



TEXAS A&M
UNIVERSITY®

Human Research

Denise Puga

Human Research Protection Program

Human Research Protection Program (HRPP)



TEXAS A&M
UNIVERSITY

- The HRPP provides administrative support to the Texas A&M University and Texas A&M University College of Dentistry Institutional Review Boards (IRBs).
- IRBs are charged with protecting the rights and welfare of human research participants and ensuring that the criteria for approval are met, as defined by the federal regulations.
- The HRPP assists the research community by serving as a liaison between the IRB and the research community.
- IRB coordinators are assigned by department:
 - IRB coordinators work with researchers to ensure that their protocols are ready to be reviewed by the IRB
 - IRB coordinators also works with other compliance offices, as needed, to ensure that all applicable federal, state, and institutional requirements are met.
- The HRPP, IRBs, and the research community follow Standard Operating Procedures (SOP's) and use checklists, worksheets and templates to guide the design, conduct, review and approval of human research.



Texas A&M HRPP research policies and guidance apply to the following campuses:

- Texas A&M University
 - Including the Health Science Center and all its locations
- Texas A&M University - Galveston
- Texas A&M University - Qatar
- School of Law - Fort Worth

The Texas A&M IRB is the IRB of record for the following agencies:

- Texas A&M AgriLife Extension Service
- Texas A&M AgriLife Research
- Texas A&M Engineering Experiment Station (TEES)
- Texas A&M Engineering Extension Service (TEEX)
- Texas A&M Transportation Institute (TTI)

Tools to help determine if an activity is Human Research can be found in the IRB Policies & Procedures section of the IRB Web site : [Toolkit – Division of Research](#):

- WORKSHEET: Human Research Determination (HRP-310)
- SOP: Activities that Require IRB Review (HRP-093).
- The IRB makes the ultimate determination in all cases as to whether an activity constitutes Human Research subject.
- If you have questions about whether an activity is Human Research, contact the IRB Office who will provide assistance.
 - A written determination will be provided when the request is submitted through the electronic system (Huron).
 - **Determinations are not issued through emails or phone calls.**



Human Subject Research

Research

“a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(l)).

Humans Subjects

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (1) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or
- (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Three ways to involve humans in research

Intervention

using either physical or psychological procedures or manipulations of the subject or the subject's environment.

Interaction

through communication or interpersonal contact between the investigator and the subject.

Private Information

observing or recording behavior that is considered private or using private information that is identifiable.

Interventions



TEXAS A&M
UNIVERSITY®



Testing biomedical or behavioral processes:

drugs
dietary supplements
weight loss strategies
performance strategies
behavioral therapies and testing
cognitive therapies and testing
treatment or prevention strategies



Testing new or revised educational or instructional methods:

students or teachers in classrooms
children or adults in special programs or general public



Human factors evaluation – human experience with:

Equipment
Systems
Technologies



Interaction

Face to face, phone, remote or online communications for:
focus groups
interviews
surveys

Private Information

Obtaining identifiable data from:
medical records
student records
research records
data repositories
observations/monitoring

Obtaining identifiable human biospecimens (blood or tissue):
directly from humans,
established repositories,
secondary use

Red Flags: Human Subjects



TEXAS A&M
UNIVERSITY

- clinical investigations (therapeutic or non-therapeutic)
- classroom research conducted by faculty
- interviews and focus groups about human experiences, opinions, behaviors, learning, needs
- surveys about human experiences, opinions, behaviors, learning, needs
- identifiable data or records
- identifiable human biological specimens
- innovative or novel procedures, treatment, or instructional methods that will be generalized
- internet research involving humans or their private information
- human factors evaluation
- in vitro device studies
- case report studies OF 3 or more
- pilot studies involving humans
- professional recognition through research collaborations
- program evaluation and quality improvement activities that will be generalized
- self-experimentation
- student research, thesis or dissertation that involves humans in one of the above activities

Submit for IRB review



TEXAS A&M
UNIVERSITY

Protocol



Supporting Documents



Identify project PI

Student may not serve as PI



Complete online CITI training



Submit online IRB application via **Huron**



1

Approved

STUDY2023-0001: IRB_COI test study

Entered IRB: 12/10/2023 10:57 AM
Initial approval: 12/10/2023
Initial effective: 12/10/2023
Effective: 10/24/2024
Last updated: 11/10/2024 1:00 AM

Principal investigator: Denise Puga
Submission type: Initial Study
Primary contact: Denise Puga
PI proxies:

IRB office:
IRB coordinator:
Letter:

IRB - TAMU CS
Heather Cline
[Correspondence_for_STUDY2023-0001.pdf\(0.01\)](#) ...

Regulatory authority: 2018 Requirements

PI Department: Research Compliance & Biosafety

3

Next Steps

- [View Study](#)
- [Printer Version](#)
- [Create Modification/CR](#)
- [Report New Information](#)

2



4

5

- [History](#)
- [Funding](#)
- [Contacts](#)
- [COI](#)
- [Documents](#)
- [Sites](#)
- [Follow-on Submissions](#)
- [Reviews](#)
- [...](#)

- 1. Status of Study
- 2. Study Workflow
- 3 View Full Application
- 4. Funding
- 5. Study Documents (including protocol)



ATM | TEXAS A&M UNIVERSITY

Validate Compare

You Are Here: Taboo

Editing: STUDY2024-0822

Go to forms menu

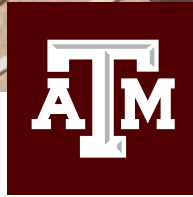
Study Funding Sources ?

1. Maestro Funding Source:

M

ID	Project Title
M2500372	** AGRILIFE NON-SPONSORED ** Intrasystem Agreement with Texas A&M Forest Service
M2500432	ReDDDoT Phase 2: Responsible Multi-Modal AI Systems for Multi-Hazard Resilience and Situational Awareness
M2500498	Sub w Tufts University - Advancing Cellular Agriculture Through Gut Microbial Communities Fermentation
M2500499	** AGRILIFE NON-SPONSORED ** Incoming MTA with University of Dundee
M2500500	Sub w/PVAMU -Transformation of Undergraduate Education in Construction Science Through Serious Simulation Game
M2500501	Canine Chagas Disease Prevalence, Prevention, & Operational Capability Protection Study
M2500502	GIS and Natural Resources Support for U.S. Army Environmental Command
M2500503	** AGRILIFE NON-SPONSORED ** Service Agreement with UNC Chapel Hill
M2500504	TO: Hawthorne Army Depot Integrated Natural and Cultural Resources Plan Update and Support U.S. Army Environmen

1. Study Funding Source page (contains funding information and funding documents)
2. Maestro Funding Source (pulls project M number from Maestro)



Thank you

