

**UNIVERSITY OF TEXAS SYSTEM**

# **IRB TASK FORCE REPORT**

**Trust, Integrity, and Responsibility in the Conduct of Human Subjects Research**

**UT IRB TASK FORCE  
APRIL 2009**

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## EXECUTIVE SUMMARY

The University of Texas Institutional Review Board (IRB) Taskforce was formed in February, 2008 by Executive Vice Chancellor for Health Affairs, Kenneth Shine, M.D. and Interim Executive Vice Chancellor for Academic Affairs, Geri Malandra, Ph.D. Specifically, the Taskforce was charged to:

- Review literature and data about human subjects research protection programs (including IRBs) and consider IRB authority, mission, and functions within the UT System institutions.
- Identify areas of concern (especially with regard to unnecessary obstruction of research and lapses of effective human subject protection).
- Identify IRB "best practices" within the UT System and from the available literature.
- Identify ways UT System institutions and the UT System Administration can increase the effectiveness, efficiency and productivity of IRBs while protecting research subjects.
- Assess the feasibility of regional IRBs and/or a system-wide IRB for collaborative research protocols, including a major effort to reduce duplication of effort among IRBs.
- Consider the effectiveness and efficiency of programs to assure good practices following initial IRB approval of research protocols.

The Taskforce was comprised of senior officials from both medical and academic campuses across the UT System, representing a variety of academic disciplines (Appendix 1). It met 8 times between February, 2008 and February, 2009, rotating the meeting locations in order to include in the dialogue, guest from all UT System components. Experts from outside of University of Texas were also consulted, including Tina Gunsales; John Heldens, C.I.P; Moira Keene, M.A.; Dan Nelson; Ivor Pritchard, Ph.D.; and Marjorie Speers, Ph.D. (Appendix 2) .

The Taskforce developed a set of eight recommendations. These recommendations were discussed in a series of "road shows," during which the Taskforce Co-Chairs visited with Institutional Officials, IRB Chairs, and investigators from virtually every UT System Campus to collect feedback.

The specific recommendations set forth by the Taskforce are:

1. **Define the boundaries of regulated human subjects research** – Is it human subjects research? To address this aspect of "mission creep", the Taskforce recommends development of a roster of types of research activities that can be used as a guide to determine which research projects do or do not qualify as human subjects research. (Appendix 3).
2. **Utilize the flexibility that already exists in the regulations** – The Taskforce recommends that UT System components fully utilize the considerable flexibility that already exists in the regulations and make efforts to explore available options to expand institutional knowledge of such flexibility while meeting regulatory requirements (Appendix 4).

3. **Consider modifying the federal-wide assurance (FWA)** – The Taskforce recommends that institutions consider the option of filing an assurance that is limited to federally-funded research. Limiting the FWA to federally-funded research is an important way to increase flexibility in review processes for non-federally-funded studies and can reduce reporting obligations (Appendix 5) and help address “mission creep”.
4. **Ensure adequate scientific or scholarly review** – To address another aspect of “mission creep,” institutions should consider a range of options to assure that each protocol receives an appropriate scientific or scholarly review. Although IRBs must consider merit in order to perform a risk/benefit assessment, an in-depth scientific review can be performed by another body prior to IRB submission.
5. **Promote efficiencies and reduce burdens for faculty and research staff** – Each campus should optimize the operations of their human research protections programs in ways that promote the most efficient use of faculty time and institutional resources and that minimize the regulatory burdens on investigators. Institutions should ensure that researchers and research staff have access to appropriate resources and training to conduct human subjects research in the most efficient and effective manner. In some cases this may require acquisition of electronic data management systems. UT system can help to defray the costs for these systems to enhance IRB recordkeeping and management, and to improve the degree to which system-wide reporting may become possible (Appendix 6).
6. **Reduce the number of IRBs that review a single protocol** – To avoid duplicative reviews, the Taskforce recommends that institutions consider a range of alternatives (Appendix 7) to local, institution-based IRB review, including:
  - a. Establish reciprocal agreements between UT campuses so that they can rely on each other’s IRB reviews;
  - b. Establish reciprocal agreements between UT campuses and other collaborating institutions;
  - c. Use central IRBs, such as the NCI Pediatric and Adult IRBs, for multi-site trials; and
  - d. Create multi-institutional specialty IRBs.
7. **Recruit, retain and reward IRB members, staff**– UT System components should offer or fund organized training and continuing education activities for all the stakeholders involved in the conduct and oversight of human subjects research. Recruitment and retention of qualified IRB members should be a priority. Funding for continuing education and promotion/tenure credit for service should be established. Institutions should encourage professional certification for IRB staff by supporting funding for certification exams. Institutions should also develop career ladders for research staff with different levels of knowledge/expertise based on experience and/or certification.

8. **Foster a culture of conscience** – Institutions and their leaders should vigorously foster a climate that encourages respect for trust, integrity and accountability at all levels. Responsibility for ethical behavior invites appropriate scrutiny, oversight, accountability, and verifiability in an atmosphere of mutual respect, confidence and professionalism. Trust between IRBs and investigators (and among UT System and all component institutions) is earned and reciprocated when each addresses the common goal of protecting human subjects while advancing the goals of research.

Engaging stakeholders, trustees, institutional officials and community members in trust building activities helps align the strategic goals of the organization with the humanistic needs of the public. Relevant axes of trust building include:

- a. Trust between IRBs and investigators to work together on the conduct of research that benefits humankind while protecting the rights and welfare of subjects, and
- b. Trust between institutions collaborating on research that would permit greater reciprocity (and less duplication) of reviews and oversight.
- c. Trust by the public of the university and its researchers, and a shared understanding that research is critical for improving human health and welfare,

## INTRODUCTION

Dr. Kenneth Shine, Executive Vice Chancellor for Health Affairs and Dr. Geri Malandra, Interim Executive Vice Chancellor for Academic Affairs appointed the UT System-wide IRB Taskforce to review human research protection programs across the UT components, and to provide recommendations for making the IRB review and oversight processes more efficient and effective. Because of specific concerns about the potential for IRB overreaching, a specific charge to the Taskforce was to investigate the phenomenon of “mission creep” and to make recommendations for reducing it.

Research is central to the missions of all 15 institutions of the University of Texas system. The UT System includes nine academic campuses and six health care centers. The scope of research performed at each site varies. The medical centers perform clinical trials, prevention studies, and research on health behaviors. Some academic campuses conduct only social, behavioral and educational research, while others conduct biomedical research as well. What all the campuses share, independent of the scope of their research portfolios, is a commitment to the ethical conduct of human subjects research.

Institutional Review Boards (IRBs) are the center of any university’s human research protections program. They provide a local peer review of proposed human subjects research to protect the rights and welfare of study subjects and to ensure regulatory compliance, and they oversee ongoing studies to monitor safety and research integrity. Although other administrative entities also have roles to play in the management of a university’s research enterprise, IRB members and staff serve as the conscience of any institution that uses humans in research.

Despite the importance of IRBs, they have come under fire for being too rigid, for over-regulating, and for reaching into areas of inquiry beyond their regulatory authority. The idea of unwarranted expansion of responsibilities, “IRB mission creep”, has received considerable academic attention recently. The perception is that some IRBs have begun to 1) oversee and regulate research that does not meet the federal definition of human subjects research, and 2) require modifications in human subjects research that are not actually required by regulations or accepted scientific standards.

Ironically, concerns about IRBs over-reaching have not diminished the extent to which IRBs have continued to be the “dumping grounds” for all manner of bureaucratic and regulatory gate-keeping functions. Institutions themselves contribute to mission creep by their own tendencies to assign to IRBs areas that are not directly related to human research protection and for which the IRBs do not have adequate time or resources. For example, many IRBs have been assigned oversight of quality improvement data collection, development of conflict of interest management plans, and submission of INDs and IDEs.

As a part of its charge to review the operations of human research protection programs within the component institutions of the UT System, the Task Force considered the specific regulatory requirements that govern the conduct of human subjects research within the broader ethical principles that are the foundation for the responsible conduct of human subjects research. The University of Texas

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System and its component institutions are committed to the operation of research programs that are founded on a shared culture of trust, integrity, and accountability in the conduct of human subject research. It is of critical importance that the operations of the human research protection programs of these universities be configured to promote and sustain these core values.

The Task Force in its deliberations went to considerable lengths to ensure that the review of institutional programs and the subsequent recommendations addressed the important issues of the ethical foundation for the operation of human research protection programs. These recommendations were framed in recognition of the fact that securing and preserving the public trust is the foundation of all research endeavors and is critical to the operation of a meaningful human research protection programs.

## PROCESS

The Taskforce was formed in February, 2008 by Executive Vice Chancellor for Health Affairs Kenneth Shine, M.D. and Interim Executive Vice Chancellor for Academic Affairs, Geri Malandra, Ph.D. At the first meeting, Dr. Shine formally charged the Taskforce with the following tasks:

- Review literature and data about human subjects research protection programs (including IRBs) and consider IRB authority, mission, and functions within the UT System institutions.
- Identify areas of concern (especially with regard to unnecessary obstruction of research and lapses of effective human subject protection).
- Identify IRB "best practices" within the UT System and from the available literature.
- Identify ways UT System institutions and the UT System Administration can increase the effectiveness, efficiency and productivity of IRBs while protecting research subjects.
- Assess the feasibility of regional IRBs and/or a system-wide IRB for collaborative research protocols, including a major effort to reduce duplication of effort among IRBs.
- Consider the effectiveness and efficiency of programs to assure good practices following initial IRB approval of research protocols.

The Taskforce met 8 times between February, 2008 and February, 2009, rotating the meeting locations in order to include in the dialogue guest discussants from every region of the state. Meetings were held in February 2008 (Austin), March 2008 (Houston), May 2008 (Dallas), June 2008 (San Antonio), August 2008 (Edinburg), September 2008 (Austin), December 2008 (Houston), and February 2009 (via teleconference).

The Taskforce consulted with national experts on topics addressing both the protections to be provided to research subjects, and the logistical challenges of facilitating research, both within and across campuses, including Tina Gunsales; John Heldens, C.I.P; Moira Keene, M.A.; Dan Nelson; Ivor Pritchard, Ph.D.; and Marjorie Speers, Ph.D. (Appendix 2)

In face-to-face meetings and via teleconference, the Taskforce members worked to develop a shared understanding of the issues and concerns faced across the UT System with regard to the ethical conduct and effective review of research.

Over the course of our meetings, a set of draft recommendations was developed. These recommendations were then shared with the campuses and health centers through a series of regional meetings and a teleconference in Austin, Dallas, Houston, San Antonio, Edinburg and El Paso in which representatives from all the UT campuses participated. At each meeting, Institutional Officials, IRB Chairs, investigators and other interested personnel were asked for comments and suggestions on the Taskforce's draft recommendations, and they were encouraged to raise additional concerns.

These concerns and suggestions were considered by the Task Force in February 2009 and incorporated into the final set of recommendations.



## RECOMMENDATIONS

The Taskforce acknowledges the enormous diversity in human subjects research programs across the breadth of the UT System. This diversity reflects not only large differences in the scale and scope of research programs at different UT System component institutions, but also the diversity in fields of study that involve human subjects. Despite the differences between the research portfolios and missions of the 15 components (from bench research in biomedical engineering to subspecialty clinical drug and device trials to wide variety of social and behavioral science research), there are many issues and challenges that cut across the spectrum of individual research programs. The Taskforce has chosen to focus its attention on many of these broader challenges and to develop recommendations that may be of value to the leadership of the UT System and its component campuses in drafting human subjects research programs that meet the responsibilities to research subjects and investigators. The following is a list of major recommendations developed by the Taskforce.

### **Recommendation One: Define Boundaries of Regulated Human Subjects Research**

*The Taskforce recommends that institutions clearly define the boundaries of research involving human subjects that is subject to federal regulations.*

To address one aspect of “mission creep”, the Taskforce recommends adoption within the institution’s IRB policies and procedures of a roster of types of activities that do or do not qualify as human subjects research. This guidance is detailed in Appendix 3. It may be particularly useful for institutions conducting social and behavioral research.

It is the responsibility of each institution to establish a process for determining whether an activity does or does not constitute human subjects research. This determination can be made within the IRB office or it may be assigned to other entities in the human research protection programs. The UT System can assist institutions in their efforts to delineate the boundaries of regulated research by developing guidance that can be used to identify data collection activities that qualify or do not qualify as human subjects research. This guidance could also identify those research areas that fall into “gray zones” and require individual determination based on the specific activities proposed.

As a simple but useful aide to the campuses, the Taskforce recommends that UT System develop a consult capability available to institutions to provide advice on issues related to the interpretation of federal regulations. Each component would be asked to generate lists of both local expertise and frequent IRB concerns. The lists would be matched across the campuses, to generate consultants in such areas of IRB review as: privacy, data security, research involving subjects with impaired capacity, internet research, IDE management, etc. Campuses that rarely do biomedical research could benefit from the extensive knowledge of the health-related institutions within UT System when considering a complex biomedical ethical question. Alternatively, a campus struggling with review of research conducted over the internet might ask for help from experts at other UT campuses that already have worked through the unique challenges of such studies.

In addition, institutions should establish clear distinctions boundaries between the responsibilities of the IRB and other entities within the human research protection programs such as Conflict of Interest Committee, Embryonic Stem Cell Oversight Committee, Good Clinical Practices Oversight, etc.

## **Recommendation Two: Utilize the Flexibility Existing within the Federal Regulations**

*The Taskforce recommends that institutions consider making maximal use of the flexibility available within federal regulations to streamline review and approval of research.*

In order to enable institutions to utilize the considerable flexibility that already exists in the regulations, the Taskforce provides concrete recommendations (Appendix 4) for interpretation of regulations.

There exist important opportunities for institutions to improve the operation of their human research protection programs by taking full advantage of areas of flexibility that already exist in the Common Rule. The federal regulations allow for flexibility in meeting requirements in several areas such as determination of whether research involves human subjects, exempt determinations, expedited determinations, waivers of documentation of informed consent, waivers of parental permission, waivers of children's assent, and continuing review by expedited review. The tendency for most IRB staff is to assign protocols to the most stringent level of regulatory review. The Taskforce recommends that the emphasis be shifted to providing an efficient level of regulatory review compatible with adequate protection of human subjects. In addition, it is recommended that IRBs make maximum use of opportunities to use administrative and expedited review processes rather than a full committee review for minimal risk research.

Institutions should develop mechanisms to support and enable IRB staff to make these determinations. UT System should promote use of flexibility in the application of regulatory requirements by offering training for IRB administrators, Chairs and members on increasing familiarity with the opportunities for utilizing the flexibility in federal regulations.

UT System could assist institutions to make these determinations by providing a system level "consult" service with regulatory experts to provide advice on issues related to the interpretation of federal regulations. For instance, campuses that rarely do biomedical research could benefit from the extensive knowledge of the health related institutions within UT System when considering a complex biomedical ethical question. Or alternatively, a campus struggling with review of research conducted over the internet might ask for help from experts at other UT campuses that already have worked through the unique challenges of such studies.

Often IRB staff and members are reluctant to lower the requirements for minimal risk research. They do so in part, because evidence-based research is only now becoming available to support these decisions to assure that protection of human subjects is not threatened. Can commensurate protections to subjects be accomplished while (for example) reducing the length of a consent form, increasing the length of IRB approval? The Taskforce along with many national research institutions and colleagues believes these changes in standards provide robust protection, but look to empirical studies to support these conclusions. UT System should encourage institutions to initiate demonstration projects to assess the impact of on the operation of human research protection programs. Funding for such projects could be made available by System to foster the performance of empirical research on IRB functions.

### Recommendation Three: Consider Modifying the Federal Wide Assurance

*The Taskforce recommends that institutions consider the option of filing a federal-wide assurance (FWA) that limits compliance obligations only to federally-funded research or that reduces reporting requirements for non-federally funded studies.*

Under the applicability section of the FWA, institutions may elect to comply with all applicable regulations for all their human subjects research (regardless of the source of funding support), or to limit applicability of the regulations based on a study's funding source by "unchecking" the Common Rule and/or Subparts B, C, and D boxes (Appendix 5). Historically, in 1993, more than 95% of institutions agreed to apply their Multiple Project Assurance to all research conducted at the institution. Current data from AAHRPP (Marjorie Speers, President and CEO of AAHRPP) shows that for accredited institutions, that number is fewer than 50%. It is primarily the major research universities that are considering unchecking the box. Typically most institutions are unchecking all boxes, thus committing to follow the Human Subjects Regulations only for federally funded research. Anecdotal information from OHRP confirms these trends. The flexibility gained is used primarily for research that involves no greater than minimal risk. Examples of such flexibility in review processes for studies that are not federally funded include:

1. Flexibility in assignment of continuing review intervals;
2. Expanded categories for expedited review, including administrative reviews;
3. Expanded opportunities for documenting informed consent by alternative processes;
4. Administrative approval of minor changes to a protocol;
5. Liberalization of requirements for research involving pregnant women;
6. Alternative system of safeguards for studies involving prisoners;
7. Liberalization of the criteria for protocol deferral versus "approved pending changes."

The Taskforce recommends consideration of three options for limiting the FWA. These include:

**Option I:** Uncheck both the Common Rule box and the Subparts B, C, D box but enforce the same set of policies for all human subjects research. Establish institutional policies and procedures that apply equally to federally-funded (or supported) and non-federally funded research. This option relieves the institution of the obligation to meet federal reporting requirements for issues related to non-federally funded (or supported) research. Institutions retain the option of reporting to OHRP incidents of significant deviation from approved protocols or research misconduct involving non-federally funded research.

**Option II:** Uncheck both boxes and develop a different set of policies for human subjects research that is not federally-funded. All research will be subject to the same ethical principles, but for non-federally funded research, institutions may choose to have greater flexibility while providing equivalent protections to research subjects. If adopting Option II, institutions must implement data management systems to identify and track the source of funding for each study in order to apply the correct policies.

**Option III:** Elect to apply the Common Rule for all research, regardless of source of support but uncheck the box for applicability of Subparts B, C, D. The policies and procedures applied to federally-funded and non-federally funded research involving pregnant women, fetuses or neonates; prisoners; and children must provide equivalent protections to research subjects. Again, taking this approach will require institutions to implement data management systems for identification and tracking of funding sources for each study in order to apply the correct policies.

For a more detailed explanation of the options and the flexibility offered by a limited assurance, please refer to Appendix 5. It should be noted that all of an institution's human subjects research activities, regardless of whether the research is subject to federal regulations, must be guided by the ethical principles articulated in the Belmont Report. Institutions should have a set of policies and procedures that commit to the highest ethical standards for all research involving human subjects.

### **Recommendation Four: Ensure Adequate Scientific or Scholarly Review**

*The Taskforce recommends that institutions have in place processes that ensures that all human subjects research receive adequate scientific or scholarly review.*

Scientific review or scholarly review by the IRBs is sometimes viewed by investigators as mission creep. However, IRBs cannot perform a risk/benefit assessment without assessing the scientific or scholarly merit of research protocols. Such review is often misunderstood by faculty and researchers, and labeled as a form of “mission creep”. Scientific merit review, however it is accomplished, must be included in the materials supplied to IRB reviewers and should be a formal section of the initial application to the IRB.

Sharing the task of scientific or scholarly review with other bodies can reduce the workload of the IRB and may improve the quality of the scientific review. It should be noted, however, that the IRB retains the authority to perform its own risk/benefit analysis and may disagree with the assessment of an outside body about both 1) the likelihood and magnitude of harm and 2) the anticipated benefits to subjects and/or society.

Institutions may consider various options to ensure that each protocol receives appropriate scientific or scholarly review:

1. Rely on reviews by independent bodies such as national funding agencies,
2. Require review by an Institutional Scientific Review Committee prior to IRB review,
3. Require review by a Departmental Scientific Review Committee prior to IRB review,
4. Perform the scientific review at the IRB with appropriate use of consultants.

### **Recommendation Five: Promote Efficiencies and Reduce Burdens for Faculty and Research Staff**

*The Taskforce recommends that institutions optimize the operations of the human research protection programs in ways that promote the most efficient use of faculty time and institutional resources and that minimize the regulatory burdens on investigators engaged in human subjects research.*

The Taskforce recognizes that it is a UT system-wide priority to promote and support human subjects research and the faculty and staff who conduct it. Institutions should ensure that researchers and research staff have access to appropriate resources and training to conduct human subjects research in the most efficient and effective manner. Continuing education opportunities should be made available in a variety of media targeted to meet the needs of researchers, such as structured training, web-based information, monitoring to insure best practices, consultations, and mentoring.

Research staff (i.e., clinical coordinators, research coordinators) should work in areas appropriate to their education, training and experience. The Taskforce recognizes that the challenge in this area is the wide variability in qualifications, skills and classifications accorded to personnel with the title of “Study Coordinator.” The Taskforce encourages each campus to work with its Human Resources office to 1) examine the training and job qualifications of individuals in this role, 2) establish recommended skill sets for standardized job titles and roles, 3) set pay scales accordingly, and 4) establish a career ladder for research staff. Institutions also may choose to have formal training certification for research staff to enhance the quality of their human research protection programs. Acquisition of professional certifications (such as CCRA, CIP) should be encouraged and rewarded. Salaries should be commensurate with responsibility. System should work with institutions to share best practices and to make available access to shared training resources, such as case studies.

The Taskforce recommends that the Institutional Official at each component convene an annual meeting to bring together stakeholders in the research protection program (investigators, individuals with responsibility for HRPP such as IRB chairs and members, IRB staff, institutional leaders and study participant representatives) to review opportunities for promoting efficiency and reducing regulatory burdens at their institution.

Other opportunities for UT System and campus collaboration for improving efficiency and streamlining include:

1. System dissemination of updates on regulatory changes and guidance that impact HRPPs,
2. Establishment and evaluation of metrics and benchmarks to evaluate attempts at improvement in the efficiency and effectiveness of the institutions’ HRPPs,
3. Promotion and sponsorship of new educational and training initiatives,
4. Consultation from UT System and/or experts from the component institutions on human subjects policies, best practices and examples of improvements.

Researcher and research staff burden can be reduced by the effective use of technology to support management of human subjects research operations including electronic IRB systems and other technologic tools to streamline clinical research operations such as electronic informed consent, web-based submission with auto population of fields, electronic routing, and smart forms with algorithm-based branching.

Each institution was asked to identify the electronic systems used for IRB, IACUC, IBC, COI and Pre-Award research administration (Appendix 6). At the time of the survey, each institution used a different process to capture their IRB review information. Three institutions had no electronic system in place; five institutions had built their own system. For future interoperability, a shared research database might enable sharing of information between human research protection programs across institutions.



### **Recommendation Six: Establish Agreements to Reduce the Number of IRBs that Review a Single Protocol**

*The Taskforce recommends that institutions explore ways to address the problem of duplicative review of human subjects research studies subject to responsibility of multiple IRBs.*

A survey (Appendix 7) was conducted by the task force to map current IRB agreements between UT System institutions. Fifteen institutions creates opportunities for a total of 105 possible agreements, only 6 (5.7%) of which exist today.

The Taskforce strongly recommends that UT components that have close collaborative relationship with other UT campuses should establish reciprocity agreements to reduce duplicative review. UT System can support the development of inter-institutional agreements by the creation of templates that provide clear delineation of responsibilities of both parties entering into a reciprocal IRB review agreement. These templates may be used to frame inter-institutional agreements between UT components, multi-institutional IRB agreements (for specialty IRBs or regional IRBs) and agreements with non UT research organizations or central IRBs such as NCI pediatric or adult IRBs for cooperative group trials.

Institutions should be encouraged to consider alternative processes to local, institution-based IRB review, such as reciprocal agreements between IRBs of collaborating institutions or use of central IRBs, such as the NCI Pediatric and Adult IRBs for cooperative group trials.

### **Recommendation Seven: Recruit, Reward and Support IRB Members and Staff**

*The Taskforce recommends that institutions establish administrative processes that recruit, reward and support personnel responsible for the operation of the human research protection program including provision of appropriate resources and training to enable them to meet their responsibilities.*

An effective program for human research protections requires leaders, stakeholders and staff who are trained properly and compensated in a manner commensurate with their level of responsibility. Organized training and continuing education activities (intramural or extramural) must be made available for the following categories of individuals: Institutional Officials, IRB Chairs, IRB members, IRB directors and staff, investigators and research staff.

**Institutional Officials:** As the leaders of an institution's human research protection programs, Institutional Officials play a critical role in defining the fundamental ethical, regulatory and operational aspects of the program. The UT System and its component institutions should implement a structured program to insure that Institutional Officials are fully familiar with their responsibilities and with best practices by developing web-based training modules and an annual meeting that focuses on the challenges and responsibilities faced by the Institutional Officials.

**IRB Chairs:** As the leaders of the IRBs, IRB Chairs play a very important role in enhancing the effectiveness of an HRPP. Institutions and UT System should collaborate to plan and resource regular regional meetings at which IRB Chairs can be brought together to discuss challenges and best practices that impact the operations of their IRBs. Institutions should be encouraged to develop and implement an explicit system of rewards to recognize the value of their commitment to the institution's human research protection programs by payment, course release, performance appraisal and/or recognition for tenure and promotion. UT System should consider developing guidelines for responsibilities of IRB Chairs that can be used by the campuses when recruiting and selecting IRB Chairs. IRB Chairs should work closely with IRB Directors as partners in the leadership process.

**IRB Members:** Recruitment and retention of qualified IRB members must be a high priority. The Institutional Officials should ensure that the institution's disciplines are well represented in the IRB. During review of research, IRB members should be encouraged to focus on issues that impact human research protections. Institutions should be encouraged to develop and implement an explicit system of reward that recognizes the value of their commitment to the institution's human research subject protection program by payment, course release, performance appraisal and/or recognition for tenure and promotion. Training must be made available to new members and opportunities for continuing education, such as attendance at PRIM&R conferences or local "IRB 101" sessions should be supported.

**IRB Director and Staff:** The efficient and effective operation of an institution's IRB is dependent on having knowledgeable staff familiar with the regulatory obligations and IRB best practices. This can be promoted by a structured program of training and continuing education. Such a program should include attendance at workshops and access to distance learning technologies. Consideration should be given to

the development of a “mentoring” program in which IRB staff at smaller institutions or newcomers can have structured access to individuals willing to serve as a consultative or mentoring resource. Acquisition of professional certifications should be encouraged and rewarded. Salaries should be commensurate with responsibility. IRB Directors should work closely with IRB Chairs as partners in the leadership process.

### **Recommendation Eight: Foster a Culture of Conscience**

*The Taskforce recommends that the UT System and its component institutions promote a culture of conscience in the conduct of human subjects research.*

Institutions and their leaders should vigorously foster a climate that encourages respect for trust, integrity and accountability at all levels. Responsibility for ethical behavior invites appropriate scrutiny, oversight, accountability, and verifiability in an atmosphere of mutual respect, confidence and professionalism. Trust between IRBs and investigators (and among UT System and all component Universities) is earned and reciprocated when each address the common goal of protecting human subjects while advancing the goals of research.

Establishing a culture of conscience that defines barriers to the effective implementation of these values is a means to improving overall trustworthiness. Engaging stakeholders, trustees, institutional officials and community members in trust building activities helps align the strategic goals of the organization with the humanistic needs of the public. The essence of a culture of conscience should be reflected in the attitudes and activities of the leadership of the university as well as within the attitudes and activities of the faculty, trainees and staff directly involved in the conduct of human subjects research.

The Taskforce recommends that UT System articulate expectations of component institutions with respect to the conduct of human subjects research and the protection of research subjects. Institutions should be encouraged, in ways that are most appropriate to their individual institutional character, to engage in activities and programs that reflect the university's commitment to the importance of trust as the foundation for the conduct of human subjects research.

Examples of activities that institutions may consider to promote a culture of conscience:

1. Demonstrated interest and participation by campus leadership in award ceremonies, lecture series, workshops and pronouncements related to the ethical conduct of research.
2. Campuses should promote conversations about important issues involving human subjects research, such as transparency regarding financial relationships with industry.
3. Campuses should actively consider where IRB is placed, such that the IRB reports to an institutional leader of sufficient authority, independence, and knowledge of human research protection issues and relevant regulations to ensure implementation, resourcing, and maintenance of the program.

It is the responsibility of university leadership and the leadership of the human research program to promote trust as the foundation of all aspects of the human research programs. Responsible university leaders and researchers must share in a mutual understanding of the critical role that trust plays in the conduct of human subjects research.

In order to promote trust, it is very important for institutions to have a transparent mechanism for handling financial conflict of interest. Financial relationships between researchers or research universities and third parties generate incentives that may influence the conduct of human subjects

research, and therefore that may create real or perceived conflicts of interest. Clinical investigators have regulatory and ethical responsibilities to research participants, and may also have legal and ethical obligations to patients. Clinical investigators have legal obligations to the research universities that employ them, which in turn make it possible for those institutions to honor their own legal, ethical, and regulatory obligations to participants, patients, sponsors, and the public.

IRBs are properly concerned with both individual and institutional financial incentives in connection with the following IRB responsibilities, and should expect and receive full cooperation from research universities, researchers, and their own members:

1. Judging the reliability and completeness of information the IRB receives about the risks to participants and benefits to society of a research protocol.
2. Evaluating the objectivity and therefore the effectiveness of a protocol's procedures for protecting participants' safety and reporting research results.
3. Conveying sufficient information to research participants to enable them to make an informed decision about participation in a protocol.
4. Maintaining public trust in, and support for, the research enterprise.
5. Ensuring the integrity of the IRB's own procedures and the decisions that emerge from them.

IRBs should establish open communication and good working relationships with other entities concerned with financial incentives within their institutions (e.g., conflict of interest committees, objectivity in research committees, and scientific misconduct committees) so that each entity can understand the others' missions, responsibilities, standards, and procedures.

Each institution should commit effort and resources to actively promote trust-building with respect to human subjects research. Relevant axes of trust include trust by the public of the university and its researchers in the shared goal of improving human health and welfare through research. This trust should be fostered by the maintenance of an active program of dialogue with the community and its leaders about the importance of issues related to the conduct of research and its impact on the community. Some of the options that institutions may consider include public events, public affairs initiatives, community engagement and representation in all aspects of the human research protection programs. Reciprocal trust between the IRBs and the investigators should be founded on the common goal of conducting research that benefits humankind while not overlooking the critical elements in the protection of subjects engaged in research. Reciprocal trust between the University and its IRB is founded in the common goal of promoting human subjects research through the operation of a comprehensive human research protection programs.

Finally, institutions may wish to consider the implementation of a research ombudsperson to increase the opportunity for rapid resolution of issues involving human subjects research.

## CONCLUSION

The University of Texas System and its component institutions are committed to the promotion and sustainability of a shared culture of trust, integrity, and accountability in human subject research. Through its leadership and resources, UT System expresses its abiding commitment to securing the public trust that is the foundation of all research endeavors. This commitment is expressed in the cultivation of an enduring infrastructure of trustworthiness, set forth in practices, standards, communications, and relationships. In promoting these values the UT System recognizes that that all members of the university communities engaged in human subjects research are expected to comply with applicable laws and regulations that bear on their areas of responsibility. Adherence to existing rules and legal requirements is a necessary component of all our institutions' human subject research programs. Many of the recommendations of this Task Force are designed to support and promote the most efficient and effective application of these principles on the responsible conduct of human subjects research.

However the promotion of programs to support the responsible conduct of human subjects research, sometimes referred to as the promotion of a "culture of compliance", represent at most a minimum level of operation of an institution's human research protection programs. Institutions have an essential stake in promoting a "culture of conscience" that engages all members of the university community involved in every aspect of human subjects research. This culture of conscience is founded on the integrity and accountability of all who participate in research that involves human subjects and is reflected in a shared commitment to the ethical principles that underlie the operation of human subjects research programs. The Task Force in its recommendations has stressed the shared responsibility of university leaders, IRB's and investigators to work together in a trust-based relationship to promote the ethical and responsible conduct of human subjects research. In the final analysis it is the institutionalization of a culture of conscience, founded on the principles of trust, integrity and responsibility in the conduct of human subjects research that is the essence of an institution's human research protection programs.

## FUTURE TOPICS

1. Ongoing Advisory Group - The Taskforce recommends that UT System consider having a small ongoing IRB Advisory Group. Such a group could assist with implementation of the Taskforce recommendations and could provide assistance and advice on system-wide human subject policy issues.
2. Quality assurance - The Taskforce recognizes the importance of implementing quality assurance programs across all UT System components. Formal accreditation by national organizations like AAHRPP is one way of improving quality. UT System should facilitate the availability of a System-based peer review for institutions who do not wish to seek AAHRPP accreditation. A systematic review either by an external accrediting organization like AAHRPP or through a UT System peer review would help to demonstrate the overall excellence of an institution's HRPP.
3. Compensation for Subject Injury – There are non-regulatory issues such as compensation for subject injury that impact many, if not all UT components. The development of uniform recommendations for addressing these issues may be of value to the institutions.
4. Demonstration Projects - There are important opportunities for UT System and its component institutions to advance human subjects research by supporting demonstration projects to evaluate the effectiveness of various regulatory processes and procedures. The Taskforce recommends that an ongoing program of UT sponsored system-wide demonstration projects will be of great value in improving the efficiency and effectiveness of our human subject protection program. Some examples for demonstration projects discussed by the taskforce include:
  - a. Reengineering the exempt process to move the process for determination of exemptions outside the IRB and track to see if appropriate determinations are being made more expeditiously.
  - b. To work with IRBs staff and members to implement mechanisms to decrease deferrals at IRB meetings to track if 'contingent approval' provides equivalent human subjects protections as compared to deferrals.
  - c. To restructure IRB composition by designating several members as alternates will enable the IRB to have a larger pool of members to insure that expertise is available to the IRB while maintaining a smaller quorum. This will also help by reducing the workload as not all members have to attend meetings every month.
  - d. Pre-IRB consultation service will help to get the proposal through the IRB quickly and save time for IRB members as well as investigators.
  - e. Allowing protocols that do not involve greater than minimal risk to have a longer approval period and demonstrating if this provides equivalent protections.
  - f. Different electronic programs are in use for research administration and IRBs in various institutions. A system-wide data warehouses might help bridge the differences in various electronic programs and foster collaborations between IRBs.
  - g. A pilot project for review of social behavioral projects at regional level.

## APPENDIX 1 – UT SYSTEM IRB TASK FORCE MEMBERS

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## APPENDIX 2 – LIST OF CONSULTANTS

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## APPENDIX 3 – BOUNDARIES OF REGULATED HUMAN SUBJECTS RESEARCH

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

IRBs should have policies and procedures that help determining whether an activity is human subjects research. Policies and procedures should describe how a determination of ‘research’ is made e.g. whether the activity is a systematic investigation and whether it will be used to develop or contribute to generalizable knowledge. Policies and procedures should define human subjects. In general, an activity that does not meet the regulatory definition of human subjects research should not require IRB review and approval.

### Determination of Human Subjects Research

**Research** - Determine if the activity meets the definition of research. Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Human Subjects** - Determine if research involves human subjects. Human subject is a living individual about whom an investigator conducting research obtains data (including tissue, specimens, and cognitive phenomena) through intervention or interaction, whether identifiable or not, or private information.

**Intervention** includes both physical procedures by which data are gathered and manipulations of the participant or participant’s environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and participant.

**Private Information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining information to constitute research involving human subjects

### Examples of Activities that may or may not be Human Subjects Research

**Classroom activities** may include instructing students in research methodologies and techniques. If the sole purpose of the activity is to teach students research techniques or methodology and not to develop or contribute to generalizable knowledge, it is not considered to be research. However, if students will practice research methodologies on human beings, they should be instructed in the ethical conduct of such activities and should be advised to obtain informed consent from their practice subjects.

**Service surveys** issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary may not meet the definition of human subjects research. If the survey is being conducted to produce generalizable knowledge or survey data is used in the future for a new study producing generalizable knowledge, IRB review may be required.

**Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thoughts regarding themselves such as canvassing librarians about inter-library loan policies or rising journal costs may not meet the definition of human subjects research.

**Biography or oral history** research involving a living individual is not generalizable beyond that individual. Oral history does not involve meet the definition of research and therefore may be excluded entirely from IRB review, without seeking formal exemption.

**Case reports** – Case reports do not involve systematic investigation; however the intent is to contribute to generalizable knowledge. Case reports do not meet the definition of research involving human subjects and does not require prior IRB review and approval. However, a report of a series of cases may qualify as human subjects research and hence should be submitted for review and approval by IRB prior to initiation.

**Publicly available data** – Research involving publicly available data do not require IRB review. Examples: census data, labor statistics. Investigators should contact the IRB if they are not sure whether the data qualifies as “publicly available”.

**Research involving secondary use of data** - If the data set contains no identifiers (either direct or linked code numbers), the project does not meet the definition of human subjects research. If the data set contains identifiers, and does not contain private information (information about behavior that occurred in a context in which the individual could reasonably expect that no observation was taking place or involved no information which had been provided for specific purposes for which the individual could reasonably expect would not be made public), the project may not meet the definition of human subjects research.

**Outbreak investigations** – Outbreak investigations are important activities that benefit public health. Such activities are not considered to be research and do not require IRB review. However any interventional studies conducted during an outbreak would require review and approval by IRB. IRB will make an effort to expedite the review and approval process for such protocols.

**Infection control** – Rapid investigations to reduce the current or future spread of disease or infection carried out as part of an infection control program are not considered as research and these do not require review by IRB. Planned research conducted by Infection Control department requires review and approval by IRB.

**Educational tests, surveys, interviews or observations** – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior meets the definition of human subjects research.

**Retrospective medical records review** – A retrospective medical record reviews conducted to develop generalizable knowledge is human subjects research. If the investigator records the data in a manner that subjects cannot be identified directly or through identifiers linked to the subjects, the research may qualify for exemption. However, a medical records review done for the purposes of department audit or outcomes research may not meet the definition of human subjects research.

**Data warehouse or research database** - Operation of data warehouses or databases management center are subject to oversight by IRB. IRB should review and approve protocols specifying the conditions under which data may be accepted and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. IRB will also review and approve a sample collection protocol and consent document.

**Leftover biological materials** – Leftover material is the biological material that was originally collected for clinical or diagnostic purposes but some of the material is leftover after the original purpose has been met. Research involving leftover biological materials is human subjects research and needs IRB review. Leftover material that is anonymous may not meet the definition of human subjects research.

**Extra biological materials** - Extra material is biological material that is collected above and beyond what is needed for a clinical or diagnostic procedure, i.e. collecting a few extra mls of blood during a blood draw for diagnostic purpose. Research involving collection and use of extra biological material is human subjects research and needs IRB review.

**Tissue repositories** - Operation of Human Tissue Repositories and its data management center are subject to oversight by IRB. IRB should review and approve protocols specifying the conditions under which data and specimens may be accepted and shared, and ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. IRB will also review and approve a sample collection protocol and consent document.

**Deceased individuals**- Autopsy material or bio-specimens from now deceased individuals is not human subjects research, however, research in this category, such as genetic studies providing private or medical information about live relatives, may need meet the definition of human subjects research.

**Quality assurance and improvement projects (QA / QI)** – Activities designed to determine if aspects of any practice are in line with established standards are called quality assurance. When an activity is designed to improve the performance of any practice in relation to an established standard, it is called quality improvement. QA / QI projects may involve systematic investigation and contribute to generalizable knowledge and may meet the definition of human subjects research.

**Innovative therapy** is an intervention designed solely to enhance the well being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individual and they do not meet the definition of human subjects research. When innovative therapies differ significantly from routine practice they should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.

**Emergency use of investigational drug** - When a physician wishes to use an investigational drug for treatment of an individual patient for a single use or a single course of treatment, and the use is not covered by an existing IRB approved protocol, this is not research, but does need IRB notification.

**Emergency use of unapproved medical device** - If an emergency arises where an unapproved medical device may offer the only possible life-saving alternative, but an Investigational Device Exemption (IDE) for the device does not exist, or the proposed use is not approved under an existing IDE, a physician may use the device if some conditions are met. The physician must notify the IRB within 5 days of the emergency use.

**Off-label use of marketed drugs, biologics and medical devices** - Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB).

**Investigational use of marketed drugs, biologics and medical devices** - All such activities require prior IRB review and approval. When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, submission of an IND or IDE may be required.

Source:

1. Amdur, Robert; Speers, Marjorie; Bankert, Elizabeth. "Identifying Intent: Is This Project Research?" Institutional Review Board: Management and Function. Ed. Elizabeth A. Bankert and Robert J. Amdur. 2006. 101-105.

## APPENDIX 4 – FLEXIBILITY EXISTING WITHIN THE FEDERAL REGULATIONS

**Flexibility in determinations of Exempt** - There is considerable confusion within the research community regarding how the categories should be interpreted. The confusion leads to inconsistency in review and can create unnecessary delays in the review process for these low risk studies. Many IRBs are reluctant to grant exemptions. When they do allow exemptions, IRBs often add additional criteria. For example, though regulations allow for surveys with identifiers to be exempted if the disclosure of the responses outside of research would not place the subject at risk, many IRBs prefer to expedite surveys with identifiers.

**Flexibility in expedited determinations** - There is some confusion amongst IRBs in the interpretation of expedited determinations. IRBs often prefer to err on the side of caution and review the research at a convened meeting.

**Waiver of Documentation of the consent process** - The regulations permit an IRB to waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. The regulations permit an IRB to use an expedited procedure to review research when the research involves no more than minimal risk and appears in one of the categories published in the Federal Register. In almost all cases, written consent is normally not required when procedures in categories (1)-(7) are performed outside of the research context. IRB's should consider waiving consent documentation for research that is approved using the expedited procedure.

**Waiver of Parental Permission** - In addition to the provisions for waiver contained in §46.116 of subpart A, an IRB may determine that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). In such instances, the regulations allow the IRB to waive the parental permission requirements.

**Waiver of Children's Assent** - Regulations allow IRBs to waive assent requirements even where the IRB determines that the subjects are capable of assenting.

**Consent Elements** - Under the regulations that list the basic elements of informed consent, several of the disclosures are required only when applicable, for example:

1. A description of **any** reasonably foreseeable risks or discomforts to the subject - disclosure needed only if there are any foreseeable risks.
2. A description of **any** benefits to the subject or to others which may reasonably be expected from the research - disclosure needed only if there are any foreseeable risks.

3. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject - for research that does not have any 'therapeutic' component, this may not be relevant.
4. A statement describing the extent, **if any**, to which confidentiality of records identifying the subject will be maintained - disclosure needed only if there is a plan to maintain confidentiality.
5. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained - only for research that involves more than minimal risk, the disclosure about compensation is needed. For most expedited review protocols, this disclosure may not be required.

**Continuing Review** - Regulations do allow for continuing review of research that was initially reviewed at a convened meeting to be reviewed by expedited review when it meets certain conditions. IRBs should use this flexibility to use the expedited review process for research initially reviewed at a convened meeting when it meets the conditions listed in the Federal Register.

#### **Resources**

1. Flexibility in Regulations – Presentation by Marjorie Speers, PhD at the 2008 annual AAHRPP conference.
2. Code of Federal Regulations 45 CFR 46

## APPENDIX 5 – MODIFYING THE FEDERALWIDE ASSURANCE

When an organization is engaged in human subjects research that is conducted, supported or otherwise subject to regulation by a federal agency that has adopted the federal policy, the organization must have a federalwide assurance. In this assurance, the organization may decide whether to commit to follow the regulations, including the subparts, for all research, follow Subpart A for all research, follow the regulations, including the subparts, for some research or follow Subpart A for some research.

If the organization does not commit to follow the DHHS regulations for some research, there are several options. The organization may follow the DHHS regulations and subparts without a formal commitment or the organization may decide to apply equivalent protections. This accords a great deal of flexibility in how you may word the optional part 4(b) of the organizations federalwide assurance. Some examples of the flexibility that organizations may exercise:

**Reporting to regulatory authorities** – Under a federalwide assurance, the organization commits to promptly report to OHRP, any unanticipated problems involving risks to participants or others, serious or continuing noncompliance and any suspensions or terminations of IRB approval. When the research is not subject to the federal regulations and the organization has not elected apply the regulations to all research, institutions may choose to report the above to OHRP.

**Collaborative Research with Other Institutions** – Under the DHHS regulations, any institution involved in conducting covered research should have a federalwide assurance. When research is not subject to federal regulations, and the organization has not elected to apply DHHS regulations to all research, the organization may engage in collaborative research with other institutions without requiring that the other institution be covered by an FWA.

**At least annual continuing review** – Under the DHHS regulations, IRBs must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. When the research is not subject to the federal regulations and the organization has not elected to apply DHHS regulations to all research, the organization may choose to allow the IRB to determine that continuing review can be conducted at intervals greater than annually or may allow the IRB to determine that continuing review is not required unless a specific event occurs, such as until a certain enrollment has been reached, statistical significance has been met, or a phase has completed. An IRB may even determine that for a particular research, continuing review is not required.

**Categories of research eligible for review using the expedited procedure** – Under the DHHS regulations, an IRB may use the expedited review procedure to review either or both of the following some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk. When the research is not subject to the federal regulations and the organization has not elected to apply DHHS regulations to all research, the organization may allow the use of the expedited procedure for all research involving no more than minimal risk, regardless of category and omit use of other applicability criteria or may allow qualified IRB staff who are not IRB members to conduct review.



**Research involving pregnant women** – Under the DHHS regulations, research may involve pregnant women when there is no such prospect of benefit only when the purpose of the research is the development of important biomedical knowledge. This limits the ability of researchers to involve pregnant women in social and behavioral research where there is no prospect of benefit. When the research is not subject to the federal regulations and the organization has not elected to apply DHHS Subpart B regulations to all research, organizations may follow Subpart B, but omit “biomedical” and may opt to have no specific additional protections when the research does not target pregnant women and involves no more than minimal risk to pregnant women.

**Incidental incarceration after enrollment** – The DHHS regulations on involving prisoners in research are applicable to all biomedical and behavioral research covered under a federalwide assurance. When a participant becomes incarcerated after enrollment and the research does not focus on prisoners or individuals at increased risk of incarceration, the IRB must apply Subpart C to that research. When the research is not subject to the federal regulations and the organization has not elected to apply DHHS Subpart C regulations to all research, the organization may opt to follow Subpart C, but omit requirement for a prisoner representative or may decide to review administratively to determine whether participant is at unexpected increased risk of harm, and if so have convened IRB review as unanticipated problem involving risk to participants or others.

**Documentation of consent process** – DHHS regulations require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant’s legally authorized representative and a copy of the consent document be provided to the person signing the form. When the research is not subject to the federal regulations and the organization has not elected to apply DHHS regulations to all research, informed consent may be documented by other means such as video or audio taping, documentation by a witness, clicking “I agree” on a Web site.

### **Resources**

1. Flexibility in Regulations – Presentation by Marjorie Speers, PhD at the 2008 annual AAHRPP conference.
2. Code of Federal Regulations 45 CFR 46

UT SYSTEM IRB TASK FORCE REPORT

**APPENDIX 6 - UT SYSTEM ELECTRONIC MANAGEMENT SYSTEMS FOR RESEARCH ADMINISTRATION**

	<b>IRB</b>	<b>IACUC</b>	<b>Pre-award</b>	<b>COI</b>	<b>IBC</b>
Arlington	homegrown: Profile System	homegrown: Profile System		homegrown: Profile System	homegrown: Profile System
Austin	homegrown; soon implementing ePROTOCOL	homegrown; implementing ePROTOCOL	homegrown-research manager system; have joined the Kual Consortium and may use that as a platform for a new system	None	homegrown; beginning implementation of ePROTOCOL
Brownsville/TS C	Sharepoint	Sharepoint	None	homegrown: Word documents	Sharepoint
Dallas	None; plan to adopt UTA's Profile System	None; plan to adopt UTA's Profile System	MS Access database; plan to move to UTA's Profile System	None; plan to adopt UTA's Profile System	None; plan to adopt UTA's Profile System
El Paso	IRBNet ( <a href="http://www.irbnet.org">http://www.irbnet.org</a> ) prepaid use agreement for online protocol management	Protocol are submitted either in paper or electronic format. The protocols are then converted to searchable and secure .pdf documents and posted on an institutional shared web space. Data is managed through a "home grown" Microsoft Access database file	A) "Budget Tool", A home built software application integrated with other campus systems to assists in the development of consistent budgets for proposals, and timely notification to IRB, IACUC, Etc. B) "Faculty Expertise Database", A UT-Arlington software application to identify faculty expertise, institutional resources, and faculty bio's for consideration during the of proposals. C) "Questys" Commercial software package for document filing.	Hardcopy forms are submitted and transferred into an electronic form. Forms are stored and reviewed on a secured institutional shared web space that is accessed using Xythos. Data is managed through a "home grown" Microsoft Access database file.	Hardcopy forms are submitted and transferred into an electronic form. The protocols are posted on an institutional shared web space that is accessed using Xythos. Data is managed through a "home grown" Microsoft Access database file.
Pan American	homegrown	homegrown	homegrown	homegrown	homegrown
Permian Basin		Click Commerce			

UT SYSTEM IRB TASK FORCE REPORT

	<b>IRB</b>	<b>IACUC</b>	<b>Pre-award</b>	<b>COI</b>	<b>IBC</b>
San Antonio	Click Commerce	Click Commerce	Cayuse	Click Commerce	Click Commerce
Tyler	None	None	None	None	None
SWMC	homegrown; looking to buy	eSirius (an NTM product)	homegrown	homegrown	homegrown
UTMB	InfoEd	InfoEd	InfoEd Proposal Tracking; minimal use of Proposal Development for actual submission to grants.gov	None	InfoEd
HSC-H	iRIS (iMedRIS Data Corp; electronic submissions)	Granite (Topaz Technologies; in the process of upgrading to an online protocol submission module)	Cayuse; no other internal submission system	Online forms currently incorporated in the IRB system	EHSA (OnSite Systems; currently in implementation stage)
HSC-SA	Key Solutions eProtocol	Key Solutions eProtocol	homegrown electronic Certificate of Proposal (eCOP), Cayuse	TBD	Key Solutions eProtocol
<b>MDACC</b>					
HSC-T	ProIRB StudyManager (for clinical research projects)	Paper hardcopy. Approved protocols are stored as .pdf files and entered into an excel spreadsheet	homegrown Access database	Paper hardcopy. Excel spreadsheet to track receipt	Paper hardcopy

## APPENDIX 7 ALTERNATIVE IRB MODELS

The last several years has seen an increasing interest in alternative IRB models. Participants at the workshop on alternative models of IRB review in November 2006, identified various models of IRB review including:

1. A single site research study is reviewed by the local IRB of the site.
2. In a multi-site research study, the research is reviewed by the local IRB of each participating site.
3. In a multi-site research study, the research is reviewed by the local IRB of each participating site, but the IRBs share common materials and exchange information to facilitate work. (e.g. IRBNet)
4. An institution relies on the review of another institution's IRB for a particular research study or a particular group of research. (e.g. Reciprocity Agreements or Memorandum of Understanding)
5. A single independent IRB conducts review on behalf of one or more research sites for single or multi-site research studies (e.g. Western IRB, Chesapeake Research Review, etc)
6. A local IRB participates in a facilitated review for a multi-site research study following review by a central IRB. (e.g. NCI Central IRB process).
7. Research sites form a consortium and use the IRB of one of the sites to review a collaborative protocol (e.g. Multicenter Academic Clinical Research Organization)
8. Research sites form a consortium and a new entity is created for review purposes (e.g. Biomedical Research Alliance of New York – BRANY).

One of the main concerns of institutions with alternative models is the perceived increase in regulatory liability. This fear of liability may be managed by establishing a relationship between the institutions, building trust, transparency, good communication and having clear written agreements.

Institutions may be concerned that use of alternative models might result in a loss of institutional control over research. This may be managed by having robust electronic systems which allow sharing of information between the collaborating institutions.

Perceived loss of quality of oversight when the research is not reviewed by the local IRB is yet another factor. Loss of control and quality may be managed by clear written agreements that allow the local IRB to conduct quality assurance activities for all research conducted within the institution, including those reviewed by outside IRBs. It should be clear that institutions are responsible for conduct of research even though the review has been conducted by another IRB. Agreements should spell out more detailed respective responsibilities of each party – the IRB responsible for the review and the institution where the research is being conducted. Such responsibilities include – initial review, continuing review, continuing review reminders, review of unanticipated problems, reporting to regulatory agencies etc. The agreement should also detail the communication mechanism between the IRB and the institution including timelines of reporting problems to each other. A series of written templates should be developed and made available to institutions to facilitate these agreements.

Institutions should consider several factors before deciding the model that best suits them. Implementing several alternative models would accord maximum flexibility. Agreements between institutions that do not traditionally collaborate with each other may not be terribly beneficial.

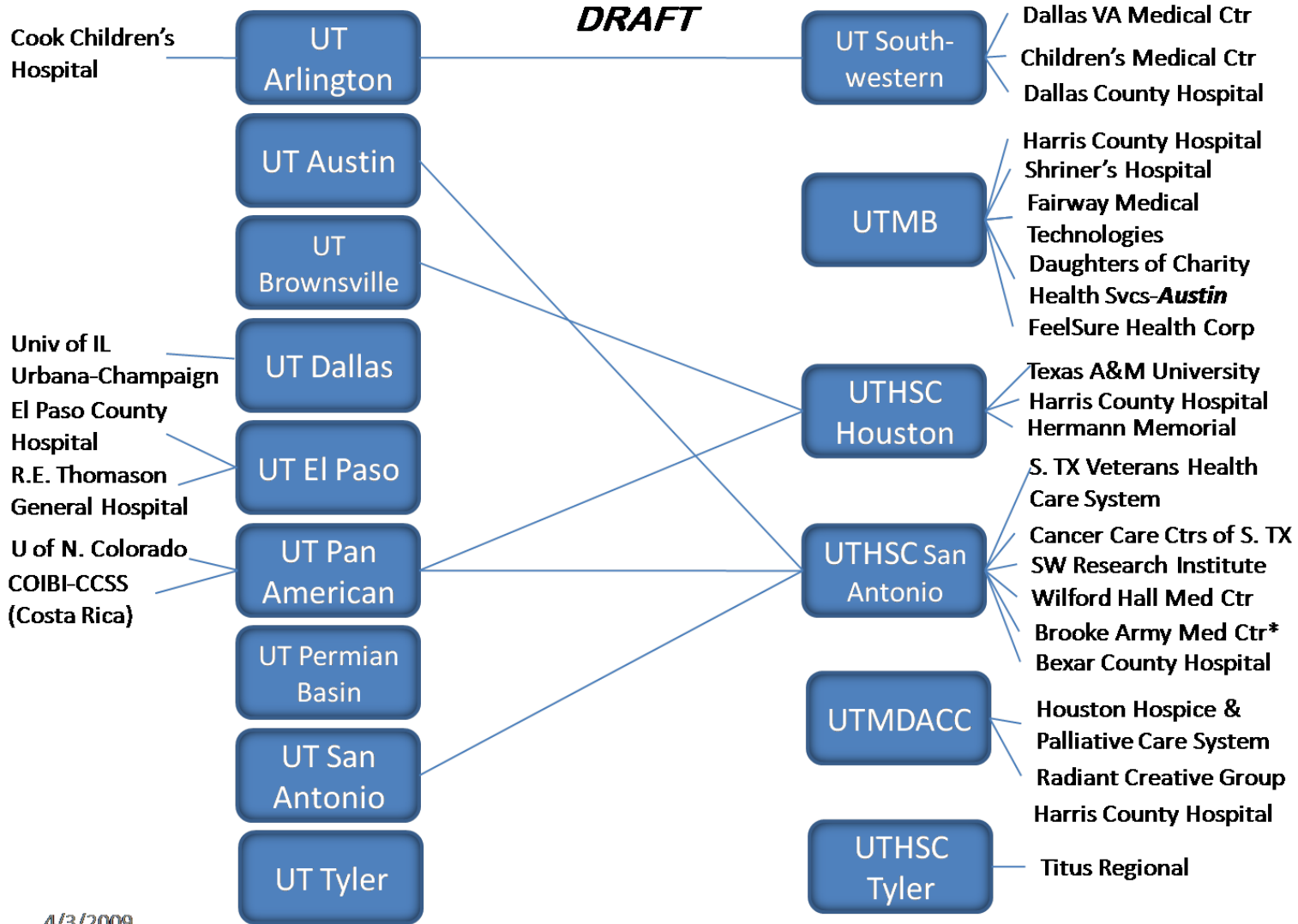
One of the greatest benefits of having reciprocity agreements is the good will that it builds in the research community. Establishing these agreements will help strengthen a collegial relationship with faculty. Even faculty whose protocols do not fall within the scope of the agreements would be pleased to see the IRB engaging in alternative models as it emphasizes the fact that IRBs are here to facilitate ethical research and protecting human subjects.

**Resources**

3. National Conference on Alternative IRB Models: Optimizing Human Subject Protection, Nov 19 – 21, 2006, Washington, DC.
4. Presentation on Alternative IRB Models by Dan K. Nelson, MS, CIP to the UT System IRB Task Force.

## Collaborative IRB Agreements

*DRAFT*



4/3/2009

\* pending