UTSA The University of Texas at San Antonio™
AUDITING & CONSULTING SERVICES

Human Subjects Research
Internal Audit Report
Project # 2016-40
July 26, 2016

Reviewed by:

Dr. Ricardo Romo
President

Executive Summary
Human Subjects Research
Internal Audit Report Project # 2016-40

Objectives:

- Determine if UTSA's policies and standard operating procedures address the human subject research federal requirements.
- Determine if researchers are educated about their duties and responsibilities to keep human subject data secure.
- Determine if researchers listed on human subjects research protocols complete required training prior to receiving approval to perform research.
- Determine if the IRB (Institutional Review Board) has implemented Office of Human Research Protection (OHRP) conditional approval requirements outlined in the OHRP determination letter to UTSA dated February 23, 2016.
- Survey human subject researchers to collect IRB process strengths and weaknesses.

Conclusion:

In our opinion, the Office of Research Integrity and the Institutional Review Board has policies and standard operating procedures that address federal requirements and data security requirements, but include formatting that can be updated to better reflect current practices. Researchers obtain required training prior to receiving approval to perform research. The policies and standard operating procedures address requirements outlined in the February 23, 2016 OHRP determination letter. Limited survey responses indicated satisfaction with the performance of the IRB.

A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole*." Non-Priority Findings are ranked as High, Medium, or Low, with the level of significance based on an assessment of applicable Qualitative, Operational Control, and Quantitative risk factors and probability of a negative outcome occurring if the risk is not adequately mitigated. This audit resulted in two medium findings, but no Priority Findings.

Non-Priority Recommendations:

- Update the UTSA Handbook of Procedures (HOP) 2.26 Human Research (Medium)
- Update Policies and Standard Operating Procedures (Medium)

Scope:

The scope of the audit was human subjects research protocols effective September 1, 2014 – April 30, 2016.

Background

In accordance with UTSA Handbook of Operating Procedures (HOP) 2.26 Human Research, the University of Texas at San Antonio's (UTSA) Institutional Review Board (IRB) is the university committee that reviews and approves human subject research for the purpose of protecting the rights and welfare of those subjects. The IRB is regulated by the Office for Human Research Protections (OHRP) under the Department of Health and Human Services (DHHS) and provides the requirements for the formation and composition of the IRB Committee as well as the IRB's duties in authorizing research involving human subjects.

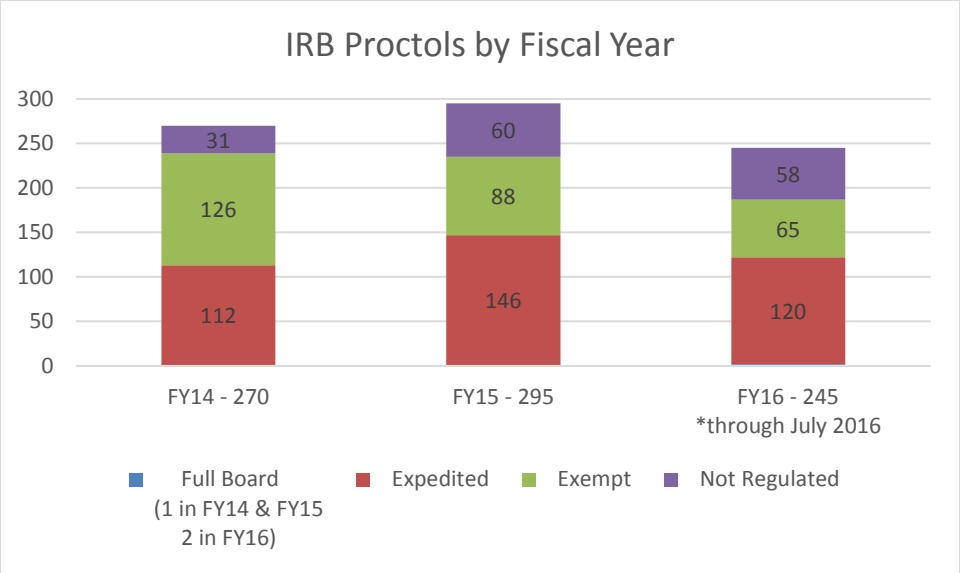
IRB Committee

The Vice President for Research is responsible for appointing all members of the IRB Committee. The IRB Committee consists of the IRB Chair who is one of nine voting members.

Office of Research Integrity

The Office of Research Integrity reports to the Vice President for Research. The Office of Research Integrity, also referred to as the IRB Staff, supports the IRB Committee and periodically reports key statistics to the Vice President for Research. The Assistant Vice President for Research Integrity manages the Office of Research Integrity that consists of the Executive Director of Research Integrity, the Senior Research Compliance Coordinator, and the Research Compliance Coordinator. The IRB Staff have policies and standard operating procedures for the operation of the IRB.

The statistics of protocols reviewed by IRB staff and the IRB Committee (Full Board) in the chart below were provided by the Senior Research Compliance Coordinator. See Appendix A for definitions and examples.



Authorizing Research and Training	The IRB Staff and IRB Committee are collectively responsible for reviewing and authorizing research involving human subjects by UTSA researchers. Prior to obtaining authorization to conduct human subjects research, all researchers are required to obtain training through the Collaborative Institutional Training Initiative (CITI) program. This training is from an on-line website which provides ethical and case study modules to highlight the risks and care necessary for such research.
Data Security Standards	UTSA Office of Information Technology (OIT) has standards for data classification, protection, and security since the risk of inadvertently disclosing data continually increases as technology enhancements increase. Human subjects research data must follow UTSA OIT standards.
External Consulting Report	In 2013, WCGIRB Consulting performed a best practices evaluation of UTSA IRB practices and reviewed compliance with federal regulations. The review concluded that in general, the IRB demonstrated a high degree of compliance with obligatory requirements. Boilerplate IRB policies and standard operating procedures were provided as part of the evaluation and were adopted by UTSA.
OHRP Determination Letter	In February 2016, OHRP issued a determination letter to UTSA in response to an allegation of noncompliance with federal regulations made in October 2012. The letter included a recommendation that the IRB update procedures for protocols containing conditional approvals including requirements for following up to ensure conditional approval stipulations are met prior to final protocol approval and prior to research commencing.

AUDIT RESULTS

Audit Objective: Determine if UTSA's policies and standard operating procedures address the human subject research federal requirements.

Authoritative Guidance	Human Research is governed by Handbook of Operating Procedures (HOP) 2.26 Human Research. HOP 2.26 references the ethical principles of research involving humans and includes a reference to federal guidance (45 Code of Federal Regulations [CFR] Section 46) and institutional policies. Researchers, the IRB Committee, and IRB Staff utilize IRB Policies and Standard Operating Procedures (SOPs) posted on the IRB website that were provided by the external consulting firm WCGIRB in 2013, as part of their review. The policies and SOPs were put into place to ensure compliance with federal requirements.

Observation:	The UTSA Handbook of Operating Procedures (HOP) 2.26 Human Research http://www.utsa.edu/hop/chapter2/2-26.html was last updated on July 2005 and has outdated references.
Risk:	Conflicting or outdated guidance may exist between HOP 2.26 and IRB Policies and Standard Operating Procedures, which could result in confusion or non-compliance by Researchers, IRB Board Members, IRB Staff, and other Research leadership staff.
Management's Response:	Given that UTSA has a customized set of human subjects protections program policies, procedures, forms, and guidance documents, the Assistant Vice President for Research Integrity will submit and implement a general HOP policy that states that UTSA will adhere to 45 CFR 46. The details about the human subjects protections program will continue to be outlined in internal documents and will be referenced in the new HOP policy.
Responsible Person:	Assistant Vice President for Research Integrity
Implementation Date:	August 31, 2016

Policy and SOP Updates Needed	As part of their review, WCGIRB Consulting provided boilerplate IRB Policies and Standard Operating Procedures (SOPs). The Policies and SOPs were adopted by UTSA.

The SOPs include boilerplate annual, monthly, and daily tasks performed by IRB Staff. Some of the tasks listed in the SOP on Monthly Tasks are not conducted monthly.

The Human Subjects Research Policies and SOPS contain boilerplate formatting. Specifically:

- Key terms are marked with brackets.
- Effective date fields on are not completed in policies and procedures and read as "dd MMM yyyy".
- UTSA headers were not noted for two IRB Standard Operating Procedures.

Observation:	The UTSA Policies and Standard Operating Procedures related to Human Subjects Research contain tasks that are not performed and formatting that is incomplete.
Risk:	IRB Staff and Research leadership staff may not comply with Policies and Standard Operating Procedures because they are not clear.
Management's Response:	➢ The outstanding monthly task on self-assessments has been implemented. All other routine tasks (annual, monthly, and daily) will be reviewed for consistency with current operations. Adjustments to operations or procedures will be made accordingly. ➢ All key terms marked with <> brackets and key generic terms marked with [] will be removed from all of the documents used by PIs that are found on the website. These documents will indicate that defined terms are located in policy. ➢ The use of titles, rather than individual's names, will continue to be utilized to ensure consistency even when staff turnover occurs. Thus, no changes will be made. ➢ All effective date fields will be completed in all IRB Policies and Standard Operating Procedures. ➢ UTSA headers will be included in the remaining two IRB Standard Operating Procedures.
Responsible Person:	Executive Director, Research Integrity
Implementation Date:	August 31, 2016

Audit Objective: Determine if researchers are educated about their duties and responsibilities to keep human subject data secure.

Data Confidentiality Requirements

Researchers are informed about human subject data security, both with personal identifiers and without personal identifiers, through:

- VPR Communication such as monthly newsletters,
- CITI training modules,
- IRB protocol forms and dialogue with IRB staff, and
- OIT website guidance and other OIT communication such as the Quick Reference Card for File and Data Storage.

OIT has standards for data classification, protection, and security since the risk of inadvertently disclosing data continually increases as technology enhancements increase.

Data on human subjects that contains personal identifiers is category I data which means the disclosure, destruction, display, or modification would violate state or federal laws or regulations, UT System policies, or the Texas Open Records Act. Category I data can only be stored on UTSA's secure network.

Data on human subjects that does not contain personal identifiers is category II/controlled data not otherwise protected as confidential data but is releasable with the Texas Public Information Act. At UTSA, the majority of the human subjects research data is anonymous and without sensitive or otherwise personal identifiable information. Category II data storage guidance allows more flexibility.

Audit Objective: Determine if researchers listed on human subjects research protocols complete required training prior to receiving approval to perform research.

Training

Our testing determined that researchers are appropriately completing training prior to receiving approval to perform research. Training areas include:

- Regulatory requirements and ethical standards,
- IRB processes including protocol submission procedures,
- Informed consent of subjects requirements,
- Record retention requirements, and
- Researchers' responsibility to keep data secure.

Audit Objective: Determine if the IRB has implemented Office of Human Research Protection (OHRP) conditional approval requirements outlined in the OHRP determination letter to UTSA dated February 23, 2016.

OHRP Determination Letter

On February 23, 2016, the HHS Office of Human Research Protections sent a letter to the UTSA Vice President of Research stating "the institution's Standard Operating Procedures does not distinguish between the two situations of:

1) An IRB approving research with conditions and having those conditions verified in some other way other than by the convened IRB, and
2) Tabling research due to required modification and having the modified research come back to the convened IRB for review and approval."

The Office of Research Integrity clarified the SOPs on Committee Review Conduct and Non-Committee Review Conduct to clearly articulate the degree of review required to clear a conditional approval by either the IRB Committee or IRB Staff. A review of the SOPs and a sample of committee minutes substantiated that the IRB complies with requirements from OHRP.

Audit Objective: Survey human subject researchers to collect IRB process strengths and weaknesses.

Survey Results

Over forty human subject researchers were surveyed to gather information on IRB process changes and improvement and data security guidance. Of the four surveys returned, the researchers were satisfied with the performance of the IRB. The survey responses were provided to the Assistant Vice President for Research Integrity.

CONCLUSION

In our opinion, the Office of Research Integrity and the Institutional Review Board has policies and standard operating procedures that address federal requirements and data security requirements, but include formatting that can be updated to better reflect current practices. Researchers obtain required training prior to receiving approval to perform research. The policies and standard operating procedures address requirements outlined in the February 23, 2016 OHRP determination letter. Limited survey responses indicated satisfaction with the performance of the IRB.

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This engagement was conducted in accordance with The Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

Appendix A - Human Subject Research Study Categories Definitions and Examples

- Full Board: Study under IRB purview that is reviewed and approved by the convened IRB Committee (full board). A full board study is *more than minimal* risk to subjects. The full board reviews and approves consent or a waiver of the documentation of consent for a full board study. A full board study requires continuing (usually annual) review by the full board until the study is closed, unless the full board determines that continuing review may be conducted by the IRB staff.

- Expedited: Study under IRB purview that is reviewed and approved by the IRB staff. An expedited study is *minimal* risk to subjects. An expedited study does not require review by the Full Board. The IRB staff reviews and approves consent or a waiver of the documentation of consent for an expedited study. An expedited study requires continuing (usually annual) review until the study is closed.

- Exempt Study: Study under IRB purview that is reviewed by the IRB staff. An exempt study does not require documentation of consent or annual review. Any revisions made to an exempt study must be reviewed by the IRB staff as long as the study is being conducted.

- Not regulated determination/research not involving humans: Study that is not under IRB purview that is reviewed by the IRB staff. A not regulated study requires no further review unless substantive changes are made to the research.

Table of Research Study Categories examples available at
http://research.utsa.edu/research-funding/human-subjects/

Non-Regulated Research	Research Not Involving Humans	Human Research Determined Exempt	Human Research Not Exempt but eligible for Expedited IRB Review	Human Research Not Exempt That must be reviewed by convened IRB
Submit to IRB for Determination	**Submit to IRB for Determination**	**Submit to IRB for Determination**	**Submit to IRB for Approval**	**Submit to IRB for Approval**
Examples: • Quality Improvement • Health Surveillance • Program Evaluation	**Examples:** • Only using leftover, de-identified specimens • Only using commercial cell lines • Data / specimens from a repository/databank de-identified datasets	**Examples:** • Extant data record review & not recording identifying information • anonymous surveys • comparing two educational methods • Interviews/Focus Groups where NO identifiable or sensitive data is collected	**Examples:** • Prospective data (future/not yet existing information) or data collection with identifiers. • non-invasive/minimal risk measurements or procedures • Surveys with identifiers or coding. • Interviews/Focus Groups where identifiable or sensitive data is collected	**Examples:** • All greater than minimal risk research • Any research use of radiation • Any research use of anesthesia • Any research using invasive procedures
Required documents	**Required documents**	**Required documents**	**Required documents**	**Required documents**
• Initial Review • Project description or Plan	• Initial Review • Project description or Plan	• Initial Review • Research Personnel form • Protocol • Information sheet	• Initial Review • Research Personnel form • Protocol • Consent	• Initial Review • Research Personnel form • Protocol • Consent