AnSRS4U

Guidance on Minimizing Delays

Human Research Protection Program

Institutional Review Board

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Director

TEXAS A&M UNIVERSITY

Numerous Regulations and Ethical Guidelines

- Belmont Report – Autonomy, Beneficence, Justice
- **45 CFR 46 – OHRP Common Rule**
- 45 CFR 160 and 164 – HIPAA
- 42 CFR 50 – Conflicts of Interest
- 21 CFR 50 – FDA (Human Protections)
- 21 CFR 56 – FDA (IRBs)
- 34 CFR 99 – FERPA
- 34 CFR 98 – PPRA
- Funding Agency Rules
- TAMU SAPs and Rules
- HRPP/IRB SOPs

Federal Agencies and Departments Adopting the Common Rule (45 CFR 46)

1	Department of Homeland Security
2	Department of Agriculture
3	Department of Energy
4	National Aeronautics and Space Administration
5	Department of Commerce
6	Social Security Administration
7	Agency for International Development
8	Department of Housing and Urban Development
9	Department of Justice (still under old Common Rule)
10	Department of Labor
11	Department of Defense
12	Department of Education
13	Department of Veterans Affairs
14	Environmental Protection Agency
15	Department of Health and Human Services
16	National Science Foundation
17	Department of Transportation
18	Office of the Director of National Intelligence
19	Central Intelligence Agency
20	Consumer Product Safety Commission

OHRP
Office for Human Research Protections

What is the authority given to the IRB under the Common Rule?

- *Approve research*
- *Disapprove research*
- *Require changes to research*
- *Suspend research*
- *Terminate research*
- *Observe (audit) research*

Does the IRB have authority over funding?

- The IRB does not make policies on when or how funding is obtained or released.
- The IRB requires that no human subjects activities take place prior to IRB review and approval.
- The institution or the funding agency controls when funding is released.
- This is *generally* after the investigator obtains IRB approval.
- The IRB does have the authority to make a ‘Delayed Onset’ determination under 45 CFR 46.118

Delayed Onset

45 CFR 46.118 - Applications and proposals lacking definite plans for involvement of human subjects.

- 46.118 determinations can be granted to satisfy federal sponsor requirements (e.g., Just- In-Time) to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Human subject research activities cannot begin until a full application and all applicable material (e.g., consents, surveys, tools)
- Definite plans involving human subjects are not set forth in the application or proposal. These can fall under three categories:
  1) institutional type grants when selection of specific projects is the institution's responsibility;
  2) research training grants in which the activities involving subjects remain to be selected; and,
  3) *projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.
- *Research instruments refers to measurement devices and can include surveys, tests, questionnaires, etc.
- Procrastination and poor planning are not appropriate reasons for a delayed onset determination.

Grant Application

IRB Application

What about Congruency Requirements?

- The old Common Rule required the IRB to review and approve federal grant applications in addition to the IRB application for congruency.
- The revised 2018 Common Rule removed this requirement for the IRB.
- Institution's are responsible for congruency due to the widespread use of external IRBs.
- It is our practice at the TAMU IRB to still take a look at the grant to ensure the objectives and activities involving humans match the IRB application.
- In most cases a PI cannot just choose from existing IRB studies to support a grant.
- Generally, a new grant needs a new IRB application.

Q: When is IRB Review is Required?

A: When an Institution is *engaged* in Human Subjects Research

Three ways to involve Humans in Research

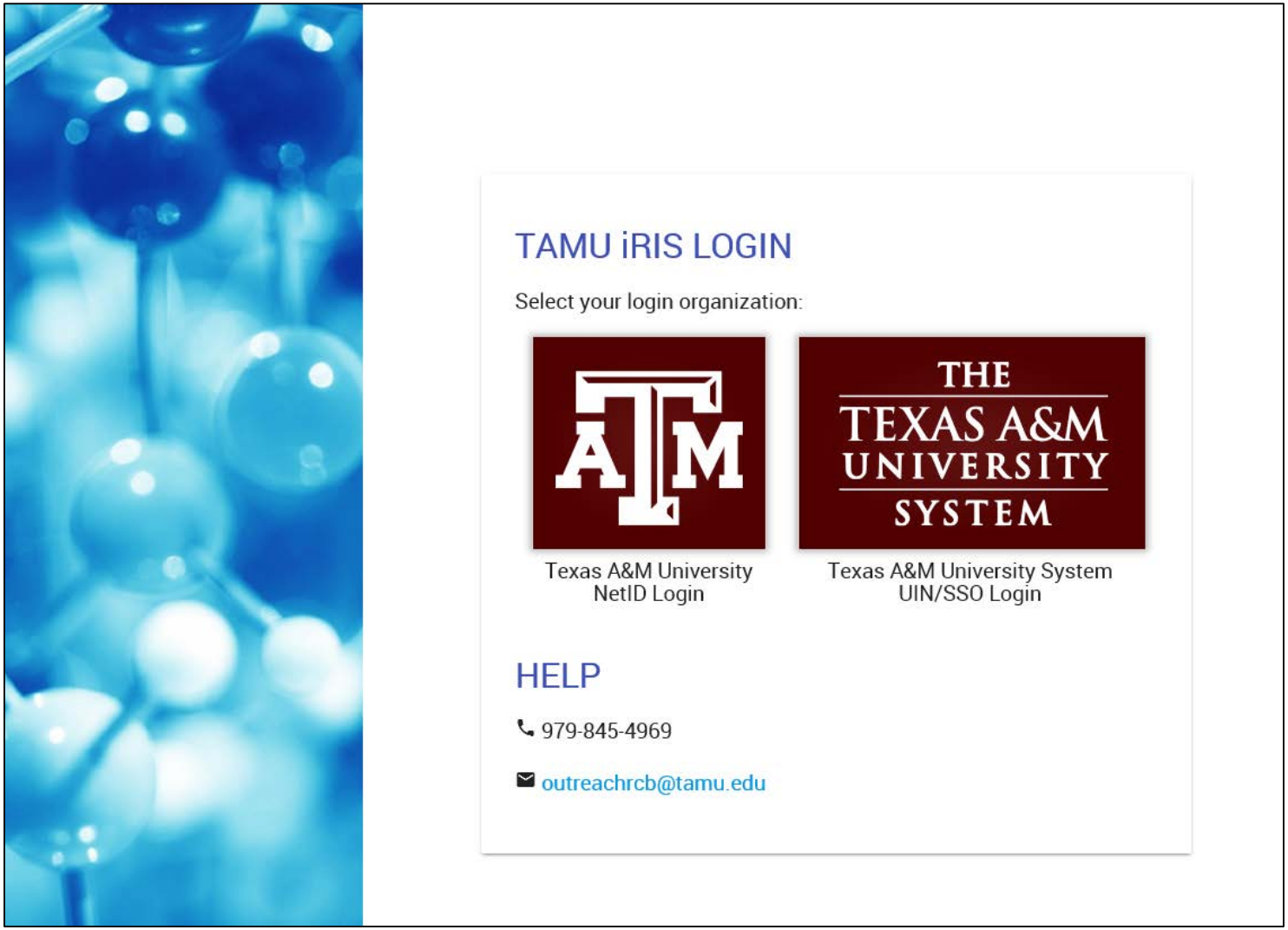
Intervention	***Interaction***	***Private Information***
using either physical or psychological procedures or manipulations of the subject or the subject's environment.	through communication or interpersonal contact between the investigator and the subject.	observing or recording behavior that is considered private or using private information that is identifiable.

Comprehensive list of activities found in SOP HRP-093 on HRPP website

TEXAS A&M UNIVERSITY	SOP: Activities that Require IRB Review		
	NUMBER	DATE	PAGE
	HRP-093	1/21/2019	Page **1** of **1**

- HRP - 093 contains a table of the types of common activities carried out as research.
- Each activity has a description and a directive as to whether or not investigators are required to submit the activity to the IRB.
- When there is any question about whether or not an activity is human research, the investigator it to send a request to the IRB for a determination through iRIS.

Online system – iRIS http://iris.tamu.edu



Request a Determination

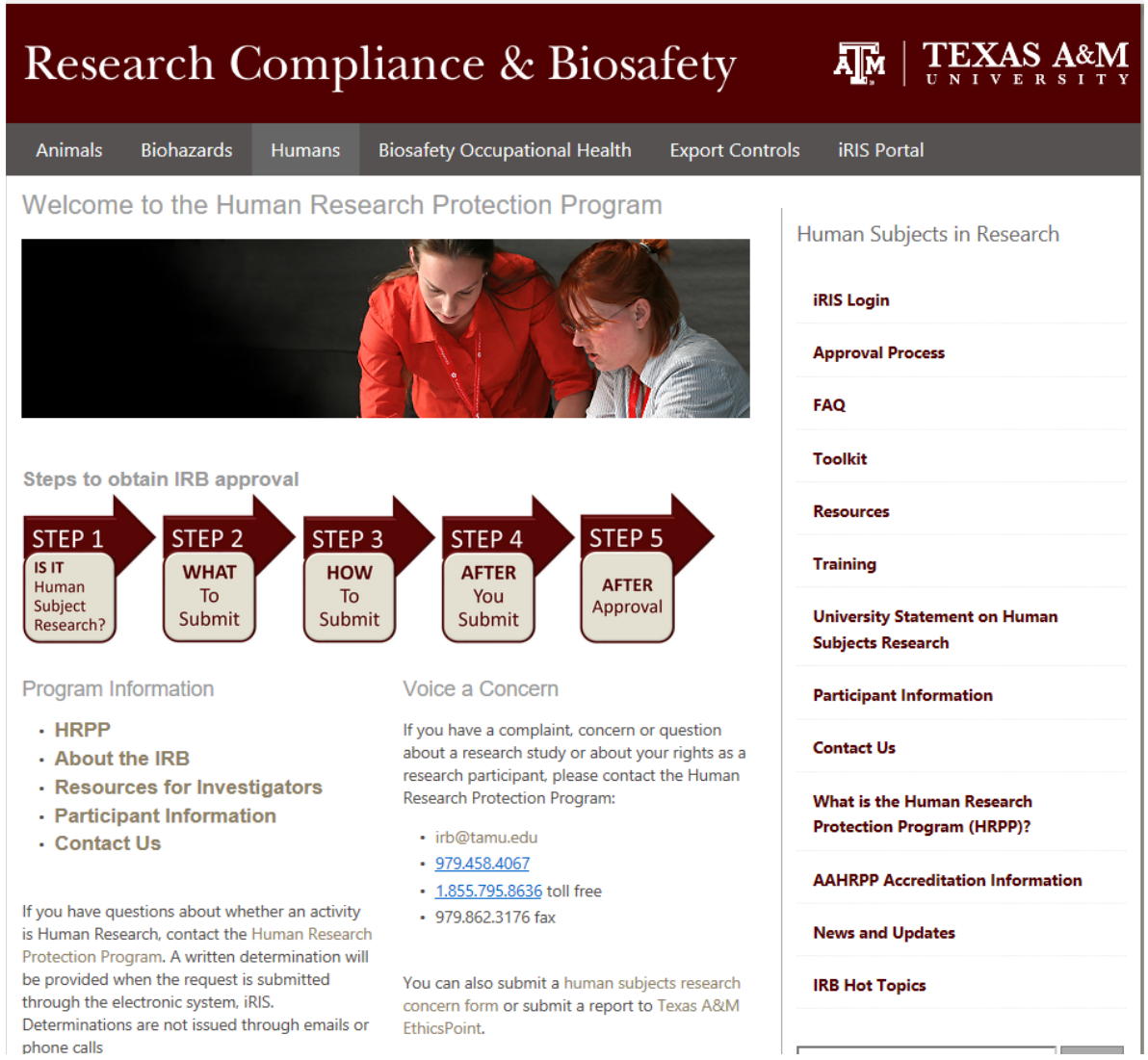
- Work-flows were implemented in iRIS in an effort to improve consistency and generate reliable records without unnecessarily increasing the burden to investigators.
- The following three areas have a truncated application that requires a reduced amount of input compared to the standard iRIS application for human subjects research.
- Choose this option in section 4 of the iRIS application to request a determination about whether or not an activity requires IRB review.

Human Subject's Determination:
Does my project involve human subjects research?

Delayed Onset Determination (45 cfr 46.118) Request for delayed onset of human subjects research in funded studies, only.

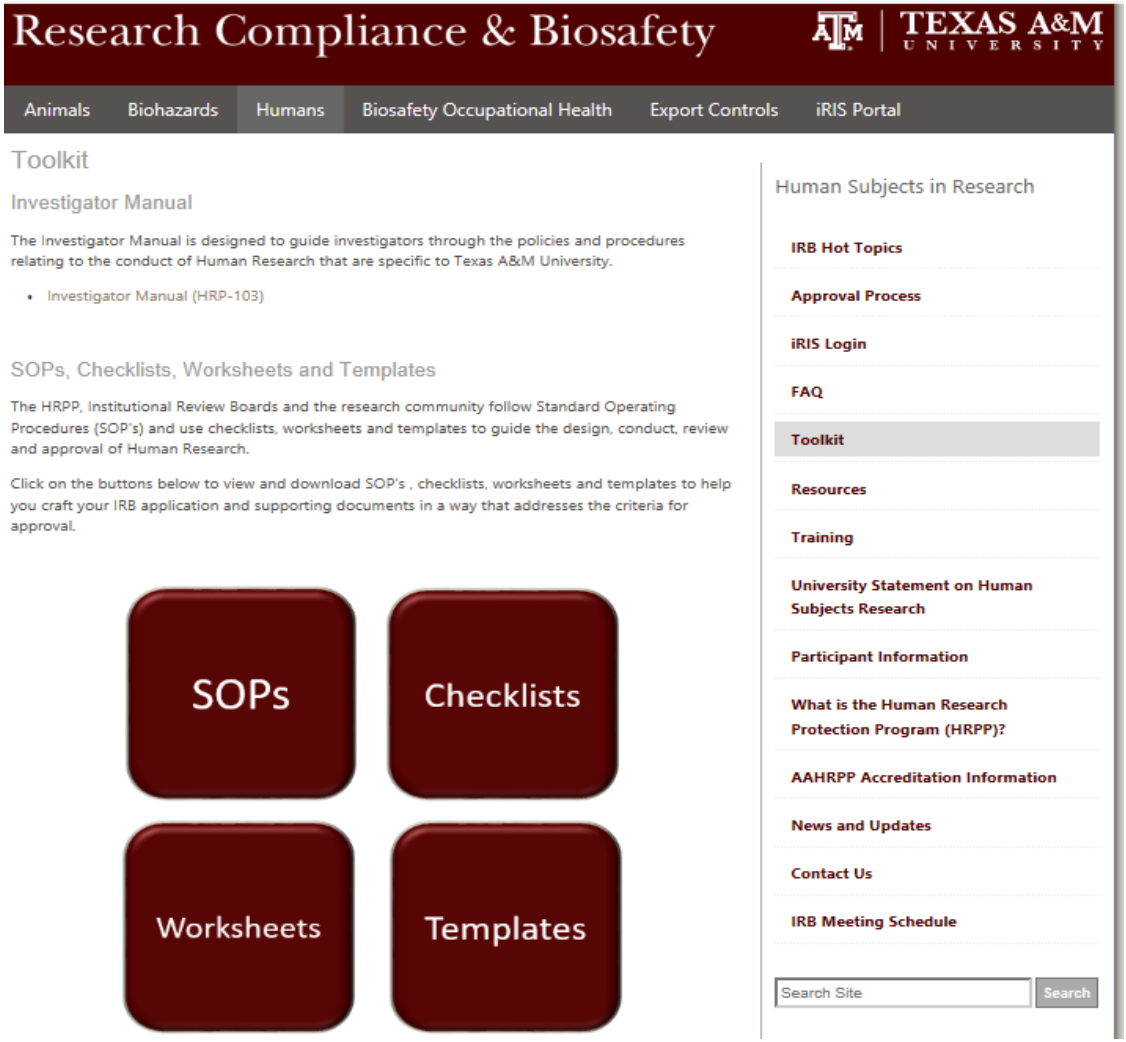
External IRB Review: Deferral to an external IRB that is not part of TAMU. (Limited circumstances)

rcb.tamu.edu/humansubjects



Tools for Following the Rules

http://rcb.tamu.edu/humansubjects/forms



Helpful Information to Minimize Delays

- Prepare early:
  - Do not wait until notice of funding is received or a deadline is close before starting the IRB application.
  - Make sure all members of research team have completed the required modules in CITI and Traintraq.
- Know that collaborating with external researchers may require an agreement. This is determined by research administration.
- Know that carrying out the research at another institution or using an external IRB has additional requirements and the TAMU IRB must be notified.
- Know that receipt or disclosure of data or specimens may require Data Use or Material Transfer Agreements.
- Know ancillary approvals are needed: (FERPA, Export Controls, IBC, IACUC, Radiation Safety, Information Technology)

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TEXAS A&M UNIVERSITY
Division of Research

Research Road Map: Human Research

Research often involves specialized review by ancillary groups outside the IRB. This tool provides examples of some ancillary reviews that may be required before research can begin. ***Hover or click text within the tool for more information.*** *Ancillary reviews, if required, should be initiated by the PI in parallel with PI's IRB submission. Requests for ancillary reviews should be directed to the applicable ancillary group.*

Planning and Proposing Human Research*

Seeking Ancillary Approval(s) related to Human Research

Involves international collaborator/activity? (No / Yes/Unsure)	→	**Export Controls Review/Determination***	In Process / Complete / N/A
Involves use of animals, biohazardous material, or TAMU student information? (No / Yes/Unsure)	→	**IBC*, IACUC*, and/or Registrar* Approval**	In Process / Complete / N/A
Involves use of chemicals, lasers, physical hazards, or radiological material? (No / Yes/Unsure)	→	**Radiation Safety Committee License*** and/or **Environmental Health & Safety Review***	In Process / Complete / N/A
Conflict of interest disclosure current for funded research? (Yes/N/A / No/Unsure)	→	**Submit Conflict of Interest Disclosure***	In process / Complete / N/A
Involves collaboration with external entity or transfer of tangible material? (No / Yes/Unsure)	→	**Determine Need for MOU, MTA, DUA, CDA, contract or other agreement***	In process / Complete / N/A

Develop Plan to protect Privacy/Confidentiality of Incoming and Outgoing Data/Information

↓

Use the Research Resources Tool (CAS authentication required) to Determine:

- **1) Data Classification of your data or research***
- **2) Available Platforms, Storage, and Compute Environments at TAMU***

Complete / In Progress

↓

Determine Need for/Adequacy of Agreement for Access/Use/Transfer* — In Process / Complete / N/A

Required if PHI/PII involved*

Seeking IRB Approval to Conduct Human Research*

Submit an online application in iRIS* to conduct human research

↓

Include a description of the Plan to protect Privacy/Confidentiality of Data/Information and identify Ancillary Approvals obtained or requested

↓

IRB Approval/Determination (may be contingent upon ancillary approvals involving PHI/PII)

Complete / Inprogress

Click link for additional information*

Helpful Information to Minimize Delays

- Use the current consent and protocol templates posted on the HRPP website: http://rcb.tamu.edu/humansubjects/forms/templates
  - ➢ Do not copy information from old templates.
- Be thorough – the **completeness** of the application is directly related to turnaround time.

Participant Materials

- Recruitment materials
  - Flyers, emails, Ads
- Consent Documents
- HIPAA Authorization
- Data Collection Instruments, surveys
- Participant Instructions
- Anything else the participant will see

Administrative Materials

- Written Protocol or Proposal
- Grants, Contracts, Agreements, DUA, MTA
- Translation Documents
- Site Authorizations
- Labels and brochures for items used by subjects:
  - drugs,
  - devices,
  - equipment

Do not hesitate to contact the HRPP staff for help.

TAMU HRPP/IRB Policy

TAMU 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 TAMU IRB is the IRB of record for the following agencies:

- **AgriLife**
- **AgriLife Extension**
- **TEES**
- **TEEX**
- **TTI**

HRPP/IRB Contact Information

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Go to https://rcb.tamu.edu/humansubjects to see departmental assignments.

Polling Questions:

Multiple choice questions may have more than one correct answer.

1) **The Common Rule gives the IRB the authority to:**
   a) Terminate investigators
   b) Confiscate research funds
   c) Require changes to research
   d) Edit research publications

2) **The IRB can make a delayed onset determination when:**
   a) The researcher is on vacation and cannot submit an IRB application
   b) The grant application indicates that human subjects activities will not begin until a later phase of the project.
   c) The researcher must complete instrument designs prior to involving human subjects
   d) Anytime an investigator requests a delayed onset

3) **The TAMU IRB does not need to be notified when all the research activities will take place at a Houston medical center that has an IRB.**
   a) True b) False

4) **The IRB determines when collaboration agreements are needed.**
   a) True b) False

Answer Key

1) c
2) b and c
3) False
4) False

Questions?