IRB Red Flags

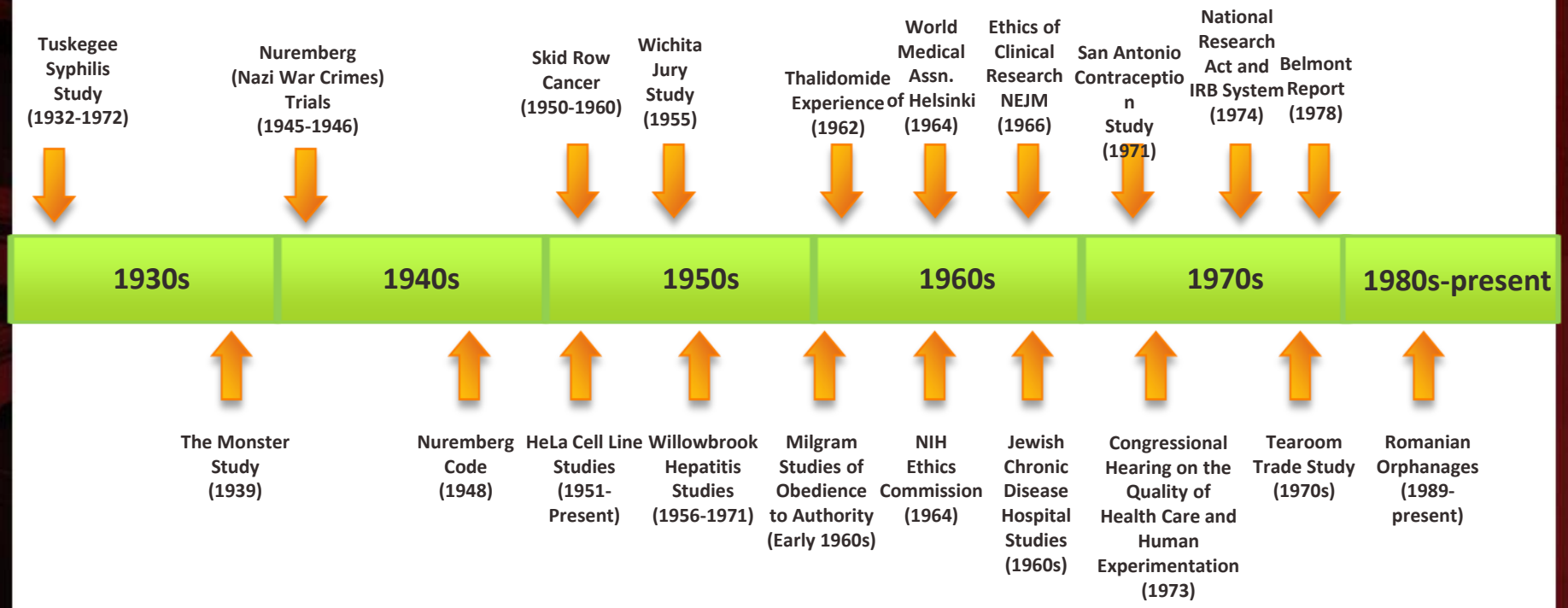
How to Know When IRB Review May Be Needed

Human Research Protection Program

Presented by
Catherine Higgins, Ph.D., CIP, CIM
HRPP Director

TEXAS A&M UNIVERSITY

Historical Ethical Atrocities



Resulting Key Concepts

Voluntary consent

Freedom from coercion

Comprehension of risks/benefits

Minimization of risk and harm

Qualified investigators

Appropriate research design

Freedom of subjects to withdraw

Favorable risk/benefit ratio

Basic Ethical Principles

- Respect for Persons
  - autonomy of subject
- Beneficence
  - benefits outweigh risks
- Justice
  - selection of subjects is equitable

Where We Are Today

- Federal Regulations
  - "The Common Rule" – June 18, 1991
  - 45 CFR 46 – Basic Department of Health and Human Services Policy for Protections of Human Research Subjects
    - Definitions of Research and of Human Subjects
    - Criteria for review of Human Subjects Research

Additional Regulations

- Special considerations for research funded or regulated by:
  - Agency for International Development
  - Department of Agriculture
  - Department of Commerce
  - Consumer Product Safety Commission
  - Department of Defense
  - Department of Education
  - Department of Energy
  - Environmental Protection Agency
  - Food and Drug Administration
  - Department of Health and Human Services
  - Department of Housing and Urban Development
  - Department of Justice
  - National Aeronautics and Space Administration
  - National Science Foundation
  - Department of Transportation
  - Department of Veterans Affairs

Is it Research?

- The federal regulations define research as:
  - “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45CFR46.102(d)).

- As described in the Belmont Report:
  - “...the term ‘research’ designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”
  - Data must be generated and analysis of the data should occur.

Is It a Human Subject?

- A human subject is defined by Federal Regulations as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46.102(f)(1),(2))
  - Intervention includes physical/psychological procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.

Where We Are Today

- Institutional Role
  - Institutions that “engage” in human subjects research conducted or supported by HHS must sign a written assurance committing them to compliance with HHS regulations.
  - Research conducted (1) by or using Texas A&M faculty, staff, and/or students and/or (2) on Texas A&M property must be reviewed by the TAMU IRB.
  - TAMU HRPP involves all human subjects research.
  - We work collaboratively with other IRBs.

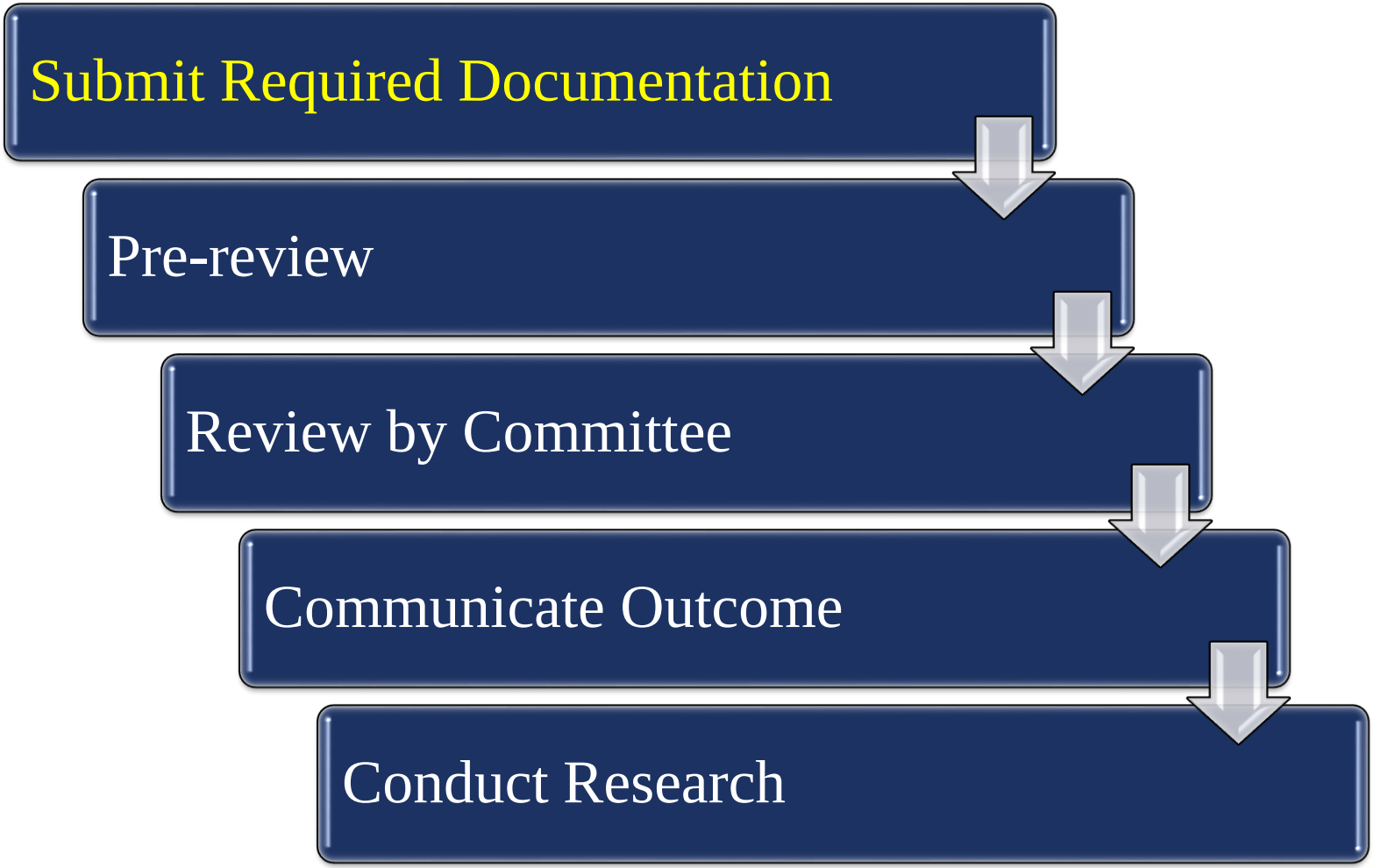
Intrasystem Agreements

- TAMU IRB reviews for:
  - Texas A&M University
    - Galveston
    - Qatar
  - Texas A&M University Health Science Center
  - Texas A&M Transportation Institute
  - Texas A&M AgriLife Extension Service
  - Texas A&M AgriLife Research
  - Texas A&M Engineering Experiment Station
  - Texas A&M Engineering Extension Service
- BCD IRB reviews only BCD studies.

Training

- CITI Training
  - Must be renewed every five years
  - Web-based ethics course
  - All study personnel must complete CITI training with a minimum score of 90 percent.
  - www.citiprogram.org
  - More information available at: http://rcb.tamu.edu/humansubjects/training
- Alternative Training
  - Possible for special circumstances
  - Guidance available on the website: http://vpr.tamu.edu/compliance/rcc/irb/irb-guidance/Alternativetrainingforspecialcircumstances.pdf

Submission Process for Research with Human Subjects

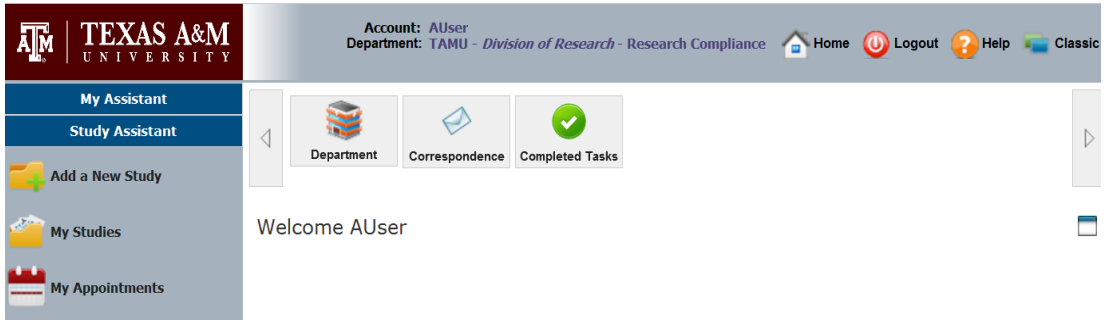


Why?: The Submission Process

- Purpose: To gain approval to conduct research involving human subjects
- Goal: To protect the rights and welfare of research subjects
- Perspective: From the viewpoint of the human subject

How to Submit Your Project

- Online system – iRIS
  http://imedris.tamu.edu
- Information
  –Help line (979.845.4969)
  –HELP button
  –FAQs on the website:
  http://rcb.tamu.edu/humansubjects/faqhumansubjects



Submission Process for Research with Human Subjects

Liaison Assignments

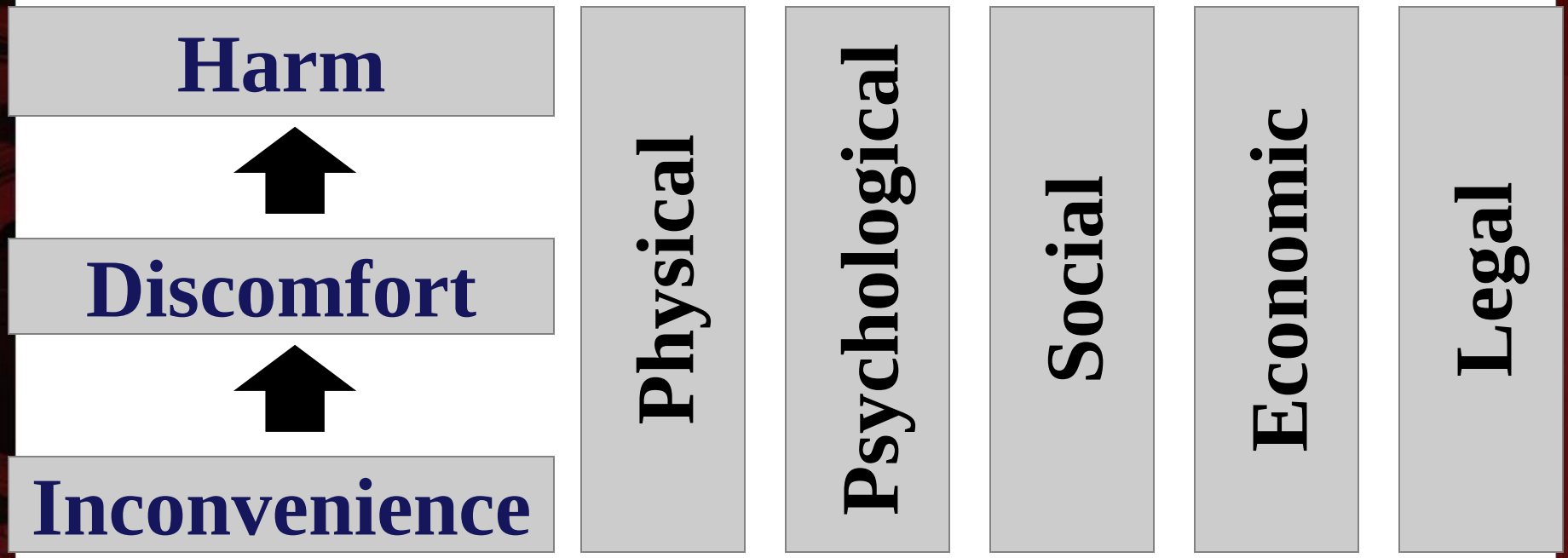
Liaison	Email	Telephone	Assigned Areas
Ms. Amy Donnellan	adonnellan@tamu.edu	979.862.3653	AgriLife Extension Service
			AgriLife Research
			College of Agriculture and Life Sciences
			Department of Teaching, Learning and Culture
Alternate: Ms. Jennifer Rau-Hug			College of Veterinary Medicine & Biomedical Sciences
Dr. Denise Puga	denisepuga@tamu.edu	979.458.5590	College of Education & Human Development (except HLKN, TLAC)
Alternate: Mr. Graeme Wright			Department of Psychology
Ms. Jennifer Rau-Hug	jenniferhug@tamu.edu	979.845.7037	Bush School
			College of Geosciences
			College of Science
			Department of Health and Kinesiology
			Health Science Center
Alternate: Dr. Denise Puga			Mays Business School
Mr. Graeme Wright	graemewright@tamu.edu	979.862.4681	Baylor College of Dentistry (alternate Jennifer Rau-Hug)
			College of Architecture
			College of Liberal Arts (except Psychology)
			Dwight Look College of Engineering
			Other areas
			School of Law
			Texas A&M Galveston
			Texas A&M Qatar
			Texas A&M Engineering Experiment Station
			Texas A&M Engineering Extension Service
Alternate: Ms. Amy Donnellan			Texas A&M Transportation Institute
Dr. James Fluckey, TAMU IRB Chair	jfluckey@hlkn.tamu.edu	979.458.4067	
Dr. Emet Schneiderman, BCD IRB Chair	emet@bcd.tamhsc.edu	214.828.8377	
Dr. Catherine Higgins, HRPP Director	clhiggins@tamu.edu	979.458.4117	

Submission Process for Research with Human Subjects

Eight Ethical Assessment Criteria

- Risks are minimized
- Risks are reasonable vs. benefits
- Selection is equitable
- Informed Consent is obtained
- Participation is voluntary
- Data and Safety are protected/monitored
- Privacy and confidentiality are upheld
- Vulnerable population protections are enhanced

Types of Risks



Categories of IRB Review

EXEMPT	EXPEDITED	FULL BOARD
• No/minimal risk • Existing data • 5-year continuation • HRPP staff	• Minimal risk • Prospective data • Annual continuing review • Single IRB member	• Greater than minimal risk • Annual continuing review • Review by two IRB members then IRB

Vulnerable Populations

- Additional safeguards must be implemented for populations in which research may pose additional and/or unknown risks.
- For example
  - Pregnant Women, Human Fetuses, and Neonates
  - Prisoners
  - Children
  - Economically disadvantaged
  - Socially disadvantaged
  - Educationally disadvantaged
  - Cognitively impaired
  - Disabled

How Is the Category Determined?

- The IRB chair or designated reviewer will make the regulatory determination.
- The project methodology and administration can play a role in determining the category.
  - Choices can raise/lower risk to subjects

Criteria For Exempt Research

- Research conducted in established educational settings
- Use of educational tests, surveys, observation unless:
  - Information is recorded so that subjects can be identified
  - Responses could place the subjects at risk of liability or be damaging
- Use of educational tests that is not exempt if:
  - Subjects are public officials or candidates for office
  - Federal statutes require confidentiality be maintained throughout the research and thereafter

Criteria For Exempt Research

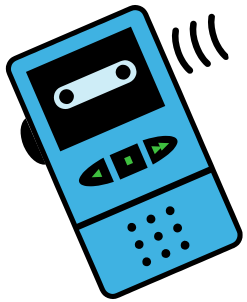
- Research involving collection of existing data if these sources are publicly available or de-identified
- Research and demonstration projects, conducted by the approval of department or agency heads, which are designed to examine:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services
  - Possible changes to those programs
  - Possible changes in methods of payments for benefits or services
  - Project must be conducted pursuant to specific federal statutory authority
  - Must be no statutory requirement that the project is reviewed by an IRB
  - Must not involve significant physical invasions upon the privacy of participants
  - The exemptions should have authorization of concurrence by the funding agency
- Taste and food quality evaluation studies

Criteria for Expedited Review

- Clinical studies of drugs and medical devices for which IND or IDE applications are not required
- Collection of blood samples (with specific parameters)
- Prospective collections of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures routinely employed in clinical practice (excluding X-ray and microwave).
- Materials collected or to be collected solely for non-research purposes

Criteria for Expedited Review

- Collection of data recordings (voice, digital, etc.)
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.



Full Board Operations

- Meetings first Wednesday of the month
- Protocols must be through pre-review a week prior to meeting
- Meetings are closed but PI or study personnel should be available
  - Phone
  - In-person
- Communicate outcome by Friday after meeting

Submission Process for Research with Human Subjects

Possible Outcomes

- Can be expected by the end of business the Friday after an IRB meeting
- Additional Revisions
  - Reviewers may request additional revisions.
  - Revisions may breed the need for more revisions or clarification.
- Review Status
  - The review status available in submission tracking in iRIS. Your liaison rarely knows more about the review status than iRIS knows.
  - Reviewers are allowed at least two weeks to review.
  - Deferred, pending, disapproved
- Approval

Modified IRB Approval

- Sponsor request
  - At proposal submission
  - To release funds to institution
- SRS to release funds and initial aims do not apply to human subjects research
- Multi-institutional studies/subcontracts in which TAMU investigators are not PI

Submission Process for Research with Human Subjects

Approval

- How will I know when I can begin?
  - Official approval letter sent through iRIS
  - Use stamped recruitment documents
  - Keep careful track of participation as appropriate for your study

Am I Done?

- Not quite!
  - Keep HRPP informed and study documents current
    - Submit any desired project changes as Amendments
    - Submit any new documents (such as grant approval) or provisions
    - Yearly Continuing Review for Expedited and Full Board projects (exempt – five years)
    - Report any adverse events or deviations
    - Submit a completion report when all study procedures **and** data analysis are complete

Red Flags List

- human samples, cells, tissues;
- research on education instructional strategies;
- research on involving normal educational practices;
- research involving educational tests, surveys, interviews, observation of public behavior;
- research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;
- research and demonstration projects designed to study, evaluate, examine public benefit or service programs;
- taste and food quality evaluation;
- consumer acceptance studies;
- research on drugs;
- research on medical devices;
- collection of blood samples;
- collection of biological specimens;
- collection of data routinely employed in clinical practice;

Red Flags List (continued)

- x-ray;
- microwave;
- collection of data from voice, video, digital, or image recordings made for research purposes;
- research on individual or group characteristics or behavior;
- research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior;
- survey;
- interview;
- oral history;
- focus group;
- program evaluation;
- human factors evaluation;
- quality assurance methodologies

Potential Consequences of Noncompliance

- Suspend and/or terminate study
- Loss of funding
- Letter of apology
- Re-training

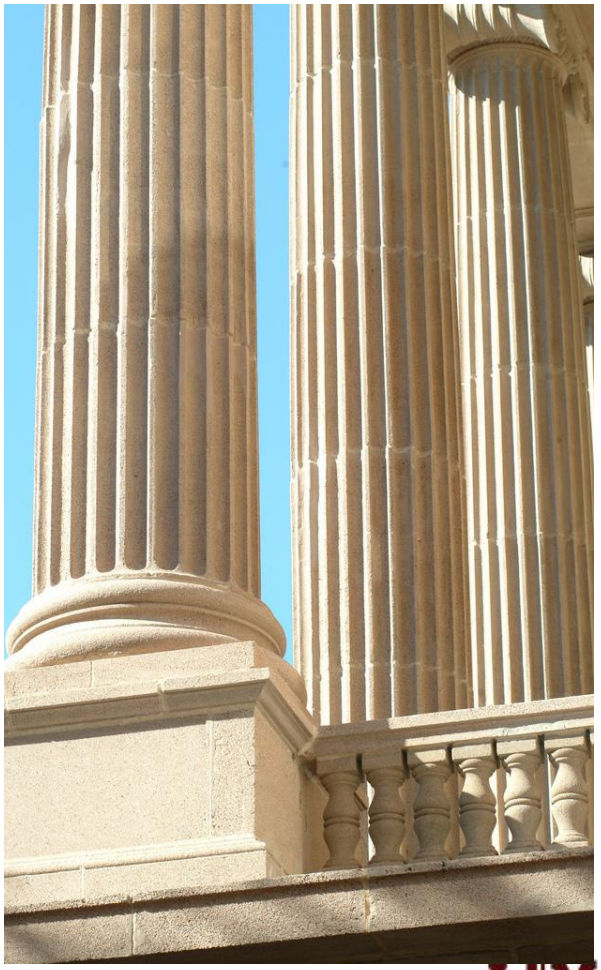
Prevent Common Deviations

- Unapproved consenting process
- Failure to provide signed consents to subjects
- Data collection prior to obtaining consent
- Consent translations
- Expired or incorrect consents
- Unapproved persons obtaining consent
- Over-enrollment (evaluable subjects vs. consented subjects)
- HIPAA documentation
- Missing laboratory values and clinical assessments
- Altering protocol procedures without IRB approval
- Time to retain documents are three to seven years after completion of study

Questions?

Human Subjects in Research

- Website:
  - http://rcb.tamu.edu/humansubjects
- Phone:
  - 979.458.4067



Questions?

HRPP Director

Catherine Higgins
clhiggins@tamu.edu
979.458.4117

TAMU IRB Liaisons

Amy Donnellan
adonnellan@tamu.edu
979.862.3653

Denis Puga
denisepuga@tamu.edu
979.458.5590

Jennifer Rau-Hug
jenniferhug@tamu.edu
979.865.7037

Graeme Wright
graemewright@tamu.edu
979.862-4681

iRIS Support Team

outreachrcb@tamu.edu
979.845.4969

Resources


http://rcb.tamu.edu/humansubjects/resources
Institutional Review Board — D...
Resources for Human Subje...
Research Compliance & Biosafety
TEXAS A&M UNIVERSITY
Animals
Biohazards
Humans
Biosafety Occupational Health
Export Controls
iRIS Portal
Resources for Human Subjects Research
Information for Investigators
Certificate of Confidentiality
Conflict of Interest Information
Consent Information
FAQ
Glossary of Terms
HRPP Outreach Sessions - WebEx
Investigator Self-Assessment Checklist for Human Subjects Research (PDF)
IRB Classroom Guidance and Checklist
Participant Feedback Form (for researchers and IRB)
Payment of Survey and Research Participants SAP
Protection of Pupil Rights Amendment (PPRA)
Recruitment
Responsibilities for Investigators
Rules for FERPA in Research
Study Personnel Attestation text
Submission Deadlines for IRB Meetings
U.S. Food and Drug Administration
Food
Drugs
Medical Devices
Vaccines, Blood, and Biologics
Center for Biologics Evaluation and Research (CBER): Development and Approval Process
Investigational New Drug/Investigational Device Exemption Information
Texas A&M Information for Human Subjects in Research
Human Subjects in Research
iRIS Login
Approval Process
FAQ
Forms
Participant Information
Resources
Roles and Responsibilities
Training
University Statement on Human Subjects Research
Search Site
Search
Quick Links
ABOUT
tamu.edu/h