

**Report from the Task Force on
Education on the Responsible Conduct of Research**



THE UNIVERSITY *of* TEXAS

HEALTH SCIENCE CENTER AT HOUSTON

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EXECUTIVE SUMMARY

A Task Force on Education on the Responsible Conduct of Research was established by the Executive Vice President for Research's (EVPR) predecessor to recommend strategies to comply with a PHS Policy that was issued December 1, 2000 and would have required research staff "who have direct and substantive involvement in proposing, performing, reviewing, or reporting research" on PHS-funded projects to receive instruction on responsible research conduct. The Policy was suspended February 20, 2001 by the PHS for further review, but the EVPR asked the Task Force to continue to pursue the charge of assessing educational programs that support the institution's commitment to promoting responsible research conduct. In addressing its charge, the Task Force reviewed drivers for providing education on responsible research conduct, current UHSCH policies/programs in this arena, and strategies to promote effective educational programs.

The Task Force identified multiple drivers for UTHSCH to provide faculty, staff, and trainees education on responsible research conduct. They include: Federal regulations/expectations for academic institutions to provide training; public expectations for the scientific community to maintain high ethical standards/integrity in its research; UT System expectations for component institutions to have effective research compliance programs that include training; the institution's commitment/obligation to promote scientific integrity and protect the interests of investigators, research sponsors, research participants, and the public; and institutional risks if research is not conducted responsibly and in compliance with applicable laws/regulations.

Responsible conduct of research instruction, as defined by the PHS Policy, addresses nine content areas: data acquisition, management, and sharing; human subjects; animal subjects; research misconduct; conflict of interest/commitment; mentor/trainee responsibilities; publication practices/responsible authorship; peer review; and collaborative science. UTHSCH currently provides education in these areas through informal interactions with mentors/colleagues and through formal courses organized by: research support offices reporting to the EVPR; individual UTHSCH schools; and principal investigators (PI) with NIH training grants. The research support offices provide focused training on the protection of human research subjects and care/use of research animals for faculty, staff, and trainees. The schools' educational programs primarily target students, and include elective and/or required courses on one or more of the nine content areas. The Graduate School of Biomedical Science (GSBS) and Dental Branch are the only schools that require all trainees conducting research to take a comprehensive course on responsible research conduct. The GSBS course is a one semester credit hour course, and the Dental Branch course is a four hour non-credit seminar series. Finally, PIs of NIH training grants are required to provide trainees education on responsible research conduct, and UTHSCH had twelve active NIH training grants in FY2001. Several of the PIs utilized the GSBS course to meet the NIH requirement.

The Task Force advocates that UTHSCH strengthen its policies, resources, and educational programs on responsible research conduct, and it identified four recommendations to achieve these goals. The recommendations are summarized below and are in keeping with a recent Institute of Medicine recommendation that research institutions "develop and implement a comprehensive program designed to promote integrity in research using multiple approaches adapted to the specific environments within each institution" ([*Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct*, 2002](#)).

- I. *Develop institutional guidelines on responsible research conduct* – A study on medical school guidelines on research conduct recently released by the DHHS Office of Research Integrity (ORI) advocates that research institutions develop comprehensive guidelines on research conduct. The study found current guidelines are fragmented and have a limited focus, and it suggested comprehensive guidelines would be useful as: educational tools for new/visiting researchers; easily accessible guides for experienced researchers; and a tool to promote a positive research environment. UTHSCH does not have a comprehensive guide that provides faculty, staff, and trainees a single easily accessible resource on research conduct/policies. Therefore the Task Force recommends that UTHSCH develop comprehensive guidelines on responsible research conduct, and it developed draft guidelines based on the ORI study to serve as a model and stimulate discussion (Appendix G).
- II. *Create a UTHSCH website on responsible research conduct with educational resources* - UTHSCH has a large research enterprise that spans six schools, is geographically dispersed, and addresses diverse areas of research where the content/context of ethical issues varies. The faculty, staff and trainees conducting the research also have constrained schedules, varying expertise/responsibilities, and varying needs for knowledge/skills on responsible research conduct. Given these multiple needs/constraints, the Task Force recommends that UTHSCH create a website on responsible research conduct with educational resources to accommodate users' needs for flexibility in when, where, and what resources are utilized.
- III. *Strengthen and expand UTHSCH's educational programs on responsible research conduct*
 - A. *Provide all trainees in programs where research is required a comprehensive introduction to responsible conduct of research issues* - UTHSCH has a wide range of educational programs, and many of the programs require research. Research trainees participating in these programs must have the knowledge/skills to conduct research responsibly and in compliance with applicable laws/regulations. The knowledge/skills can be acquired through informal interactions with mentors, but it is difficult to ensure informal interactions consistently provide trainees a comprehensive introduction on responsible research conduct. Therefore the Task Force recommends that all UTHSCH schools provide trainees in programs where research is required formal instruction on the responsible conduct of research.
 - B. *Provide all new faculty and staff an introduction to responsible conduct of research issues during new employee orientation* - Research is an integral part of UTHSCH's mission and culture, and its integrity is maintained through the collective efforts of the numerous faculty, staff, and trainees who contribute directly or indirectly to its success. Therefore, the Task Force recommends that all new faculty and staff receive an introduction to responsible research conduct during new employee orientation to help ensure they understand the importance of and expectations for maintaining the integrity of UTHSCH research. Several responsible conduct of research issues are currently addressed in a compliance training video shown during new employee orientation, but the video is outdated and scheduled to be redone. Therefore, responsible conduct of research issues could be included in the new compliance training video or in a separate video focused specifically on research issues.
 - C. *Develop an infrastructure to promote and expand responsible conduct of research training for UTHSCH faculty and staff involved in research* - There are growing pressures to provide faculty and staff who conduct research instruction on responsible research conduct, but UTHSCH does not currently have the capacity to provide institution-wide training. Elements lacking include: curricular guidelines that identify content areas and learning objectives;

courses on responsible conduct of research beyond the focused training currently required for research involving human subjects or animals; and a system for tracking and documenting training. Therefore the Task Force recommends that an infrastructure be developed to promote and expand responsible conduct of research training for faculty and staff.

D. *Encourage UTHSCH faculty and staff involved in research to participate in training on responsible research conduct* - Federal regulations currently require training on two of the nine content areas identified in the PHS Policy on Instruction in Responsible Conduct of Research (protection of human subjects, care and use of animals), and, to date, those are the areas where UTHSCH has focused faculty/staff training on research conduct. One exception is the Dental Branch which requires segments of its research faculty/staff to attend seminars on research ethics. Given the pending federal regulation that may soon require similar training for investigators conducting PHS funded research and the institution's interest in promoting responsible research conduct, the Task Force recommends that UTHSCH encourage all faculty and staff conducting research to participate in training on responsible research conduct. When the final PHS Policy is issued and/or an infrastructure is in place to provide institution-wide instruction, UTHSCH should develop an institutional policy that makes participation in education on responsible research conduct mandatory rather than voluntary for faculty and staff who conduct research.

IV. *Maintain the Task Force on Education on Responsible Conduct of Research as an advisory body to the EVPR to oversee implementation of the Task Force recommendations* - The Task Force developed considerable knowledge during the review process about responsible conduct of research training, institutional needs for training, and resources for providing it. Therefore, the Task Force recommends that it continue to serve as an advisory body to the EVPR to facilitate/oversee implementation of the recommendations.

The Task Force has identified several recommendations to strengthen UTHSCH's efforts to promote responsible research conduct. Implementation will require the executive administration's leadership and the collaborative efforts of faculty and staff, and it will be enhanced by the institution's commitment to fostering the integrity of its research and by UTHSCH faculty expertise in bioethics, learning, and educational technology.

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THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
REPORT FROM THE TASK FORCE ON EDUCATION ON RESPONSIBLE CONDUCT OF RESEARCH

The Task Force on Education on Responsible Conduct of Research was charged with reviewing The University of Texas Health Science Center at Houston's (UTHSCH) educational programs on responsible conduct of research and recommending what, if any, changes might be appropriate to further promote the institution's commitment to research integrity and to comply with external mandates. In addressing its charge, the Task Force reviewed drivers for providing education on responsible research conduct, current UHSC policies/programs in this arena, and strategies to promote the effectiveness of UTHSCH education on responsible research conduct. These findings and the Task Force's charge, membership, review process, and recommendations are briefly discussed below.

Task Force Charge and Membership

The Task Force on Education on the Responsible Conduct of Research was established by the Executive Vice President for Research's (EVPR) predecessor to recommend strategies to comply with a PHS Policy issued December 1, 2000 on Instruction in the Responsible Conduct of Research (Appendix A). The Policy was suspended February 20, 2001 for further review, but it would have required research staff "who have direct and substantive involvement in proposing, performing, reviewing, or reporting research" on PHS-funded projects to receive instruction on responsible research conduct. Despite the temporary suspension, the current EVPR, Dr. George Stancel, asked the Task Force to continue to pursue its charge for several reasons: the institution's commitment to research integrity; the expectation a revised policy with similar requirements would be issued in the near future; and public concern about and scrutiny of research conduct.

The Task Force had twelve members that included faculty and staff in research ethics and administration (Appendix B). Its charge was to review UTHSCH's educational programs on responsible conduct of research and to recommend what, if any, changes might be appropriate to further promote the institution's commitment to research integrity and comply with external mandates. In developing the recommendations, Dr. Stancel asked the group to consider the following issues.

- ***Institution's commitment/obligation to promote research integrity*** – UTHSCH is committed and obligated to promote research integrity, and instruction in responsible research conduct is one mechanism available to meet this obligation. Even though the instruction is not currently required by the PHS, requiring all faculty and staff to receive at least an introduction to responsible conduct of research topics helps to communicate the importance of conducting research responsibly and in compliance with applicable regulations.
- ***Modular training approaches that would facilitate the institution's ability to meet a variety of training needs*** – Dr. Stancel also emphasized that UTHSCH's faculty, staff and students' needs for responsible research conduct instruction varies in terms of the depth/breadth of knowledge/skills required. He therefore encouraged the Task Force to explore modular training approaches that would enhance the institution's ability to effectively meet these varied needs.

- ***Flexible implementation plans that would enable the institution to comply quickly with future external mandates*** – Finally, Dr. Stancel noted that, since the revised PHS policy on responsible conduct of research instruction has not been issued, there is considerable uncertainty about the federal training requirements. Therefore he encouraged the Task Force to consider flexible implementation plans that could be quickly adapted to meet the PHS requirements when they are mandated.

Review Process

The Task Force utilized a variety of methods to gather information to assess UTHSCH needs for education on the responsible conduct of research. The methods included: reviews of applicable regulations/policies; reviews of relevant literature/resources; participation of three Task Force members in a national meeting addressing responsible research conduct; solicitation of input from UTHSCH Associate Deans for Academic Affairs about training needs within their schools; and consultation with UTHSCH individuals with an interest/expertise in providing responsible conduct of research instruction (Dr. John Powers, Associate Dean for Research, Dental Branch, Dr. Jon Tyson, Director of the Center for Evidence Based Medicine, and Dr. Fred Moore and Dr. Neal Waxham, PIs of two of UTHSCH's National Institute's of Health (NIH) training grants).

Drivers to Provide Education on Responsible Research Conduct

There are several drivers for UTHSCH to provide its faculty, staff, and trainees education on responsible research conduct. The drivers are briefly discussed below and include federal, public, and UT System expectations, institutional commitments and risks, and investigators' needs.

- ***Federal regulations/expectations for institutions to provide training to promote responsible conduct of research***– There are Federal regulations and expectations for academic institutions to provide training to promote responsible research conduct (Appendix C). Personnel involved in the care, treatment and use of warm-blooded research mammals (Animal Welfare Act) or vertebrate species for PHS-funded research (Health Research Extension Act) must have training on humane methods of animal maintenance and experimentation. Investigators conducting PHS-funded research that involves human subjects must have education on the protection of human subjects (NIH Grants Policy Statement, Part II), and trainees involved with NIH training grants must have instruction on the responsible conduct of research (NIH Grants Policy Statement, Part III, Section III C. 4). Additionally, a PHS Policy on Instruction in the Responsible Conduct of Research published December 1, 2000 but suspended in February, 2001 would have required institutions to provide responsible conduct of research instruction to research staff 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 Policy will be reissued in 2002, but the requirements have not been released. Despite the temporary suspension, the Department of Health and Human Services' Office of Research Integrity is continuing to sponsor conferences and develop educational resources, and would be responsible for implementing the revised Policy.

- ***Public expectations for the scientific community to maintain high ethical standards and integrity in its research programs*** – The public expects the scientific community to maintain high ethical standards and integrity in its research programs. This issue was emphasized in a recently released report from the Institute of Medicine (IOM) on *Integrity in Scientific Research*, and the report also identified individual and institutional level practices that promote responsible conduct and research integrity and help to preserve this trust (Table 1). If UTHSCH investigators violate the standards of conduct for research and the public’s trust, the institution may be subject to public scrutiny and press coverage that will negatively impact the institution. Educating investigators about expected standards of conduct in research may help minimize the risks that breaches in the standards for research conduct will occur, and it also demonstrates the institution’s commitment to maintaining the integrity of its research programs.
- ***UT System expectations that component institutions maintain effective research compliance programs*** – UT System expects component institutions will maintain effective compliance programs that have the seven elements the Federal Sentencing Guidelines consider essential to demonstrate institutions have exercised due diligence to prevent criminal conduct by employees and to detect violations of law. The seven elements are training, written standards, effective oversight, due care in delegation of authority, monitoring, discipline, and corrective action. UT System also expects compliance programs/efforts will focus on areas where the level of risks associated with non-compliance are high, and five of the high risk areas for research compliance are included as topics for instruction in the PHS policy on responsible conduct of research instruction (research with human subjects, research with animals, conflicts of interest, research misconduct, intellectual property/data management). Therefore, training on responsible research conduct for UTHSCH faculty, staff and trainees would also support the institution’s need to provide training in high risk research compliance areas.
- ***Institution’s commitment/obligation to promote scientific integrity and to protect the interests of investigators, research sponsors, research participants, and the public by fostering responsible research conduct*** – UTHSCH has an institutional commitment and obligation to promote scientific integrity and to protect the interests of the investigators, public, research sponsors, and research participants. Educating faculty, staff, and trainees about responsible conduct in research is one strategy to promote responsible research conduct and meet these responsibilities.
- ***Risks/potential consequences for UTHSCH if research is not conducted responsibly and in compliance with applicable rules/regulations*** – There are several potential risks for UTHSCH if investigators do not conduct research responsibly and in compliance with applicable rules/regulations, and these risks include: loss/suspension of research funding; financial penalties; legal liability; and damage to the institution’s reputation. Educational programs are one strategy to promote responsible research conduct and reduce the risks of non-compliance with applicable rules/regulations.

TABLE 1.
**PRACTICES IDENTIFIED IN THE IOM REPORT ON INTEGRITY IN SCIENTIFIC RESEARCH
TO PROMOTE RESPONSIBLE CONDUCT AND INTEGRITY IN RESEARCH¹**

Individual level practices

- Intellectual honesty in proposing, performing, and reporting research
- Accuracy in representing contributions to research proposals and reports
- Fairness in peer review
- Collegiality in scientific interactions, including communications and sharing of resources
- Transparency in conflicts of interest or potential conflicts of interest
- Protection of human subjects in the conduct of research
- Humane care of animals in the conduct of research
- Adherence to the mutual responsibilities between investigators and their research teams

Institutional level practices

- Provide leadership in support of responsible conduct of research
- Encourage respect for everyone involved in the research enterprise
- Promote productive interactions between trainees and mentors
- Advocate adherence to the rules regarding all aspects of the conduct of research, especially research involving human participants and animals
- Anticipate, reveal, and manage individual and institutional conflicts of interest
- Arrange timely and thorough inquiries and investigations of allegations of scientific misconduct and apply appropriate administrative sanctions
- Offer educational opportunities pertaining to integrity in the conduct of research
- Monitor and evaluate the institutional environment supporting integrity in the conduct of research and use this knowledge for continuous quality improvement

¹From the Institute of Medicine report *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct*, Committee on Assessing Integrity in Research Environments, Institute of Medicine and National Research Council, National Academy Press, Washington, D.C., 2002
(<http://www.nap.edu/catalog/10430.html>)

- ***Investigators' needs to have knowledge/skills to conduct research responsibly and in compliance with applicable rules/regulations*** – Investigators conduct research in a complex environment where there are significant regulatory requirements and growing public concerns and federal scrutiny. It is essential they have the knowledge/skills required to conduct research responsibly and in compliance with applicable rules and regulations, and training is one mechanism to help them acquire the needed knowledge/skills.

The urgency of and risks associated with these internal/external drivers to provide instruction on responsible research conduct research varies, but all of them merit serious consideration in assessing UTHSCH needs for education in this arena.

Current UTHSCH Policies and Education on Responsible Research Conduct

UTHSCH is committed to promoting responsible research conduct, and it has policies/guidelines and educational programs to support this commitment. Responsible conduct of research is however a general term that can encompass a variety of behaviors/issues, so, for this Report, it is defined as the nine content areas in the PHS Policy on Instruction in the Responsible Conduct of Research (Table 2). UTHSCH has policies/guidelines in five of the nine areas (data management/ownership, human subjects, animal subjects, research misconduct, conflict of interest), and policies in two areas (research involving humans and animals) require specific education (Table 3). Instruction on responsible research conduct may also be required at the school level, and two UTHSCH schools (Graduate School of Biomedical Sciences and the Dental Branch) require specific constituencies in the schools to complete comprehensive instruction on responsible research conduct.

Education on responsible research conduct is provided at UTHSCH through informal interactions with mentors/colleagues and through formal courses for faculty, staff, and/or trainees that are organized through: research support offices reporting to the EVPR; individual schools; and PIs with NIH training grants. These courses that focus on one or more responsible research conduct issues are briefly discussed below, but there may be additional courses that do not focus on responsible research conduct but nonetheless address the issue because of ethical issues raised within the context of the course.

- ***Centralized instruction offered through research support offices reporting to the EVPR*** - Research support offices reporting to the EVPR offer focused instruction on individual responsible conduct of research topics (Appendix D). The Office of Research Support Committees conducts seminars on the protection of human subjects for the institution's faculty, staff, and trainees, and it also approves external courses on protection of human subjects offered at other TMC institutions (MDACC, Baylor) and online through the NIH, University of Minnesota, and University of California at Los Angeles. The Center for Laboratory Animal Medicine and Care conducts a variety of seminars and laboratory sessions on the care and use of research animals with a target audience that includes investigators, animal care staff, Animal Welfare Committee members, and physical plant employees.

TABLE 2.
CONTENT AREAS DEFINED IN THE PHS POLICY ON INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

Data Acquisition, Management, and Sharing	Mentor/ Trainee Responsibilities	Publication Practices, Responsible Authorship	Peer Review	Collaborative Science	Research Involving Human Subjects	Research Involving Animals	Research Misconduct	Conflict of Interest and Commitment
<ul style="list-style-type: none"> • Definition of what constitutes data • Accepted practices for acquiring data • Accepted practices for record keeping (data notebooks, electronic files) • Data privacy/confidentiality • Data selection, retention, sharing, ownership, analysis • Data as legal documents (intellectual property, copyright) 	<ul style="list-style-type: none"> • Role and responsibilities of mentors • Responsibilities of trainees • Conflicts between mentor and trainee • Collaboration/competition • Selection of a mentor • Abusing the mentor/trainee relationship 	<ul style="list-style-type: none"> • Purpose/importance of scientific publication • Responsibilities of authors • Assigning credit in collaborative research • Acknowledgments • Appropriate citations • Repetitive publications • Fragmentary publications • Sufficient description of methods • Corrections/retractions • Conventions for deciding upon authors • Pressure to publish 	<ul style="list-style-type: none"> • Definition of peer review • Purpose of peer review to determine merit for funding and publications • Impartiality • How peer review works • Editorial boards/ad hoc reviewers • Responsibilities of reviewers • Privileged information/confidentiality 	<ul style="list-style-type: none"> • Setting ground rules early in collaborations • Avoiding authorship disputes • Sharing materials and information with internal/external collaborating scientists 	<ul style="list-style-type: none"> • Definition of human subjects research • Ethical principles for conducting human subjects research • Informed consent • Confidentiality and privacy of data/patient records • Risks and benefits • Preparation of research protocol • Institutional review boards • Adherence to study protocol • Proper conduct of study • Special protections for targeted populations 	<ul style="list-style-type: none"> • Definition of research involving animals • Ethical principles for conducting research on animals • Federal regulations governing animal research • Institutional animal care and use committees • Treatment of animals 	<ul style="list-style-type: none"> • Meaning of research misconduct • Institutional misconduct policies • Data fabrication, falsification • Plagiarism • Error vs. intentional misconduct • Intentional misconduct policies • Identifying misconduct • Procedures for reporting misconduct • Protection of whistleblowers • Outcomes of investigations (institutional/federal actions) 	<ul style="list-style-type: none"> • Definition of conflicts of interest • How to handle conflicts of interest • Types of conflicts encountered by researchers/institutions (e.g. collaborations, publication, financial, obligations to other constituencies)

TABLE 3.

UTHSCH POLICIES AND GUIDELINES ON RESPONSIBLE CONDUCT OF RESEARCH TOPICS

PHS Content Areas	Policies/Guidelines	Constituencies with Required Training
<i>General instruction on multiple responsible conduct of research content areas</i>	NONE	<ul style="list-style-type: none"> • Graduate School of Biomedical Sciences students pursuing M.S. or Ph.D. degrees • Dental Branch trainees conducting research and faculty and staff serving on thesis committees and/or conducting research • Trainees on NIH training grants
<i>Protection of human research subjects</i>	<ul style="list-style-type: none"> • HOOP 23.01 Conduct of Research • HOOP 23.02 Review of Research 	<ul style="list-style-type: none"> • Faculty, staff, and students conducting research involving human subjects • Committee for the Protection of Human Subjects
<i>Care and use of research animals</i>	<ul style="list-style-type: none"> • HOOP 23.01 Conduct of Research • HOOP 23.02 Review of Research 	<ul style="list-style-type: none"> • Faculty, staff, and students conducting research involving animals • Animal Welfare Committee • Animal care staff • Physical plant staff
<i>Research misconduct</i>	<ul style="list-style-type: none"> • HOOP 23.04 Honesty in Research • Guidelines/Procedures for Allegations of Scientific Misconduct 	NONE
<i>Conflict of interest and commitment</i>	<ul style="list-style-type: none"> • HOOP 2.19 Conflict of Interest • Guidelines on Faculty Conflicts of Interest 	NONE
<i>Data acquisition, management, sharing, and ownership</i>	<ul style="list-style-type: none"> • HOOP 23.03 Intellectual Property • HOOP 23.06 Research Data/Retention • HOOP 23.09 Multi-Media Creations • Intellectual Property Handbook 	NONE
<i>Mentor/trainee responsibilities</i>	NONE	NONE
<i>Publication practices, responsible authorship</i>	NONE	NONE
<i>Peer review</i>	NONE	NONE
<i>Collaborative science</i>	NONE	NONE

- Courses offered through individual UTHSCH schools*** – The majority of the responsible conduct of research instruction provided by UTHSCH schools targets students, and the courses in the School of Public Health (SPH) and Graduate School of Biomedical Science (GSBS) have the greatest depth/breadth in terms of content and hours available for instruction (Appendix E). The SPH course on Research Ethics in Public Health is a two credit hours elective, while the GSBS course on the Ethical Dimensions of Biomedical Sciences is a one credit hour required course. The GSBS also has four elective courses that address responsible research conduct topics (two on health care ethics and two on use of research animals). The Dental Branch has a comprehensive four-hour lecture series on responsible research conduct that is a required non-credit course for post-graduate students and D.D.S. students conducting research. Medical students receive a one-hour lecture on research ethics in a six lecture series on clinical ethics, and students may also take the Ethics in Medicine lecture series (ten one-hour lectures) for blue book credit where topics vary and may include research ethics. The Medical School Center for Clinical Research and Evidence Based Medicine offers a two year Clinical Research Curriculum which addresses all responsible research conduct topics except use of animals over the two year period, and it has recently received approval to offer a M.S. in Clinical Research that may provide additional formal courses addressing responsible research conduct. The School of Health Information Sciences addresses responsible research conduct content within a variety of courses with data management the most frequently addressed topic. In the School of Nursing, D.S.N. students receive an introduction to some responsible conduct of research content in a required Research Designs and Methods course. Finally, the Dental Branch has taken a proactive approach by expanding its responsible research conduct instruction beyond students, and requires its new faculty and faculty and staff conducting research or serving on thesis committees to attend seminars addressing a broad range of ethical issues in research.
- Training organized by PIs with NIH training grants*** – NIH requires that all National Research Service Awards trainees receive instruction in the responsible conduct of research, and the five recommended content areas are responsible authorship, scientific misconduct, human research subjects, research animals, and conflict of interest. PIs are responsible for developing educational programs to meet trainees' needs, and the programs are reviewed by individual funding agencies/reviewers where criteria and expectations may vary. UTHSCH had twelve active NIH training grants in FY2001, and a summary of nine of the grants' plans for instruction on responsible research conduct is provided in Appendix F (three were not available through microfilm). Three of the grants are short-term summer training programs for pre-doctoral trainees, and these three programs provide trainees a series of lectures on research ethics that vary in number but address a broad range of topics as recommended in the NIH regulation. The other nine UTHSCH training grants emphasize long-term training, and six were available for review on microfilm. Five of these six programs have trainees take the one credit hour GSBS course on Ethical Dimensions of Biological Sciences with three of the five requiring additional formal training beyond the GSBS course. The additional training includes a departmental lecture series organized by PIs for two grants (training programs for stroke and neuroplasticity) and the Clinical Research Curriculum for the third grant (role of gut in post-injury trauma).

Strategies to Promote the Effectiveness of UTHSCH Educational Programs on Responsible Research Conduct

The review identified strategies to help ensure UTHSCH's educational programs on responsible conduct of research are effective in meeting external mandates and internal needs. These criteria are briefly summarized below, and include requirements that the programs: utilize effective pedagogical and instructional design approaches; incorporate content that meets Federal/State mandates and institutional and user needs; have mechanisms to track and document compliance; use cost-effective approaches to develop, deliver, and/or manage educational programs; and accommodate to the extent possible the variety of needs that exist among UTHSCH's target audience of faculty, staff, students, and other trainees.

- ***Utilize effective pedagogical and instructional design approaches*** – Research in cognitive sciences, learning, and instructional design provides valuable information that can help guide the development of effective educational programs for the adult learners who comprise the majority of the program participants. Learning research, for example, suggests adult learners tend to be: autonomous and self-directed with teachers' primarily serving as a facilitator/guide; goal-oriented with an interest in linking instruction to individual goals; and relevancy-oriented with a focus on learning that is applicable to a work/other need (Leib, S., Principles of Adult Learning, <http://www.hcc.hawaii.edu/intranet/committees/FacDevCom/guidebk/teachtip/adults-2.htm>). Adult learners also have an extensive knowledge base and a wealth of life experiences, and linking new knowledge/skills to existing knowledge/experiences fosters learning. Learning may be facilitated if information is presented using a variety of instructional approaches because people learn in different ways using multiple intelligences. Learners also need opportunities to practice new skills to promote retention of and ability to transfer knowledge/skills. Finally, motivation is a critical factor in learning, and factors identified as motivators for adult learners include external expectations, social welfare, personal advancement, escape/stimulation, cognitive interest, and social relationships.
- ***Incorporate content that meets Federal/State mandates and institutional and user needs*** – UTHSCH's responsible conduct of research training should address Federal/State regulations and institutional/user needs. Federal/State regulations mandate institutions provide training on care and use of research animals and protection of human research subjects, and PIs of NIH training grants must provide training on responsible conduct of research. Institutional needs met by responsible conduct of research training include: promoting integrity in UTHSCH research; informing faculty, staff, and trainees about research policies; and maintaining an effective research compliance program where training is a required element. Finally, user needs are driven by individual researchers' needs for knowledge/skills that support the success, effectiveness, safety, and integrity of their research programs.
- ***Have mechanisms to track and document compliance*** – UTHSCH must document compliance with Federal/State training requirements. Therefore, mechanisms are needed to identify faculty, staff, and trainees who need training and to document training has been completed. Regulations may also specify particular information that must be

maintained to document training activities (e.g. date, attendees' name/title, instructors' name/ qualifications, topics) and the length of time information must be retained.

- ***Use cost-effective approaches to develop, deliver, and manage educational programs*** – The costs of providing education on responsible research conduct include both the costs of developing, delivering, and managing the training programs and the costs associated with providing participants release time from their normal duties to complete the training. Given UTHSCH's fiduciary responsibilities as a State agency and the limited resources available to meet institutional demands, it is essential that cost-effective strategies be used to develop, deliver, and manage education on responsible research conduct.
- ***Accommodate to the extent possible the variety of needs that exist among UTHSCH's target audience of faculty, staff, students, and other trainees*** – UTHSCH's educational programs on responsible research conduct serve a diverse audience of faculty, staff, students, and other trainees whose educational needs differ for a variety of reasons that include differences in: learning styles; scheduling availability/preferences (hour, day of the week, time of year); urgency of educational needs (e.g. deadlines for completion); and the depth/breadth of knowledge required. Therefore educational programs on responsible research conduct should be flexible and accommodate to the extent possible these diverse needs.

Recommendations to Strengthen UTHSCH Policies, Resources, and Education on Responsible Research Conduct

Given the institution's obligation/commitment to promote responsible research conduct and the multiple drivers to provide faculty, staff, and trainees instruction in this arena, the Task Force advocates strengthening UTHSCH policies, resources, and educational programs on responsible research conduct. Five recommendations to achieve these goals are summarized below and are in keeping with a recommendation in the IOM report on [*Integrity in Scientific Research*](#) that research institutions "develop and implement a comprehensive program designed to promote integrity in research using multiple approaches adapted to the specific environments within each institution."

- I. Develop institutional guidelines on responsible research conduct.*
- II. Create a UTHSCH website on responsible research conduct with educational resources.*
- III. Strengthen and expand UTHSCH's educational programs on responsible research conduct.*
 - A. Provide all trainees in programs where research is required a comprehensive introduction to responsible conduct of research issues.*
 - B. Provide all new faculty and staff an introduction to responsible conduct of research issues during new employee orientation.*
 - C. Develop an infrastructure to promote and expand responsible conduct of research training for UTHSCH faculty and staff involved in research.*
 - D. Encourage UTHSCH faculty and staff involved in research to participate in training on responsible research conduct.*

- IV. *Maintain the Task Force on Education on Responsible Conduct of Research as an advisory body to the EVPR to oversee implementation of the Task Force recommendations.*
- V. *Expand the requirement for education on protection of human subjects to include all investigators conducting this research. (This recommendation was previously submitted/approved and is not addressed in this Report, but is included here to provide a comprehensive list of Task Force recommendations to advance the proposed goals.)*

The rationale, implementation, impact and pros/cons of these recommendations are discussed below.

I. Develop institutional guidelines on responsible research conduct

A study of medical school guidelines on research conduct recently released by the Office of Research Integrity advocates that medical schools develop comprehensive guidelines on research conduct (*Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or their Components*, <http://ori.dhhs.gov/html/publications/analysisofguidelinesfortheconduct.asp>). The study found current guidelines on research conduct tend to be fragmented with a limited focus, and suggested comprehensive institutional guidelines would be useful as: educational tools for new/visiting researchers; easily accessible guides for experienced researchers; a tool to promote a positive research environment; and a mechanism to minimize poor research practices. UTHSCH has several guidelines/publications on responsible conduct of research issues, and they include the: [Guidelines on Faculty Conflicts of Interest](#); [Guidelines on Research Misconduct](#); [Handbook on Intellectual Property](#); and [Practical Guide to Research](#). The institution does not however have comprehensive guidelines on responsible research conduct that provide faculty, staff, and trainees a single and easily accessible resource about research conduct and policies. The Task Force therefore recommends that UTHSCH develop comprehensive guidelines on the responsible conduct of research, and issues to consider in assessing/implementing the recommendation are briefly discussed below.

- *Scope/contents of the guidelines* – The Task Force advocates that the recommendations and findings in the Office of Research Integrity’s *Analysis of Medical School Guidelines on Research Conduct* be used as a guide to develop comprehensive institutional guidelines on responsible research conduct. Draft UTHSCH Guidelines based on the Office of Research Integrity study were developed to serve as a model and stimulate discussion (Appendix G), and the eight content areas addressed are: 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.
- *Implementation of the recommendation to develop guidelines* - The EVPR could be responsible for implementing the recommendation to develop guidelines, and implementation would require both development of the guidelines and promotion of their use. UTHSCH constituencies with interests/knowledge in this arena should provide guidance about their development and strategies to promote their utilization and effectiveness.

- *Institutional resources for/impact of developing guidelines* – The primary institutional impact of the recommendation would be the resources required to develop, distribute, and maintain the guidelines. These costs should not be substantial if the Internet is used to promote their distribution.
- *Pros/cons of developing guidelines* - The *pros* of developing UTHSCH guidelines on responsible research conduct are that they could: highlight/codify the institution's values and expectations for research conduct; provide investigators a comprehensive/easily accessible guide on research conduct; be a resource for educational programs on responsible research conduct; facilitate the development of training programs that may be required in the future for PHS funded research; and support the institution's compliance efforts in several high risk research areas by serving as written standards and an educational resource. The *cons* of developing the guidelines are: the addition of another set of guidelines to the institution's already extensive set of policies/regulations; and resources would be required to develop/promote them although they are expected to be relatively small.

II. Create a UTHSCH website on responsible research conduct with educational resources.

UTHSCH has a large research enterprise that spans six schools, is geographically dispersed, and addresses diverse areas of research where ethical issues may vary in both content and context. The faculty, staff and trainees conducting the research have varying levels of expertise and responsibilities, and their need for knowledge/skills on responsible research conduct varies in terms of content areas and breadth/depth of knowledge. They also have multiple responsibilities, varied and constrained schedules, and substantial amounts of information to process and manage. Given these multiple needs and constraints, the Task Force recommends that UTHSCH create a website on responsible research conduct with educational resources to accommodate users' needs for flexibility in when, where, and what resources are accessed/utilized. Issues to consider in assessing/implementing the recommendation are briefly discussed below.

- *Resources available through a UTHSCH website on responsible research conduct* – Resources available through a UTHSCH website could include: information on relevant policies, regulations, and guidelines; resources to help PIs develop plans for providing instruction on responsible research conduct for NIH training grants; and materials to support schools' development/expansion of instruction on responsible research conduct. The website could also provide a portal to online courses on responsible research conduct available externally or internally if UTHSCH pursues development of its own courses.
- *Implementation of the recommendation to create a website on responsible research conduct* - The EVPR could be responsible for implementing the recommendation with implementation requiring both development and maintenance of the website. Individuals in the schools with relevant expertise and/or interests could provide guidance about needs, content, and priorities.
- *Institutional resources for/impact of creating a website on responsible research conduct* – UTHSCH has a well-developed and well-maintained computer network that could be used to house the website so the primary institutional impact of the recommendation

would be the resources required to develop and maintain the website. The magnitude of the costs would be driven by the magnitude and complexity of the website's contents.

- *Pros/cons of creating a website on responsible research conduct* - The *pros* of developing a UTHSCH website on responsible research conduct are that it would: help meet users' needs for flexibility in when, where, and what information and/or educational resources on responsible conduct of research are utilized; be accessible to the majority of UTHSCH investigators since most of them have Internet access; provide a portal for online courses on responsible research conduct that UTHSCH might develop in the future; and facilitate the development of training programs on research conduct that may be required in the future for PHS funded research. The *cons* of developing the website include: the resources that would be required to develop/maintain an effective website; and the challenge of building awareness of the site among potential users.

III. Strengthen/expand UTHSCH's educational programs on responsible research conduct.

Education is one strategy UTHSCH has to promote responsible research conduct, and, in the near future, if the suspended Policy on Instruction in the Responsible Conduct of Research is reinstated, it will be required for investigators conducting PHS funded research. The Policy recommends instruction in nine content areas, and, even though it is currently suspended, it provides a useful framework for developing and evaluating instruction on responsible research conduct that is currently required for UTHSCH trainees, faculty, and staff.

- *Required instruction on responsible research conduct for trainees* – Individual schools have several courses for students that address one or more of the nine content areas identified in the PHS Policy, but the GSBS and Dental Branch are the only schools that require trainees conducting research to take a comprehensive course on responsible research conduct. Students in the new M.S. program in Clinical Research will receive comprehensive instruction on these topics, and all trainees who conduct research involving human subjects or animals must take the appropriate training coordinated through respectively the Office of Research Support Committees and the Center for Laboratory Animal Medicine and Care.
- *Required instruction on responsible research conduct for faculty and staff* - Dental Branch employees involved in research are the only UTHSCH employees who receive fairly comprehensive instruction on responsible research conduct through the Dental Branch's seminars on research ethics. New employees receive an introduction to some responsible conduct of research topics during a discussion of research compliance in a compliance training videotape shown in new employee orientation. The tape however is dated (two featured employees have left the institution), not well done, limited in terms of research conduct issues, and scheduled to be revised. All faculty and staff who conduct research involving human subjects or animals must also take the appropriate training coordinated through respectively the Office of Research Support Committees and the Center for Laboratory Animal Medicine and Care.

The Dental Branch and GSBS are the only schools that require all trainees conducting research to take comprehensive training on responsible research conduct, and, with the exception of the Dental Branch, the majority of the training that faculty/staff receive on responsible conduct of research is focused on issues involving research with human subjects or animals. Given the gaps in UTHSCH's current educational programs in this arena, importance of responsible research

conduct, IOM recommendation in its report on [*Integrity in Scientific Research*](#) that institutions “implement effective educational programs that enhance the responsible conduct of research,” and the expectation that education on these issues will soon be required by the PHS, the Task Force advocates that UTHSCH strengthen and expand its educational programs on responsible research conduct for faculty, staff, and trainees. Specific recommendations to achieve that goal include: providing all trainees in programs where research is required a comprehensive introduction to responsible conduct of research issues; providing all new faculty and staff an introduction to responsible conduct of research issues during new employee orientation; developing an infrastructure to promote and expand responsible conduct of research training for UTHSCH faculty and staff involved in research; and encouraging UTHSCH faculty and staff involved in research to participate in training on responsible research conduct. These recommendations are briefly discussed below.

IIIA. Provide all trainees in programs where research is required a comprehensive introduction to responsible conduct of research issues.

UTHSCH has a wide range of educational programs, and many of the programs require research. Research trainees participating in these programs must have the knowledge/skills to conduct research responsibly and in compliance with applicable laws/regulations, and they must also be prepared to address ethical issues that may arise throughout their careers. The knowledge and skills can be acquired through informal interactions with mentors, and they may also be developed through formal instruction. It is however difficult to ensure that the transfer of knowledge in informal interactions consistently provides trainees a comprehensive introduction to responsible conduct of research issues. Therefore the Task Force unanimously recommends that all UTHSCH schools provide trainees in programs where research is required formal instruction on these topics. Issues to consider in assessing and implementing these recommendations are briefly discussed below.

- *Content of education on responsible research conduct for UTHSCH trainees* – The type of research conducted by trainees and the related ethical issues vary across UTHSCH schools, so individual schools are best prepared to design responsible conduct of research instruction to meet their trainees’ needs. The nine content areas identified by the PHS may provide the schools a useful framework for identifying relevant issues, and a variety of pedagogical approaches can be considered. A case-based approach has however proven effective for teaching ethics and merits consideration, and the GSBS and Dental Branch courses on research ethics may also be useful models. Finally, a summary of resources on responsible conduct of research is provided in Appendix H that may be helpful.
- *Implementation of recommendation to provide all UTHSCH trainees in programs where research is required a comprehensive introduction to responsible research conduct* – Since the schools are responsible for their own curricula, the Deans should work with their curriculum committees or other appropriate individuals/groups to implement the recommendation to provide all trainees in programs where research is required a comprehensive introduction to responsible research conduct. The schools could explore potential benefits of working collaboratively to provide the instruction, and there are also individuals throughout UTHSCH with expertise in research ethics who may be useful resources. Many of these individuals participate in a UTHSCH Health Care Ethics Network that Dr. Reiser has organized through the Program on Humanities and

Technology in Health Care to promote collaboration in scholarly endeavors addressing ethical issues in the health sciences (Appendix I).

- *Institutional resources for/impact of providing all UTHSCH trainees in programs where research is required a comprehensive introduction to responsible research conduct* – Providing all UTHSCH trainees in programs where research is required instruction on the responsible conduct of research would impact trainees required to participate in the training and faculty who provide the instruction, and it would also require institutional resources. It is difficult to estimate the number of trainees impacted by the requirement for a variety of reasons (e.g. growing enrollment in the School of Health Information Sciences, difficulty of identifying students like M.D. and D.D.S. who conduct research not required for their academic program), but one indicator of potential demand is the number of students who participate in academic programs with a research requirement (Table 4). In FY2001 this number was estimated to be 1,471, but 506 of these students (GSBS and Dental Branch postgraduate students) already receive comprehensive instruction on responsible research conduct. The Associate Dean for Academic Affairs in the Medical School also suggested that clinical fellows would benefit from this training. The number of faculty and other resources required to provide the instruction would depend on the format of instruction (e.g. large lectures, seminars, online instruction) and number of trainees.
- *Pros/cons of providing all UTHSCH trainees in programs where research is required a comprehensive introduction to responsible research conduct* - The *pros* of providing all UTHSCH trainees in programs where research is required instruction on responsible research conduct include: the benefits to trainees of having the knowledge/skills; the expertise that already exists within UTHSCH to assist in developing the courses; and the benefits to the institution of helping to ensure its trainees conduct research responsibly and in compliance with applicable rules/regulations. The *cons* of providing the instruction include: the resources that would be required to develop/deliver courses on responsible conduct of research; the additional educational requirement for students who may have time/financial pressures to graduate; and the challenge of finding time in the curricula for additional course requirements.

TABLE 4.
INDICATORS OF POTENTIAL DEMAND FOR
RESPONSIBLE CONDUCT OF RESEARCH TRAINING FOR UTHSCH STUDENTS

	Number of Students ¹
<i>Total student enrollment</i>	3,287
<i>Enrolled in graduate programs that require research²</i>	
Graduate School of Biomedical Sciences MS/PhD degree programs	420
School of Public Health masters/doctoral programs	890
Dental Branch masters/post-graduate certificate programs	86
School of Health Information Sciences masters/doctoral programs	47
School of Nursing doctoral program	28
Total	1,471

¹ Headcount enrollment, Fall, 2001

² Enrollment in School of Nursing MSN tracks is not included since those programs lack research requirements.

IIIB. Provide all new faculty and staff an introduction to responsible conduct of research issues during new employee orientation.

Research is an integral part of UTHSCH's mission and culture, and its integrity is maintained through the collective efforts of the numerous faculty, staff, and trainees who contribute directly or indirectly to its success. It is essential they understand the importance of and expectations for maintaining the integrity of UTHSCH's research programs; therefore, the Task Force recommends that all new faculty and staff receive an introduction to responsible conduct of research topics during new employee orientation. Issues to consider in assessing and implementing the recommendation are briefly discussed below.

- *Scope/format of introductory information on responsible research conduct for new employee orientation* – While all nine content areas identified in the PHS Policy on Responsible Conduct of Research Instruction are important, for a short introduction to responsible conduct of research issues in new employee orientation where time is limited, a priority should be placed on responsible conduct of research issues that are also considered high risk areas for research compliance. These issues include: research involving human subjects; research with animals; conflicts of interest; research misconduct; and intellectual property/data management. Several of these issues are already addressed in a compliance training video shown during new employee orientation (Appendix J), but the tape is dated and scheduled to be redone. Therefore, responsible conduct of research issues could be included as part of the new compliance training video or a new video could be developed that focuses specifically on responsible conduct of research. There is a precedent for utilizing a video format in research support training on environmental health and safety where it has proven effective for providing employees basic hazard awareness training during orientation.
- *Implementation of recommendation to provide new faculty and staff an introduction to responsible conduct of research issues during new employee orientation* – The EVPR could be responsible for implementing the recommendation in collaboration with Human Resources which is responsible for new employee orientation and the Office of Compliance which is responsible for developing the new compliance training video.
- *Institutional resources for/impact of providing new faculty and staff an introduction to responsible conduct of research issues during new employee orientation* – If a video format is used, the primary institutional impact of the recommendation would be the resources required to develop the video.
- *Pros/cons of providing new faculty and staff an introduction to responsible conduct of research issues during new employee orientation* - The *pros* of providing new faculty and staff an introduction to responsible conduct of research issues during new employee orientation include: the benefits to employees of having the knowledge/skills; and the benefits to the institution of helping to ensure its employees conduct research responsibly and in compliance with applicable rules/regulations. The *cons* of providing the introduction in new employee orientation include: the resources that would be required to develop the video; the amount of information employees receive in orientation is substantial so employees may have difficulty effectively processing all the information received; and the difficulty of finding time for another topic in new employee orientation.

IIC. Develop an infrastructure to promote and expand responsible conduct of research training for UTHSCH faculty and staff involved in research.

There are growing pressures to provide faculty and staff who conduct research instruction on responsible research conduct, but UTHSCH does not currently have the capacity to provide institution-wide training. Elements lacking include: curricular guidelines that identify content areas and learning objectives; courses on responsible conduct of research beyond the training currently required for research involving human subjects or research animals; and a system for tracking and documenting training. Therefore the Task Force recommends that an infrastructure be developed to promote and expand responsible conduct of research training for faculty and staff, and issues to consider in assessing and implementing the recommendation are briefly discussed below.

- *Strategies to develop an infrastructure to promote and expand responsible conduct of research training* – Potential strategies to develop an infrastructure to promote and expand responsible conduct of research training include developing: curricular guidelines; a system to track/document training; and courses on responsible research conduct. In developing courses, a variety of pedagogical approaches could be used, but a case-based approach has proven effective for teaching ethics and merits consideration. The GSBS and Dental Branch courses on research ethics may be useful models, and a summary of resources on responsible conduct of research is provided in Appendix H that may be helpful. Other issues to consider in developing courses are: promoting flexibility/convenience to maximize training effectiveness and accessibility; monitoring new requirements/unmet needs; assessing to the extent possible/reasonable the effectiveness of training programs; and exploring the costs/benefits of using a computer-based system to support the development, delivery, and/or management of the training.

Flexibility/convenience of responsible conduct of research training – Faculty and staff have diverse needs and backgrounds so providing them flexibility/convenience in terms of how, when, and what training is offered may enhance its effectiveness and/or accessibility. Several strategies are currently used to promote flexibility/convenience of training offered through offices of the EVPR, and may be useful for responsible conduct of research training. They include: scheduling courses multiple times throughout the year; providing individually tailored presentations for small groups; allowing investigators to select the course that best meets their needs from a list of approved courses offered internally, externally, and online; and utilizing distance education. Distance education may be provided in a variety of formats (e.g. printed materials, teleconferencing, CD-ROMs, Internet), and factors to consider in selecting delivery methods are: suitability for content; user preferences; workforce culture; access to technology; and cost. Potential advantages for example of web-based instruction include: ease of customizing training materials to accommodate users' needs for different breadths/depths of information; opportunities to use multiple instructional strategies to accommodate different learning styles; and ability to offer "just-in-time" training as it is needed. It is however difficult to teach some content/skills effectively at a distance, and some users prefer instructor led sessions. Web-based delivery methods in particular may also have high start-up costs and be inaccessible to users who lack appropriate hardware/software.

Effectiveness of training programs – Information obtained in training program evaluations serves a variety of purposes, and the effectiveness of training programs on responsible research conduct should be assessed to the extent possible/reasonable. Information obtained in evaluations may include assessments of: the effectiveness of training; value/return of training investment to the institution; and instructor performance. The evaluation process itself however can require significant resources, and the costs vs. benefits of the information obtained must be considered in planning/ implementing evaluation processes. The Kirkpatrick model for evaluating training may provide useful information in considering approaches/alternatives for evaluating research support training, and the elements of this model are briefly summarized in Table 5 (Long, L. N., *ROI: Capturing the Big Picture, Technical Training*, December, 1999). The model assesses four levels of training evaluation data that include reactions, learning, behavior, and results. Level 1, 2, and 3 data focus on formative evaluations about the design and implementation of training programs, whereas Level 4 data focuses on results/performance. All the information can be useful, but the cost/difficulty of collecting the data typically increases as one progresses from Level 1 to Level 4.

TABLE 5.
KIRKPATRICK MODEL FOR EVALUATING TRAINING¹

	Focus of Data	Data Measured	Data Collection Strategies
Level 1 data	Reactions	<ul style="list-style-type: none"> • What participants think/ feel about training (e.g. relevancy and accuracy of content, instructors' performance, training format) 	<ul style="list-style-type: none"> • Questionnaires
Level 2 data	Learning	<ul style="list-style-type: none"> • Increase in participants' knowledge and/or skills 	<ul style="list-style-type: none"> • Pretests and posttests of trainees knowledge/skills
Level 3 data	Behavior	<ul style="list-style-type: none"> • Job behavior to determine if there is a transfer/application of knowledge/skills 	<ul style="list-style-type: none"> • Supervisor observations • Reports of on-the-job behavior
Level 4 data	Results	<ul style="list-style-type: none"> • Impact of training on organizational performance 	<p><i>Improvements in measures like</i></p> <ul style="list-style-type: none"> • Lab safety indicators • Number of grants awarded

¹ Long, L. N., *ROI: Capturing the Big Picture, Technical Training*, December, 1999

Identification of new requirements/unmet needs – New requirements and unmet needs for responsible conduct of research training are issues research administrators must continue to assess. For example, the status of the suspended PHS policy to provide research staff instruction on responsible conduct of research has significant implications for UTHSCH and must be monitored. There also may be unmet training needs such as: topics currently not addressed that might be of benefit/interest to users; areas of concern in research administration that might be addressed by training; and training for members of the UTHSCH community who do not currently receive but would benefit from responsible conduct of research training.

Costs/benefits of using a computer-based system to support the development, delivery, and/or management of training – Instructional technology/information systems may be useful to support instructional and administrative requirements for providing responsible conduct of research training. A variety of computer-based “learning management systems” are available, and the functions/needs they support vary but may include: course management; course development; course delivery; and assessment. Several learning management systems are currently used within UTHSCH, and might be used to support responsible conduct of research training.

- *Implementation of recommendation to develop an infrastructure to promote and expand responsible conduct of research training* – The EVPR is currently responsible for research support training provided by several offices that report to him and could also be responsible for implementing the recommendation to develop an infrastructure to promote and expand responsible conduct of research training. His office could work collaboratively with the Office of Compliance and other individuals, offices, and institutions (e.g. UTMDACC, Baylor College of Medicine) with an interest/expertise in relevant areas. UTHSCH schools should provide the EVPR guidance about the content, training needs, and priorities, and they also may elect to provide school level educational programs on responsible research conduct for faculty/staff that follow UTHSCH curricular guidelines.
- *Institutional resources for/impact of developing an infrastructure to promote and expand responsible conduct of research training* – The primary institutional impact of the recommendation would be the resources required to develop the infrastructure for promoting and expanding responsible conduct of research training, and would include staff and, if a computer-based tracking system and online courses were developed using applications not currently licensed/owned by the UTHSCH/Office of Research, there would also be resources required for hardware/software. The level of resources required would depend on implementation strategies (e.g. the number/format of new courses developed).
- *Pros/cons of developing an infrastructure to promote and expand responsible conduct of research training* - The *pros* of developing an infrastructure to promote and expand responsible conduct of research training are: benefits to faculty/staff and the institution of having opportunities to develop knowledge/skills on responsible conduct of research; economies of scale that may be possible with an institution-wide effort to provide training; and an enhanced ability to provide instruction on responsible research conduct that may be required in the future for PHS funded research. The *cons* of developing an infrastructure are the resources that would be required.

IIID. Encourage UTHSCH faculty and staff involved in research to participate in training on responsible research conduct.

Federal regulations currently require training on two of the nine content areas identified in the PHS Policy on Instruction in Responsible Conduct of Research (protection of human subjects, care and use of animals), and, to date, those are the areas where UTHSCH has focused its faculty/staff training on research conduct. One exception is the Dental Branch where new faculty and faculty/staff on theses committees and/or involved in research attend seminars on research ethics. There are several drivers previously discussed for requiring faculty/staff who

conduct research in other schools to participate in similarly focused training, and they include: national pressure to provide comprehensive training on responsible research conduct; a pending federal regulation that may soon require the training for investigators conducting PHS funded research; the institution's interests in promoting responsible research conduct; and pressure from UT System to expand research compliance training where several topics overlap with responsible research conduct. Therefore, the Task Force recommends that UTHSCH initially encourage faculty and staff conducting research to participate in training on responsible research conduct. When the final PHS Policy on Instruction in the Responsible Conduct of Research is issued and/or UTHSCH has an infrastructure in place to promote the instruction, the institution should then establish an appropriate policy requiring research faculty and staff to have responsible conduct of research instruction. Issues to consider in assessing and implementing the recommendation are briefly discussed below.

- *Scope of expanded participation of UTHSCH faculty and staff in training on responsible research conduct* – UTHSCH faculty and staff conducting research involving human subjects or research animals are currently required to take training on these topics, but the Task Force advocates encouraging all faculty, staff, and “unpaid” collaborators who conduct UTHSCH research to participate in responsible conduct of research training in other content areas identified in the PHS Policy on Instruction in the Responsible Conduct of Research.
- *Implementation of the recommendation to expand UTHSCH faculty and staff participation in training on responsible research conduct* - The Task Force advocates a collaborative approach for encouraging faculty and staff to participate in training on the responsible conduct of research with the President, EVPR, and Deans sharing responsibility for implementing the recommendation. The President and EVPR are the institution's senior leaders for research, and are therefore best positioned to establish and communicate institutional standards/expectations for research conduct. The Deans establish and communicate standards/expectations at the school level, and they are also most knowledgeable about the faculty/staff needs, culture, research, and ethical research issues in their schools. Factors to consider in implementing the recommendation include: identification of faculty and staff who would benefit from the training; and strategies to communicate training expectations and opportunities.
- *Institutional impact of/resources for expanding UTHSCH faculty and staff participation in training on responsible research conduct* - Expanding participation in training on responsible research conduct would impact faculty/staff who elect to or, if required training is pursued, must participate in training, and it would also entail institutional resources. The number of faculty and staff impacted by the recommendation would depend on the level of participation, but indicators of the number of UTHSCH faculty/staff involved in research who might participate in the training are included in Table 6. The data suggest 1,160 to 1,196 faculty/staff would initially need training with an additional 217-228 new employees needing training annually. The resources required to provide the instruction would depend on a number of factors that include the: depth, breadth, and frequency of training; format of instruction (e.g. large lectures, seminars, online instruction); and number of participants.

- *Pros/cons of expanding UTHSCH faculty and staff participation in training on responsible research conduct* - The *pros* of expanding faculty/staff participation in education on responsible research conduct include: the benefits to faculty/staff of the additional knowledge/skills; the benefits to UTHSCH if education helps minimize risks of investigators not conducting research responsibly; the precedent for providing the training in the Dental Branch where faculty/staff involved in research already complete a research ethics training seminar; and the opportunity to utilize individuals within UTHSCH who have expertise in this arena to assist in developing courses. The *cons* of providing the instruction are that: resources would be required to develop/deliver courses on responsible conduct of research; and it would place an additional demand on faculty/staff who conduct research and have time constraints and pressures to meet multiple institutional responsibilities and commitments.

TABLE 6.
INDICATORS OF UTHSCH FACULTY AND STAFF INVOLVED IN RESEARCH

	Current Employees			New Employees (estimate/yr) ⁵		
	Faculty (% total)	Staff (% total)	Total	Faculty	Staff	Total
<i>Total at UT-Houston</i> ¹	1,080	3,414	4,494	142	819	961
<i>Participate in research</i>						
P.I.s on grants or contracts ²	484 (45%)	na	484	64	na	64
Salary - Contract/Grant funds ³	167 (15%)	545 (16%)	712	22	131	153
Research in job title ⁴	na	676 (20%)	676	na	164	164
<i>Use human subjects</i>						
Certified as having training	190 (18%)	395 (12%)	585	25	95	120
<i>Use animal subjects</i>						
P.I.s with animal protocols	156 (14%)	na	156	21	na	21

¹ Headcount, FY2000 (A&P staff not included)

² P.I.s on grants or contracts in FY2001

³ FTE, FY2000 (A&P staff not included)

⁴ Based on classified staff in DSS on 7/12/01

⁵ Projections – total for faculty is the average number of new faculty annually over the last five years and for staff is annual turnover rate of 24% * total number of staff in FY 2000; subcategories based on current % * total new faculty/staff projected

na – not applicable

IV. Maintain the Task Force on Education on Responsible Conduct of Research as an advisory body to the EVPR to oversee implementation of the Task Force recommendations.

The Task Force on Education on Responsible Conduct of Research developed considerable knowledge during the review process about responsible conduct of research training, institutional needs for training, and resources for providing it. Therefore, the Task Force recommends that it continue to serve as an advisory body to the EVPR to facilitate/oversee implementation of the recommendations. Its members' expertise in responsible conduct of research and insights about specific needs of different UTHSCH constituencies would facilitate and enhance the success of the implementation process. The Task Force could also consider strategies to address the IOM recommendation in its report on [Integrity in Scientific Research](#) that "research institutions should evaluate and enhance the integrity of their research environments using a process of self-

assessment and external peer review, in an ongoing process that provides input for continuous quality improvement.”

Conclusion

As a public institution, UTHSCH has a special responsibility to protect the integrity of its research and maintain the public’s trust, and this requires ensuring its faculty, staff, and trainees conduct research responsibly and in compliance with applicable laws and regulations. Several factors increase the complexity of this responsibility, and they include the: size of UTHSCH’s research enterprise; number of faculty, staff, and trainees conducting research; diversity of research projects; involvement of human subjects and animals in research; disparate geographic locations of the research; multiple funding sources; and the complex regulatory environment for research. Training is one mechanism available to institutions to promote responsible research conduct, and UTHSCH already has a substantial research support training program for faculty, staff, and trainees that addresses protection of human subjects, care/use of research animals, environmental health and safety, and securing/managing grants. There are however several responsible conduct of research topics not currently addressed, and the Task Force has recommended that the executive administration strengthen institutional policies, resources, and educational programs on responsible research conduct through collaborative efforts of constituencies with an interest/responsibilities in this arena. The success of these efforts will be enhanced by the contributions of UTHSCH faculty with expertise in bioethics, learning, and educational technology, and the Office of Research Affairs also has individuals with extensive experience providing and managing high quality research support training that meets users’/institutional needs and external requirements.