



## Office of Research Compliance

- Institutional Animal Care & Use Committee (IACUC)
  - Research and teaching activities involving vertebrate animal subjects
- Institutional Biosafety Committee (IBC)
  - Research, teaching, or testing activities involving biohazardous materials
- Institutional Research Board (IRB)
  - Research activities involving human subjects

## ORC Committees

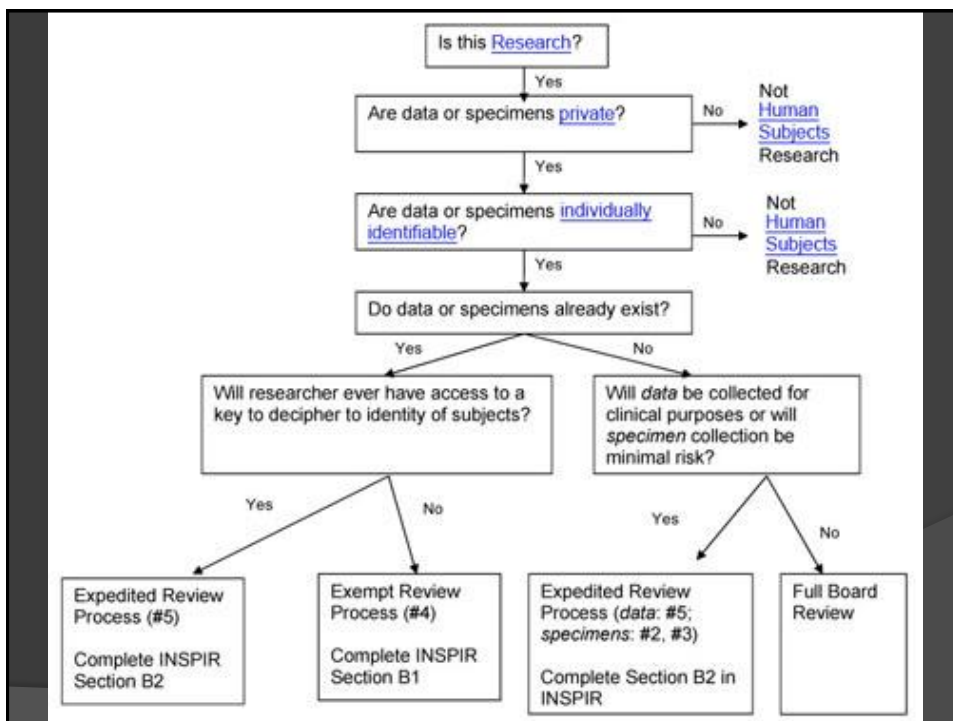
- Each committee (IRB, IBC, and IACUC) is composed of scientists, non-scientists, and community members.
  - IACUC must also have a veterinarian as a member
- TAMUCC IRB has 3 faculty members from each College represented, plus community members

## What is a Human Subject?

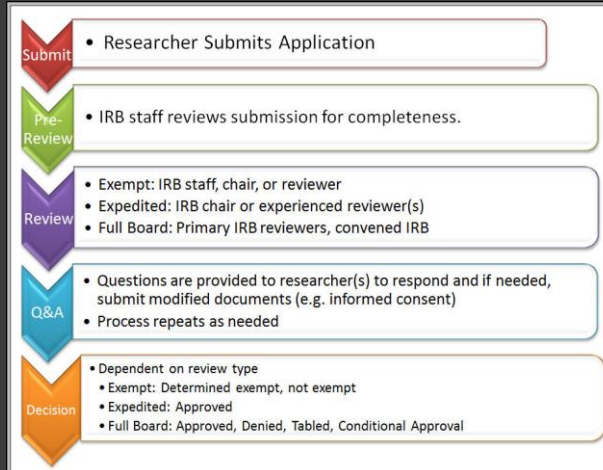
- Human Subject – a living person about whom an investigator conducting research obtains
  - data through an intervention or interaction with the individual, or
  - identifiable private information

# What is Research?

- Definition of Human Subject Research (45 CFR 46.102[d] and [f])
  - Research – a systematic investigation including research development, testing and evaluation, designed to contribute to generalizable knowledge



# IRB Process Simplified



# IRB Review Levels

- Exempt Review:
  - Lowest risk to human subjects
  - Anonymous or publicly-available data
  - Least potentially-harmful experiments
- Expedited Review:
  - Minimal risk to human subjects
  - Not anonymous
  - Requires informed consent/letter of support
- Full Review:
  - Greater than minimal risk to human subjects
  - Can include: non-exempt research involving children, vulnerable populations, experimental drugs or devices, invasive procedures, or sensitive questions about sexual practices or illegal behavior

## Investigator Training

- ⦿ Complete the required human subjects training before submitting to the IRB.
  - CITI Program – <http://www.citiprogram.org>
    - Social & Behavioral Responsible Conduct of Research - Basic Course
    - Biomedical Responsible Conduct of Research - Basic Course
- ⦿ Any key study personnel must also complete training.
  - Any co-investigators or research assistants who will have access to identifiable information or data collected that may be identifiable

## Timing is Everything

- ⦿ Start your project planning NOW. It's never too early to start planning.
- ⦿ Allow yourself more time than you think you need.
- ⦿ IRB review may take longer than anticipated depending on the complexity of your study.
- ⦿ Respond promptly to correspondence from the IRB Committee.
- ⦿ If you plan to travel abroad, make sure you have all the pieces in place before you leave. Please do not submit your project on Monday and say you're leaving on Friday.

## Use the Available Resources

- ◉ Work with your advisor and other experts in your area of study.
- ◉ Talk to colleagues that have submitted to the IRB.
- ◉ Email IRB with specific questions you have.
  - We will get back to you

## Putting Your Proposal Together

- ◉ A typical proposal/submission includes: an application, a consent form, a protocol, and additional supporting documents (e.g., questionnaires, advertisements, brochures, interview guides, etc.).
- ◉ All of the forms you may need are available on the IRB website.
- ◉ Submit your study electronically through [IRB@tamucc.edu](mailto:IRB@tamucc.edu)

## Documents to Submit with Application

- ⦿ Copy of Informed Consent
- ⦿ Survey Instrument(s), Questionnaires,
- ⦿ Interview Questions/Guides
- ⦿ Recruitment Scripts and Materials

## Common Application Problems

- ⦿ Failure to identify potential risks:
- ⦿ Do not assume that there will be no potential risks
  - ⦿ At minimum, the collection of confidential information (for non-anonymous research) poses the risks of disclosure
  - ⦿ Address any potential psychological, social, economic, or legal risks

## Common Research Risks

(Non-Medical)

- Disclosure of private/confidential information
- Psychological risks (insult, trauma)
- Social risks (embarrassment, rejection by peers)
- Economic risks (loss of job, credit, insurance)
- Legal risks (subpoena, fine)
- Inconvenience/intrusiveness (boredom, frustration)

## Common Application Problems

- Anonymity vs. Confidentiality
  - Anonymity - Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants' identities.
    - A study should not collect identifying information of research participants unless it is essential to the study protocol.
  - Confidentiality - Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.



## Tips for filling out IRB forms

- Clearly state purpose, aims and objectives of project and justification for research.
- Describe data collection methods and collection dates, location, frequency and duration.
- State sample size and describe population, including vulnerable populations, and why that sample size is warranted.
- Explain screening procedures and inclusions/exclusion criteria.
- Describe why vulnerable populations are necessary and justify any inclusion/exclusion of these populations.

## Tips cont...

- Describe setting, location and timing of recruitment.
- Describe recruitment methods and any compensation or reimbursement.
- State timing, location and setting of obtaining consent and who it will be obtained from (participant or legally authorized representative).
- Describe how identifiers will be removed and information will be kept private.
- Describe how risks to human subjects will be minimized.
- Describe anticipated benefits of research and how participants will be notified of results.

## Other IRB Application Concerns

- Missing materials – if the participant's will see, hear, read, or respond to it – the IRB wants to see it
  - Additional paperwork must be completed if you are conducting research internationally or with non-native speakers
    - [Cultural Evaluation of International Research](#)
    - [Interpreter Certification](#)
    - [Translator Certification](#)

## Other IRB Application Concerns

- Avoid jargon – use layman's terms and make it understandable
- Proofread your application
- ***Use the most recent version of the application forms***

After completing the foregoing, submit the HSRP with supporting documentation via email to the IRB Mailbox: [irb@tamucc.edu](mailto:irb@tamucc.edu)

For questions, email:

[research.compliance@tamucc.edu](mailto:research.compliance@tamucc.edu)

## The Review Process

- Once your study is sent to the IRB, it will go through the “pre-review” process.
- When your study is ready, it will be sent out for review (Exempt or Expedited) or put on the next available agenda (Full-Board).
- When the review is complete, you will receive a letter from the IRB Committee with an update on the status of your study (Approved, Approved Pending, or Deferred).

## The Review Process

- If your study is approved, no other action is needed on your part.
  - If your study is approved pending or deferred, you need to make the requested changes and submit the changes to the IRB for review.
- After your study is approved, any changes you want to make must be submitted as an amendment to the study prior to implementation.
- Expedited and Full-Board Review studies must be reviewed at least once annually (i.e., Continuing Review).

## Points to Consider

- Simple research is good research.
- Be aware of working with vulnerable populations (e.g., children, prisoners, etc.).
- Be sure to make yourself familiar with the local research context.
  - You may also need approval from a School Administration/Review Board, Hospital Administration, or other governing body associated with the site where you plan to conduct your study.
    - This can take a LONG time, so be proactive.

## When Can I Start?

- Review times are based on several factors:
  - The quality and completeness of the submission.
  - The number of studies in the queue at the time of the submission. Studies are reviewed in the order in which they are received.
  - The length of time it takes researchers to respond to pending items and inquiries. Submissions are administratively withdrawn from review if a response from the PI is not received within 60 days.
  - The availability of IRB members to review submissions.

Questions?

