
Responsible Conduct of Research	• *Training in the Responsible Conduct of Research (NIH Grants Policy Statement, Part III, Section III C. 4)* – applies to institutional training grants (T32, T34, T35)	• *NRSA trainees* - pre-baccalaureate, pre-doctoral, and post-doctoral trainees	• *Strongly encouraged topics* - responsible authorship, policies for handling misconduct, policies on using human subjects, policies on using animal subjects, conflict of interest	• *Required* – training plan in applications (describe subject matter, format, faculty participation, trainee attendance, frequency of instruction, rationale); progress report in competing/non-competing applications
	• *Instruction in the Responsible Conduct of Research (PHS Policy)* - policy temporarily suspended	• *Research staff and trainees on PHS supported projects* - staff with direct and substantive involvement in proposing, performing, reviewing or reporting research	• *Required topics* – nine areas as applicable to institution or individuals: data acquisition, management, sharing, ownership; mentor/trainee responsibilities; publication practices, responsible authorship; peer review; collaborative science; human subjects; research using animals; research misconduct; conflict of interest and commitment	• *Required* – current staff trained by 10/1/03, subsequently hires trained within 1 year; accessible, written training plan • *Recommended* - periodic continuing education • *Assurances* –on grant application and with annual report on research misconduct (Form 6349)

APPENDIX D.
COURSES ON RESPONSIBLE CONDUCT OF RESEARCH OFFERED THROUGH THE OFFICE OF RESEARCH AFFAIRS

	Target Audience	Format of Instruction	Demonstration of Competency	Training Documentation	Re-certification
Center for Laboratory Animal Medicine and Care					
Introduction to Laboratory Animal Science	Research faculty, staff, trainees using animals	3 hr seminar (uses videotapes, tours, demonstrations, lectures, handouts)	Not required, but desired	Sign-in sheets	Not required
Species Specific Methodology Class (rabbits, mice, rats or non-human primates)	Research faculty, staff, trainees using specific species	2-3 hr seminar (uses slides, videotapes, demonstrations, lectures, handouts, hands-on instruction)	Not required, but desired	Sign-in sheets	Not required
Aseptic Techniques in Rodent Surgery	Research faculty, staff, trainees conducting rodent surgery	2 hr seminar (uses slides, videotapes, demonstrations, lectures, hands-on instruction)	Not required, but desired	Sign-in sheets	Not required
One on one training as needed for additional species	Research faculty, staff, students	may use video, handouts, demonstrations and hands-on instruction	Not required, but desired	Sign-in sheets	Not required
Variety of Topics on Care and Use of Laboratory Animals	Animal Care Staff	1 hr seminar (video, slides, handouts, demonstrations, and hands-on)	Not required	Sign-in sheets	Not required
Responsibilities of Animal Care and Use Committee	Animal Welfare Committee (new members)	Lecture/handouts	Not required	Sign-in sheets	Not required
Risks/Maintenance Animal Care Facilities	Physical Plant	1-2 hr seminar (uses lecture, slides, video)	Not required	Sign-in sheets	Not required
Office of Research Support Committees					
Protection of Human Subjects, approved courses include:	Faculty, staff, trainees conducting research involving human subjects			Database	Every 3 years
• *IRB 101, UTHSCH*		Seminar	Not required		
• *IRB 101, MDACC*		Seminar			
• *IRB 101, Baylor COM*		Seminar			
• *UCLA*		On-line course	Required	Certificate	
• *Univ. Minnesota*		On-line course			
• *NIH*		On-line course	Required	Certificate	

APPENDIX E.
COURSES ADDRESSING RESPONSIBLE CONDUCT OF RESEARCH OFFERED IN UTHSCH SCHOOLS

	Target Audience	Faculty	Format of Instruction and Topics	Required/ Elective	Number of 9 Topics[1] Addressed
Dental Branch					
Graduate research seminar	Dental Branch post-graduate students	Ludington, Powers, O'Keefe,Knudson	*4 hrs of class instruction* – four 1 hr lectures on research protocol, literature review, research ethics, and human/animal subjects	required, no-credit	~ 7
Research seminar series	Dental students involved in research	Powers	*Seminar series* - research protocol, literature review, research ethics, statistics, organizing/ writing a manuscript, animal/human subjects	required, no-credit	~ 7
Research ethics seminar	Dental Branch faculty and staff doing research or on thesis committees	Powers	*2 hrs of class instruction* – 2 hr lecture on human subjects and research ethics; also take online course on human subjects	required, no-credit	~ 7
Research methodology seminar (new course being developed)	Dental Branch junior faculty	Powers	*Seminar(s)* – topics will include responsible conduct of research issues	required, no-credit	
Graduate School Biomedical Sciences					
Ethical Dimensions of Biomedical Sciences	Graduate School and other UTHSCH and Rice trainees/staff	Reiser	*1 semester credit hr/18 hrs class time* – twelve 1½ hr sessions (20 min lecture and 1 hr seminar for small group discussion of cases and/or topics)	required	9
Ethics in Health Care I	Medical, Nursing, Graduate School students	Reiser	*3 semester credit hrs* – ethical issues in medicine/ health policy; addresses clinical research ethics	elective	
Ethics in Heatlh Care II	medical, nursing, graduate school students	Heitman	*2 semester credit hrs*– applying ethical theory in clinical setting; addresses clinical research ethics	elective	
Humane Use of Animals in Biomedical Research	Graduate School students	Heitman	*2 semester credit hrs* –ethical, regulatory, scientific and practical issues of working with animal subjects in biomedical research	elective	1
Use of Experimental Animals in Biomedical Research	Graduate School students	Sastry	*2 semester credit hrs* –experimental animal models, lab techniques, animal humane care/use	elective	1
School of Public Health					
Research Ethics for Public Health	public health students	Slomka	*2 semester credit hrs* – ethical issues in health care research, including use of human and animal research subjects and conflict of interest	elective	

[1] Refers to nine core areas identified in suspended PHS policy on responsible conduct in research instruction

APPENDIX E. (CONTINUED)
COURSES ADDRESSING RESPONSIBLE CONDUCT OF RESEARCH OFFERED IN UTHSCH SCHOOLS

	Target Audience	Faculty	Format of Instruction and Topics	Required/ Elective	Number of 9 Topics Addressed
Medical School					
Clinical Research Curriculum (Center for Clinical Research and Evidence Based Medicine)	clinical researchers from UTHSCH, MDACC, and affiliated institutions (mean attendance of 35)	Tyson	*2 year curriculum* – classes meet 1.5 hrs/wk for 5 – 15 wks; courses include: Clinical Epidemiology, Clinical Trials, Clinical Research Design, Use of Computers in Clinical Research, Grant/ Manuscript Writing, Bio-statistics, Literature Appraisal, Ethical Aspects of Clinical Research, Translational Research, Seminars in Clinical Research	elective	8
Physical Diagnosis	2nd yr medical students	Reiser	*1 hr of class instruction on research ethics* – one of six 1 hr ethics lectures included in course	required	4
Ethics in Medicine Lecture Series	1st and 2nd yr medical students	Reiser	*Ten 1 hr lectures* - topics vary but medical ethics focus, some discussion of clinical research ethics	blue book elective	varies
School of Health Information Sciences[1]					
Introduction, Health Informatics (HI)	MS/PhD students		Human subjects addressed as part of 3 hr course	elective	1
Advanced Database Concepts HI	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Legal/Ethical Aspects of HI	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Health Information Systems Security	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Research Design and Evaluation in HI	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Statistical Methods in HI	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Health Informatics Data Analysis	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Triangulation Methods in HI Research	MS/PhD students		Data issues addressed as part of 3 hr course	elective	1
Practicum in HI	MS/PhD students		Publication practices, apply principles	elective	1
Grant Writing	PhD students		*Multiple topics addressed as part of 3 semester credit hr course* – data issues; peer review; publication practices; human subjects	elective	4
School of Nursing					
Research Designs and Methods	DSN students		*3 semester credit hrs* – covers several topics, including human subjects protection (Knudson)	required	

[1] Collaborative science – no formal course on this topic, but principles practiced in most classes through required group projects

APPENDIX F.

RESPONSIBLE CONDUCT OF RESEARCH INSTRUCTION IN UTHSCH TRAINING GRANTS[1]

P.I.	***Project Title***	***Trainees***	***Award*** *(direct)*	***Responsible Conduct in Research Instruction***
Dr. Castro	Short-Term Training for Minority Students	predoctoral	$63,658	***Formal Instruction*** • *Ethical Dimensions of Biomedical Sciences lecture* – 1.5 hr lecture included in seminar series for summer trainees, topics may be expanded in future to comply with revised PHS policy • *Booklet "On Being a Scientist, Responsible Conduct in Research"*- provided to participants and may serve as a starting point for instruction • *Multiple seminars on responsible conduct topics* – include: Introduction to Animal Science and Research Involving Animals (Smith); Bioethics: Ethical Dimensions of Biomedical Science (Scott); Clinical Research (Tyson); Ethical Review of Human Subjects Research and Regulations (Knudson) ***Informal Instruction*** • *Mentoring*
Dr. Castro	Short-Term Training-Students in Health Professional Schools	predoctoral	$148,000	***Formal Instruction*** • *Ethical Dimensions of Science* – eight 1 hr lectures (Reiser, Heitman)
Dr. Powers	Short-Term Training-Students in Health Professional Schools	predoctoral	$64,764	***Formal Instruction*** • *Mini-course on scientific ethics* – lectures/discussion of broad range of topics during first 3 weeks of summer program (Powers, Storthz, Knudson) • *Ethics in Biomedical Research Today* – single lecture for UTHSCH summer research programs (Heitman)

[1] Table includes training grants active in FY2001

APPENDIX F. (CONTINUED)
RESPONSIBLE CONDUCT OF RESEARCH INSTRUCTION IN UTHSCH TRAINING GRANTS[1]

P.I.	***Project Title***	***Trainees***	***Award*** *(direct)*	***Responsible Conduct in Research Instruction***
Dr. Grotta	UTHSCH Stroke Training Program	postdoctoral	$98,772	***Formal Instruction*** • *Ethical Dimensions of Biomedical Sciences, GS 210051* – 1 hr course, fall semester audited (Reiser) • *Five lecture series* – 5 biweekly lectures over 3 months that include: proper conduct of research (Grotta); data gathering, retention, interpretation (Morgenstern, Aronowski, Bratina); mentoring, authorship and misconduct (Grotta); conflict of interest, informed consent, confidentiality (Reiser); use of human and animal research subjects (Knudson, Aronowski) ***Informal Instruction*** • *Mentoring* • *Journal Clubs*
Dr. Massey	Houston Area Vision Training Program	predoctoral & postdoctoral	$139,960	Not available through Sponsored Projects microfilm system
Dr. McConkey	Toxic Mechanisms	predoctoral & postdoctoral	$199,825	***Formal Instruction*** • *Ethical Dimensions of Biomedical Sciences, GS 210051* – 1 hr course, fall semester (Reiser)
Dr. Moore	Role of Gut in Post-Injury Trauma	postdoctoral	$98,878	***Formal Instruction*** • *Ethical Dimensions of Biomedical Sciences, GS 210051* – 1 hr course, fall semester (Reiser) • *Clinical Research Curriculum* – (Tyson) ***Informal Instruction*** • *Scientific integrity/ethical principles in research concerning humans and animals* – two seminars annually (Knudson, Frankowski) • *Use of animals in research* - required for trainees using animals (Smith)

[1] Table includes training grants active in FY2001

APPENDIX F. (CONTINUED)
RESPONSIBLE CONDUCT OF RESEARCH INSTRUCTION IN UTHSCH TRAINING GRANTS[1]

P.I.	***Project Title***	***Trainees***	***Award*** *(direct)*	***Responsible Conduct in Research Instruction***
Dr. Sanborn	Training Program in Mammalian Reproduction	postdoctoral	$149,964	Not available through Sponsored Projects microfilm system
Dr. Waxham	Training in Neuroplasticity	predoctoral & postdoctoral	$131,520	***Formal Instruction*** • *Ethical Dimensions of Biomedical Sciences, GS 210051* – 1 hr course, fall semester (Reiser) • *Seminar on Responsible Conduct in Research* – monthly journal club, case presentation followed by discussion (Waxham) ***Informal Instruction*** • *Mentoring* – day to day and committee interactions
Dr. Waymire	Training in Neuroscience	predoctoral	$111,566	***Formal Instruction*** • *Ethical Dimensions of Biomedical Sciences, GS 210051* – 1 hr course, fall semester (Reiser) ***Informal Instruction*** • *Mentoring* – reinforce issues in day to day and committee interactions
Dr. Waymire	Training in Neural Plasticity	predoctoral & postdoctoral	$394,418	• Not available through Sponsored Projects microfilm system
Dr. Willerson	Molecular and Cellular Mechanisms of Heart Disease	postdoctoral	$96,776	***Formal Instruction*** • None ***Informal Instruction*** • *Provide trainees UTHSCH policies on responsible research conduct and require they be followed*

[1] Table includes training grants active in FY2001

APPENDIX G.
DRAFT UTHSCH GUIDELINES ON RESPONSIBLE CONDUCT OF RESEARCH

Introduction

The University of Texas Health Science Center at Houston (UTHSCH) is dedicated to creating and disseminating knowledge through its research programs and through programs that train future researchers. The programs serve a variety of constituencies that include the UTHSCH faculty, trainees, and staff, UT System, State of Texas, research sponsors, and public. These constituencies have a vested interest in and may benefit from the research, and they expect the research will be conducted responsibly and in compliance with applicable regulations/policies. The following Guidelines discuss elements of responsible research conduct, and issues addressed include: leadership of research teams; data management; publication and dissemination of research findings; protection of human research subjects; care and use of animals in research; honesty in science; research conflicts of interests; and intellectual property.

Leadership of Research Teams

Investigators often lead research projects with teams that include co-investigators, trainees, and staff, and, in that capacity, they may serve as principle investigators (PI) and/or mentors. Each of these roles has distinct responsibilities that require knowledge and skills in multiple areas.

As the leaders of research projects PIs have overall responsibility for all aspects of the research, and this requires managing the projects and training and supervising staff.

- *Managing research projects* – PIs are responsible for managing research projects, and the management process encompasses a variety of tasks that include: overseeing the design, conduct, analysis, and reporting of the research; managing the budget and expenditures; ensuring compliance with internal/external policies and regulations; maintaining scientific integrity of all aspects of the research; and complying with the terms/conditions of the contract/award.
- *Training research staff* – The PI also must ensure the research staff has the skills and knowledge required to conduct research in a safe and responsible manner and in compliance with applicable policies/regulations. Therefore, PIs must provide research staff appropriate training for techniques/procedures required in the research, and they also must ensure the staff completes relevant/required training in environmental health and safety, the protection of human research subjects, and the care and use of research animals.
- *Supervising research staff* – Effective supervision of research staff helps promote research productivity and integrity and a good working environment, and it may be achieved through strategies such as routinely reviewing data/laboratory notebooks, communicating with staff regularly about research goals/progress in meetings, and having an appropriate number of experienced/senior staff members to supervise less experienced personnel.

In their role as mentors, investigators guide the development of research knowledge and skills for a variety of trainees who may be seeking different levels of knowledge and expertise. Trainees traditionally include undergraduate students, graduate students, post-doctoral fellows, and clinical fellows, but they also may be junior or senior faculty members with an interest in developing new skills and knowledge.

- *Mentor responsibilities* – Effective mentoring requires: meeting with mentees regularly; supervising work closely; reviewing research data regularly; ensuring mentees are familiar with relevant academic and non-academic policies; counseling mentees about professional goals and opportunities; and maintaining good communication.

- *Number of individuals mentored* – Mentors typically have multiple professional responsibilities that may conflict/compete with the time they have available to supervise trainees. Therefore, mentors should continually assess and balance these responsibilities, and limit the number of trainees in their research projects/laboratories to a size that allows appropriate oversight and guidance.

- *Foreign students and fellows* – UTHSCH encourages an international approach in its research and recruitment of trainees. Therefore some of the institution's non-U.S. trainees may have different cultural values and customs that influence their research conduct and training expectations. UTHSCH's Offices for International Affairs and Student Counseling may be useful resources for addressing/understanding concerns/conflicts that may arise in the mentoring process because of cultural differences.

- *Assistance with establishing independence* – Mentors should guide mentees through the multiple steps required to establish themselves as independent investigators. This support may include: discussing career options; assisting in networking; and writing candid letters of recommendation that delineate their research relationship. Mentors should also have frank discussions with mentees about their plans for any continued collaboration and future research directions to avoid potential future conflicts.

- *Mentee responsibilities* – Mentees should be proactive in seeking their mentors' guidance about day-to-day research activities, short-term research goals for their training program, and long-term career goals. Mentees should however recognize mentors' multiple responsibilities, and schedule time accordingly in seeking needed advice and guidance.

Links to policies/regulations related to leadership of research teams are included in Appendix A, and case studies dealing with these issues and based on UTHSCH experiences are available to facilitate discussion of the topic (Appendix B).

Data Management

Effective data management practices are essential for a well-run research program. They help ensure accurate, reliable, and retrievable data are available to: advance the formation/testing of scientific hypotheses; facilitate collaboration with co-investigators in large research projects; and support future patent pursuits. Sound data management practices also promote compliance with internal/external requirements for data access and retention and facilitate investigators' abilities to promptly/effectively respond to external requests for data during reviews of grants/manuscripts and scientific misconduct investigations. Strategies for promoting effective

data management are briefly addressed below and include: documenting the study design and methodology; maintaining data notebooks; complying with data ownership and retention requirements; and following data sharing and access requirements.

- *Documenting the study design and methodology* – Research records should document the experimental design and methodology, statistical tests used, data that do/do not support hypotheses, and rationales for excluding experimental data/outliers. These practices facilitate future replication of experiments and minimize unintentionally biasing results from preconceived expectations.

- *Maintaining data notebooks* – Data notebooks should preserve the original data, document the research process, preserve the chronology of experiments/data collection, and minimize risks of data loss. Standard laboratory practices to preserve data integrity include: using bound notebooks with numbered pages or heavy grade paper for loose-leaf notebooks to minimize tearing/damage of pages; careful inclusion and preservation of original photographs, computer outputs, negatives, etc.; making entries/corrections in permanent ink; signing and dating entries; utilizing an index to facilitate tracking multiple notebooks; routine reviews of notebooks by PIs and supervisors; and signatures of witnesses for data that may be required to support patent pursuits.

- *Complying with data ownership and retention requirements* – Data generated by faculty, staff, trainees, or visiting scholars in internally or externally funded UTHSCH research are considered UTHSCH assets. Data are all information associated with the research regardless of the form or media (HOOP 23.06), and include laboratory notebooks/worksheets, memoranda, original notes or exact copies of notes associated with original observations, videotapes, clinical protocols, spectra, computer files, images or any other records necessary for reconstruction and evaluation of study results. Data must be retained for a minimum of five years after publication in final form or after submission of final reports to research sponsors, and PIs, as agents of UTHSCH, have primary responsibility for preserving the data and complying with UTHSCH's retention policy. In some instances, funding agencies may require longer retention periods that must be followed. If a PI transfers to a new institution during this time period, the original data may be transferred, but UTHSCH and collaborators must have access to the data during the required retention period. Transfer of tangible research resources requires a materials transfer agreement approved by the Executive Vice President for Research Affairs. Trainees/visiting scholars participating in UTHSC-H research projects may not take original data/data notebooks when they leave the institution because original data must remain with the PI. They may however make arrangements with PIs to make copies of data to take with them. Trainees/visiting scholars must also ensure data are available to PIs during their tenure at UTHSCH.

- *Following data sharing and access requirements* – Scientists in general have an obligation to share and broadly disseminate research findings for a variety of reasons that include: promoting the advancement of science; allowing other investigators to confirm, extend, and/or question research results and hypotheses; avoiding duplication of research requiring costly data collection; and facilitating the translation of research into products/procedures that improve health. UTHSC-H faculty, staff, trainees, and visiting scholars must also satisfy institutional, Federal, and State requirements to provide co-investigators, the institution, research sponsors, the research community, and the public varying levels of access to their research data and/or resources. At the institutional level,

data must be available to collaborators and university administrators, and they also may be requested by research sponsors. At the federal level, NIH "expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers" (http://grants1.nih.gov/grants/policy/data_sharing/index.htm). NIH also requires investigators to provide "prompt access to unique research resources that arise from biomedical research" supported by NIH, and those resources include synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data (http://grants.nih.gov/grants/guide/notice-files/not96-184.html). Research data from federally funded research "cited publicly and officially by a Federal agency in support of an action that has the force and effect of law" may also be requested under the Federal Freedom of Information Act (http://www.hhs.gov/foia/45cfr5.html). Finally, access may be required under the State of Texas Public Information Act (http://www.capitol.state.tx.us/statutes/go/go055200toc.html). In some instances, there may be legitimate reasons to restrict or delay access to research data or resources such as: protecting legitimate proprietary interests as allowed under the Bayh-Dole Act; protecting rights and privacy of human subjects; avoiding premature release of preliminary data; and maintaining confidentiality of data prior to publication.

Links to policies/regulations on data management are included in Appendix A, and data management case studies based on UTHSCH experiences are available to facilitate discussion of these issues (Appendix B).

Publication and Dissemination of Research Findings

Investigators face multiple pressures to publish and present their research findings. First, sharing knowledge gained in biomedical research is essential for promoting the advancement of science and for facilitating the transfer of research findings to processes/procedures that improve health. Second, academic promotions typically depend in part upon a successful record of publications, and this sometimes results in an inappropriate focus on the quantity instead of the quality of publications. Finally, NIH expects PIs/grantee organizations of NIH-funded research to "make the results and accomplishments of their activities available to the research community and to the public at large" (NIH Guide for Grants and Contracts, Part II, Subpart A). NIH also expects grantee organizations to "safeguard appropriate authorship and ensure timely disclosure of their scientists' research findings by such means as publications and presentations at scientific meetings." When meeting these pressures and obligations to disseminate research findings, investigators must consider publication practices, authorship, and peer review.

- *Publication Practices* – Significant resources are required for journals to maintain systems to review/publish scientific manuscripts and for scientists to read the literature and remain informed of the latest developments in their fields of studies. Therefore both these groups benefit from responsible publication practices that include: not submitting similar manuscripts to multiple journals; not publishing identical/similar data in multiple articles; not publishing fragmented data in order to increase the number of publications; not including preliminary data in publications; limiting references to/reliance on unpublished data in articles submitted for publication; and promptly making needed corrections or retractions of published data.

- *Authorship* – Individuals included as authors on scientific publications should be limited to those who have made significant intellectual contributions to the research through the design, conduct, analysis and/or reporting of the research. There are other types of

contributions that, while valuable, do not warrant authorship such as: the contribution of research materials, lab space or equipment; provision of patient care or samples; and proofreading or editing manuscripts. It is also not appropriate to have honorary/ghost authors who did not have a substantive role in the research, but might lend prestige or credibility to the work. The lead author typically has overall responsibility for coordinating the development of the manuscript and ensuring its validity, but all authors should read and approve the final manuscript. The order of the authors should be mutually agreed upon by those involved in publishing the research, but common practices for determining the order include having: the individual making the largest intellectual contribution as the first author; the laboratory director as the last author; and additional authors listed in decreasing order of their relative contributions to the research. In publishing textbooks, editors should be responsible for ensuring the quality of the information and appropriate attribution of contributors. Research sponsors and funding sources should also be acknowledged and clearly identified, and acknowledgements may be used to recognize minor contributions to the research that do not warrant authorship.

- *Peer Review* – A peer review system is commonly used for reviewing manuscripts and grants, and the scientific community relies upon this system to promote the quality and integrity of biomedical research. Reviewers play a critical role in the process, and it is essential they: have appropriate expertise; be unbiased, fair, and reasonable in their expectations/requests; provide a rationale for negative comments; and respond in a timely manner. Reviewers also should: recuse themselves from the review process if they have a potential conflict of interest (e.g. the possibility of a personal financial gain/loss from publication of the manuscript); treat information obtained in reviews confidentially; not use the reviewed information to further personal research prior to its publication; and not unduly delay competitors' manuscripts for publication.

Links to policies/regulations on publication/dissemination of research findings are included in Appendix A, and case studies dealing with publication and based on UTHSCH experiences are available to facilitate discussion of this topic (Appendix B).

Protection of Human Research Subjects

Translating basic scientific knowledge into products/processes that improve health is a fundamental goal of biomedical research, but the translation of the knowledge typically requires research involving human research subjects. In all research involving humans or data from human-derived materials the protection and welfare of human research subjects must be the highest priority, and UTHSC-H is committed to protecting human subjects and to complying with federal requirements governing this research. All investigators planning to conduct research involving human subjects or data from human-derived materials must complete education on the protection of human subjects, and their research protocols must also be reviewed and approved by UTHSCH's Committee for the Protection of Human Subjects. Essential principles that must be supported in protocols and throughout the informed consent process and research project are respect for persons, beneficence, and justice.

- *Respect for persons* – The principle of respect for persons requires that individuals be treated as autonomous agents and that those with diminished capacity receive special protection. The principle of autonomy recognizes individuals' rights to choose to participate in a research study, but the decision/consent must be informed and based on complete information and understanding. Requirements for the informed consent process

are that the information be complete and comprehensible, and that the consent be voluntary with no coercion to participate. People who are vulnerable or have diminished autonomy require special protection, and the degree of protection depends on the levels of risks and benefits. Vulnerable individuals include children, prisoners, and people who are mentally disabled or severely ill.

- *Beneficence* – The principle of beneficence focuses on protecting individuals and ensuring potential benefits of the research are greater than potential risks/harm. Risks are assessed in terms of type, severity, probability, and duration, and some risks may be unacceptable. The types of risks to consider include psychological, physical, legal, social, and economic risks.

- *Justice* - The principle of justice requires that all research subjects be treated fairly and equitably. No groups should be systematically selected or excluded from participation in research projects unless there are valid scientific or ethical reasons, and individuals should not receive differential treatment.

Data dealing with human subjects must also be treated confidentially. Requirements for ensuring confidentiality include: secure storage of records; use of a coding system to identify participants so only investigators know subjects' identities; use of coding systems for questionnaires; and appropriate redacting of records to remove identifiers. Personal identifiers must also be removed prior to publishing or presenting the results.

Links to policies/regulations related to human subjects research are included in Appendix A, and case studies dealing with human research subjects and based on UTHSCH experiences are available to facilitate discussion of this topic (Appendix B).

Care and Use of Animals in Research

Scientific knowledge and improvements in health are advanced in part by research involving animals. In conducting this research, scientists must ensure research animals are judiciously used for research that contributes to the health and well-being of humans and/or animals, and they must also ensure research animals receive humane care and treatment. Principles and practices that promote high standards of care of research animals include: providing species appropriate living conditions that promote health/comfort; avoiding/minimizing animals' discomfort, distress and pain; using the minimum number of animals required for valid results; avoiding unnecessary duplication of existing research; using to the extent possible alternatives to animal models (e.g. simulations, in vitro models); and ensuring personnel handling animals are appropriately trained and qualified.

UTHSCH supports research involving animals but expects that it will be conducted responsibly and in compliance with the Animal Welfare Act, PHS Policy on Humane Care and Use of Laboratory Animals, and other applicable rules/regulations. The Center for Laboratory Animal Medicine and Care oversees all activities involving research animals, and the Animal Welfare Committee must review and approve all research, research training, experimentation, and biological testing activities that involve live, vertebrate animals. To initiate the review process, investigators must submit an Animal Protocol Review Form that includes: explanations of animal manipulations required in the research project; rationales for using animals, the proposed species, and the number of animals; and an assurance the research does not unnecessarily duplicate previous research. UTHSCH requires that all personnel handling

animals complete training offered by the institution that pertains to animals used in their research activities.

Links to policies/regulations on use of animals in research are included in Appendix A, and case studies dealing with this issue and based on UTHSCH experiences are available to facilitate discussion of the topic (Appendix B).

Honesty in Research

UTHSCH strives to create a research environment that supports investigators' abilities to productively and creatively pursue research goals while also maintaining high ethical standards in their research conduct. Dishonesty, fraud, and scientific misconduct in research damage the reputations and credibility of investigators, institutions, and the scientific community at large, and are not tolerated by UTHSCH. The institution treats any allegations of dishonesty, misconduct, or fraud in research seriously, and they are evaluated promptly with due regard for the reputation and rights of all individuals involved. It is expected that complainants who make allegations of scientific misconduct are acting in good faith, and they will be protected from retaliation in accordance with federal requirements.

UTHSC-H's policy for assessing allegations of scientific misconduct (HOOP 23.04) follows the PHS requirements. Scientific misconduct is defined as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data" (42 CFR Part 50, Subpart A). When the institution receives an allegation of scientific misconduct, it conducts an initial inquiry to determine if the evidence of misconduct is sufficient to proceed with a full investigation. If there is sufficient evidence of misconduct, a full investigation is initiated to evaluate evidence, and assess responsibility and the seriousness of the misconduct. In conducting the inquiry and investigation, the institution makes every effort to ensure that: persons involved in the evaluation of the allegations and evidence have appropriate expertise; no person involved in the procedures is biased against the accused person(s) or has a conflict of interest; and affected individuals receive confidential treatment to the maximum extent possible. If it is determined that dishonesty, misconduct or fraud has occurred in research, the institution will provide research sponsors relevant information of the findings and penalties, and journal editors must also be notified if necessary. In misconduct cases involving PHS-funded research, UTHSCH is obligated to keep the Office of Research Integrity appropriately informed and to protect federal funds.

Links to policies/regulations related to honesty in research are included in Appendix A, and case studies dealing with this issue and based on UTHSCH experiences are available to facilitate discussion of the topic (Appendix B).

Research Conflicts of Interest

Biomedical research is conducted in a complex environment that may involve multiple constituencies with different and often conflicting motivations and goals. Overarching goals driving scientists, academic institutions, and non-profit research sponsors are the advancement of knowledge and improvement of health, but financial incentives and pressures for research funding, publications, and promotions may influence the pursuit of these goals and create conflicts for investigators and institutions. Commercial interests of for-profit research sponsors and licensees may conflict with academically oriented goals, and these entities may seek to

restrict the direction of research projects, dissemination of knowledge, and/or accessibility of research resources.

UTHSCH is committed to ensuring conflicting research incentives, pressures, and interests do not: bias the design, conduct or reporting of research; jeopardize the protection of human research subjects; detract from employees' teaching, research, clinical or administrative responsibilities; inappropriately influence the research training of students or fellows; or result in improper transfers of state resources to research sponsors or licensees. This commitment is fulfilled through open disclosures by investigators of potential conflicts to appropriate institutional officials who, if necessary, work with investigators to manage, reduce and/or eliminate the conflicts. Responsible management of research conflicts is a shared responsibility of UTHSCH's investigators and their supervisors, research administrators and committees, and the President.

UTHSCH's policy and processes to deal with research conflicts related to financial interests are administered by the Executive Vice President for Research Affairs and must meet federal and State requirements. Investigators must disclose significant financial interests that could reasonably appear to be affected by the investigators' research, and they also must disclose financial interests and key positions in research sponsors and entities licensing their intellectual property. Financial interests/relationships of investigators' immediate families are subject to the disclosure requirements, and financial interests include anything of monetary value (payments for services, equity interests, intellectual property rights). Disclosures are reviewed by UTHSCH's Research Conflicts of Interest Committee, and, if conflicts exist, the Committee recommends if they should be managed, reduced or eliminated. Potential conflicts of interest in research involving human research subjects should generally be avoided. Financial interests and relationships with research sponsors/licensees should also be disclosed in publications and presentations. The disclosure requirements and review processes are discussed in detail in the institution's Policy and Guidelines on conflicts of interest.

Links to research conflicts of interest policies/regulations are included in Appendix A, and case studies dealing with these issues and based on UTHSCH experiences are available to facilitate discussion of the topic (Appendix B).

Intellectual Property

Intellectual property is often a by-product of universities' research programs, and UTHSCH strives to consider the best interests of the public, creators, and research sponsors in evaluating and managing intellectual property to which it has rights. Intellectual property is any invention, discovery, trade secret, technology, scientific or technological development, computer software, or other form of expression in a tangible form, and UT has rights to intellectual property related to employees' and trainees' responsibilities and to activities performed: on UTHSC-H time; with support of state, grant, contract, or gift funds to UTHSCH; or with UTHSCH facilities/personnel (HOOP 23.03).

Mechanisms to protect intellectual properties are: patents for new processes/products and improvements to existing processes/products that are useful and not obvious; copyrights for writings and software; and trademarks for words, names, or symbols. The Board of Regents and UT System, upon the advice of UTHSCH's President and Intellectual Property Committee, determine if interests and rights in intellectual properties created at UTHSCH will be pursued through patents and commercialization/licensing. Intellectual property rights not pursued by UT may be released to inventors with or without reservations, and inventors are considered the

individuals who conceive of the processes/products. Detailed/dated records that document the development process and are witnessed may be critical for pursuing patents, and disclosure of information through publications and presentations may jeopardize patent pursuits.

UTHSCH's process for evaluating/managing intellectual property is administered by the Office of Technology Management. Inventors complete Invention Disclosure Forms, and the disclosures are reviewed by UTHSCH's Intellectual Property Committee. The Committee advises the President about what patents to pursue, and he/she in turn makes recommendations to the UT-System/Board of Regents. UTHSCH bears the cost of pursuing patents in which it has an interest, and net royalties resulting from any patents are shared as follows: 50% to creator(s); 5% to school(s) of creator(s); 5% to department, division (or equivalent); 5% to laboratory of creators; 5% for legal fees; and 30% to UTHSC-H's Research Fund.

Links to intellectual property policies/regulations are included in Appendix A, and case studies dealing with intellectual property and based on UTHSCH experiences are available to facilitate discussion of this topic (Appendix B).

APPENDIX A.
POLICIES/REGULATIONS RELATED TO RESPONSIBLE RESEARCH CONDUCT

LEADERSHIP OF RESEARCH TEAMS

- HOOP 23.02 Review of Research (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_02.html)
- HOOP 23.05 International Affiliations (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_05.html)
- HOOP 23.08 Effort Reports (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_06.html)

DATA MANAGEMENT

- HOOP 23.06 Research Data Retention and Access (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_06.html)
- Texas Public Information Act (http://www.capitol.state.tx.us/statutes/go/go055200toc.html)
- NIH Grants Policy, Part II Subpart A, Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources (http://grants.nih.gov/grants/policy/nihgps_2001/nihgps_2001.pdf)
- Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (http://ott.od.nih.gov/NewPages/RTguide_final.html)
- PHS Policy Relating to Distribution of Unique Research Resources http://grants1.nih.gov/grants/guide/notice-files/not96-184.html
- Office of Management and Budget Circular A-110 Amendment on Access of Research Data through the Freedom of Information Act (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-26264-filed)
- NIH Draft Statement on Sharing Research Data (http://grants1.nih.gov/grants/policy/data_sharing/index.htm)
- Title 45 CFR Part 5 Freedom of Information Regulations (http://www.hhs.gov/foia/45cfr5.html)

PUBLICATION AND DISSEMINATION OF RESEARCH FINDINGS

- Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org/)

HUMAN RESEARCH SUBJECTS

- HOOP 23.02 Review of Research (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_02.html)
- The Committee for the Protection of Human Subjects (http://oac.hsc.uth.tmc.edu/orsc/cphs.htm)
- Title 45 CFR Part 46 Protection Of Human Subjects (http://ohsr.od.nih.gov/mpa/45cfr46.php3)
- The Belmont Report (http://ohsr.od.nih.gov/mpa/belmont.php3)

ANIMAL RESEARCH SUBJECTS

- HOOP 23.02 Review of Research (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_02.html)
- Animal Welfare Committee (http://oac.hsc.uth.tmc.edu/orsc/#AWC)
- PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/phspol.htm)
- Animal Welfare Act and Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm)

HONESTY IN RESEARCH

- HOOP 23.04 Honesty in Research (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_04.html)
- UTHSC-H Guidelines and Procedures for Allegations of Scientific Misconduct - PHS Projects (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/app_c/c_23_04.html)
- 42 CFR Part 50, Subpart A. Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science (http://ori.dhhs.gov/html/misconduct/regulation_subpart_a.asp)
- Protection of Research Misconduct Whistleblowers (http://ori.dhhs.gov/html/misconduct/whistleblowers.asp)

RESEARCH CONFLICTS OF INTEREST

- HOOP 2.19 Conflict of Interest (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/02/2_19.html)
- UTHSC-H Guidelines on Faculty Conflicts of Interest (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/app_c/c_4_28.html)
- 42 CFR Part 50, Subpart F. Objectivity in Research (http://ori.dhhs.gov/html/policies/fedreg42cfr50.asp)
- Texas Education Code 51.912 Equity Ownership; Business Participation (http://www.utsystem.edu/ogc/Ethics/Statelaw.htm)
- Texas Government Code 572.051. Standards of Conduct and Conflicts of Interest (http://www.utsystem.edu/ogc/Ethics/Statelaw.htm)

INTELLECTUAL PROPERTY

- HOOP 23.03 Intellectual Property (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_03.html)
- HOOP 23.09 Multi-Media Creations (http://www.uth.tmc.edu/ut_general/admin_fin/planning/pub/hoop/23/23_09.html)
- UTHSC-H Intellectual Property Handbook (http://www.uth.tmc.edu/otm/iphand.html)
- University of Texas System Intellectual Property Policy, Part 2, Chapter XII, Regents' Rules and Regental Policies/Guidelines (http://www.utsystem.edu/ogc/IntellectualProperty/polguide.htm)

APPENDIX B.
RESPONSIBLE CONDUCT OF RESEARCH CASE STUDIES

LEADERSHIP OF RESEARCH TEAMS
(to be developed)

DATA MANAGEMENT
(to be developed)

PUBLICATION AND DISSEMINATION OF RESEARCH FINDINGS
(to be developed)

HUMAN RESEARCH SUBJECTS
(to be developed)

ANIMAL RESEARCH SUBJECTS
(to be developed)

HONESTY IN RESEARCH
(to be developed)

RESEARCH CONFLICTS OF INTEREST
(to be developed)

INTELLECTUAL PROPERTY
(to be developed)

APPENDIX H.
RESOURCES ON RESPONSIBLE CONDUCT OF RESEARCH

Print Resources

The Ethical Dimensions of the Biological and Health Sciences, R. E. Bulger, E. Heitman, S. J. Reiser (editors), 2nd edition, Cambridge University Press, 2002

Handbook for Instructors: Teaching the Responsible Conduct of Research through a Case Study Approach, S. Korenman, A. C. Shipp, Ad Hoc Committee on Misconduct and Conflict of Interest in Research Subcommittee on Teaching Research Ethics, Association of American Medical Colleges, Association of American Medical Colleges, 1994

On Being a Scientist, Responsible Conduct in Research, Committee on Science, Engineering, and Public Policy, the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, National Academy Press, 1995

Online Resources

Institute for the Study of Applied and Professional Ethics, Dartmouth College, http://www.dartmouth.edu/~ethics/videos.html

Responsible Conduct of Research Instructional Resources, Office of Research Integrity, U.S. Department of Health and Human Services, http://ori.hhs.gov/html/programs/instructresource.asp

Online Resource for Instruction in Responsible Conduct of Research, M. Kalichman, University of California at San Diego, and F., Macrina, Virginia Commonwealth University, http://rcr.ucsd.edu/

Videos, Films, Plays

A Stampede of Zebras - play by Robert G. Martin, Program, Program in Science, Technology and Human Values, Duke University, dav1@duke.edu

Medical Humanities Program, New York University School of Medicine, http://endeavor.med.nyu.edu/lit-med

Science in the Cinema Program, Office of Science Education, National Institutes of Health, http://science.education.nih.gov/cinema

Integrity in Scientific Research, Five Video Vignettes and a Discussion and Resource Guide, American Association for the Advancement of Science, http://www.aaas.org/spp/sfrl/

APPENDIX I.
UTHSCH HEALTH CARE ETHICS NETWORK

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APPENDIX I.
UTHSCH HEALTH CARE ETHICS NETWORK (continued)

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APPENDIX J.
AGENDA FOR UTHSCH NEW EMPLOYEE ORIENTATION[1]
Monday mornings, 8:00 - 11:30 a.m.

Sign-In/Greeting	*Human Resources facilitator*
Leadership Welcome	*Mr. Michael Jimenez*
UT Houston Overview	*Human Resources facilitator* • Discuss topics such as mission/vision • UT-H Leading the Way to Better Health (video)
Institutional Compliance [2]	*Human Resources facilitator* • Discuss general topics – e.g. standards of conduct, ethics, information security • Institutional Compliance, Truth or Consequences (24 minute video) – topics include Committee for the Protection of Human Subjects, intellectual property
EEO/Sexual Harassment	*Ms. Jodie Glaze*
Health and Safety Video	*Human Resources facilitator*
Safety, UT Police	*Sergeant Gamboa*
UT-Houston Calendar	*Human Resources facilitator*
Payroll	*Mr. Harlan Severson*
EAP, Work/Life Programs	*Mr. Sam Hester*
Parking/Shuttle Services	*Human Resources facilitator*
Other Good Stuff	*Human Resources facilitator* Staff Guide, HOOP, training classes, Credit Union, Conflict Resolution Board, publications, Auxiliary Enterprises Services, TMC Map, restaurants
Wrap-up	*Human Resources facilitator*
Lunch Break	*Note* - all employees who work with chemicals, hazardous materials, biohazards, blood, etc. attend Environmental Health and Safety Training during the lunch break. This class is required under the federal and state Hazardous Communication Acts and lasts approximately one hour. (Dr. Emery provides box lunches for these participants.)

[1] *New Employee Orientation* - all employees (classified, A&P, faculty, full/part-time, casual, temporary) are required to attend the morning session of New Employee Orientation. The afternoon session is only for benefits-eligible employees.

[2] David Kusnerik provides copies of the Intellectual Property Handbook for distribution to faculty members during Orientation.