Welcome to the Research Forum

The program will begin at 1pm

Music by ComaStudio from Pixabay
During the Forum:

✔ **Webinar Housekeeping** – Mute your mics to avoid echoing or background noise. Avoid activating your camera to preserve bandwidth.

✔ **Q&A** – In lieu of voicing your questions, use the chat function, a moderator will respond to your question. We will take questions after the presentation.

✔ **Recording** - This session is being recorded and the full presentation and slides will be available on the VPR website. [https://www.uthscsa.edu/vpr/services/vpr-services-webinar-series](https://www.uthscsa.edu/vpr/services/vpr-services-webinar-series)
Human Research Approval at UT Health San Antonio

Krista Kilpadi, MD, PhD, CCRP
Research Administration and Quality
Your study is a clinical trial if:
Research procedures may begin

Is the study a clinical trial?

Yes

PI submits clinical trial forms to CTO

Budget and Billing
(UT Health CTO and OSP)

No

PI submits non-clinical forms to IRB

IRB Approval
(UT Health IRB or External IRB)

Institutional Activation(s)
(UT Health OCR, UHS, VA, etc.)

Research procedures may begin
The Office of Sponsored Programs handles contracts, agreements, and external funds

- Agreements with sponsors
  - Nondisclosure agreements
  - Clinical trial agreements
- Grant applications
  - Federal
  - Private foundations
- Data use agreements
The Clinical Trials Office approves budgets and payments within the study
Research procedures may begin

Is the study a clinical trial?

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Research procedures may begin
The Institutional Review Board is concerned with the protection of research participants.
Code of Federal Regulations for the Protection of Human Subjects was adopted in 1981

45 CFR 46 Subpart A
Three foundational principles for ethical research

Belmont Report

Respect for Persons  Beneficence  Justice
45 CFR 46 lists 7 criteria for IRB review of human research

• Risks to subjects are minimized
• Risks are reasonable relative to anticipated benefits
• Selection of subjects is equitable
• Informed consent will be sought from each subject
• Informed consent will be documented
• Data will be monitored to protect subject safety
• There are adequate provisions to protect the privacy of subjects and confidentiality of data
All human subjects research must be reviewed and approved by an IRB.

What are “human subjects”?

What is “research”?
There are two definitions, IRB review is required if a study meets either one:

- Department of Health and Human Services (DHHS)
- Food and Drug Administration (FDA)
Research:
A systematic investigation designed to contribute to generalizable knowledge

“Human subjects” if data is obtained by:
• intervening or interacting with a living individual or
• accessing identifiable private information about a living individual
FDA definitions

Clinical investigation:
• Involves an FDA-regulated test article
• Involves one or more human subjects
• Produces data that will be used to support a marketing or research application for the test article

“Human subjects” are individuals who participate in the research as a recipient of the test article or as a control
Categories of IRB review

• Non-regulated research
• Non-human research
• Exempt research
• Expedited approval
• Full board review
**Non-regulated research** does not meet the federal definitions of research

**Examples**
- Quality improvement
- Program evaluation
- Case reports

**IRB requirements**
- No IRB review is required
- IRB can make a formal determination
- No expiration date
**Non-human research** does not meet the federal criteria for human subjects

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<tr>
<th>Examples</th>
<th>IRB requirements</th>
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<tbody>
<tr>
<td>• Deidentified clinical information or specimens</td>
<td>• No IRB review is required</td>
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<tr>
<td>• Deidentified specimens from a repository</td>
<td>• IRB can make a formal determination</td>
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<tr>
<td>• Commercial cell lines</td>
<td>• No expiration date</td>
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Deidentified specimens cannot be associated with any of these identifiers:
Coded data is **not** deidentified unless you don’t have access to the key.
Exempt research must be minimal risk and fall under one of 6 categories

- Comparison of educational techniques
- Educational tests, surveys, interviews, or observations of public behavior
- Benign behavioral interventions
- Data or specimens originally collected for other purposes
- Study of public benefit or service programs if approved by a federal agency or department head
- Taste and food quality evaluation or consumer acceptance studies
Exempt research requires institutional updates only if identifiable data is collected

Examples
• Chart reviews
• Surveys of adults
• Comparing educational methods

IRB requirements
• IRB review required
• Expires 3 years from the date of last activity with the IRB
• Changes must be submitted for IRB review
Some non-exempt minimal risk studies may be approved by **expedited** review

- FDA-approved drugs, in-vitro diagnostic tests, or devices not requiring an Investigational Device Exemption from the FDA
- Collection of blood samples
- Noninvasive sample collection
- Noninvasive data collection
- Materials collected for other purposes (clinical or other research)
- Recordings
- Surveys, interviews, or program evaluation
Expedited research usually only requires institutional updates

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<tr>
<td>• Prospective collection of clinical data or</td>
<td>• IRB review required</td>
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<tr>
<td>specimens</td>
<td>• No IRB expiration unless justified</td>
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<tr>
<td>• Noninvasive measurements</td>
<td>• Changes must be submitted for IRB review</td>
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<td>• Surveys of children</td>
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Studies that do not fit the other categories undergo full board review

Must be reviewed at least annually
Research procedures may begin

Is the study a clinical trial?

Yes

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No

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IRB Approval
(UT Health IRB or External IRB)

Institutional Activation(s)
(UT Health OCR, UHS, VA, etc.)

Budget and Billing
(UT Health CTO and OSP)
The Office of Clinical Research ensures that UT Health requirements have been met

- CITI ethics training
- Research Scope of Practice for unlicensed team members
- Confirmation of committee approvals
- Drug and device storage
- Participant recruitment with Find A Study website
- Study registration on ClinicalTrials.gov
- Institutional activation for studies using an external IRB
If you are working with our affiliate institutions, they will also review
Is the study a clinical trial?

Yes
PI submits clinical trial forms to CTO

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IRB Approval
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Research procedures may begin

Budget and Billing
(UT Health CTO and OSP)
Start the process from the VPR Services website

https://www.uthscsa.edu/vpr/services
Click appropriate category of research

The Human Study Lifecycle

Getting Approval for Your Human Study

Click on the arrows below to expand/collapse the content.

Clinical Trial Approval

Non-Clinical Trial Approval

Studies relying on the UT Health SA IRB - Submit to IRBMall@UTHSCSA.EDU
-Download the "Full Board Review" application.
-Download the "Expedited Review" application.
-Download the "Repository" application.

Studies relying on an external IRB - Submit to OCRMail@UTHSCSA.EDU
-Download the "External IRB" application.

Requesting UTHSA IRB to Review for Multiple Sites

The Human Study Lifecycle

1. Developing your human study
2. Logistics for your human study
3. Getting approval for your human study
4. Starting your human study
5. Managing your human study
6. Closing out your human study
For Chart Reviews, Surveys, Questionnaires, etc

Exempt Human Subjects Research

Exempt Human Subjects Research does not include any of the following:

- Evaluation the safety or effectiveness of a drug (approved or non-FDA approved) or medical device.
- Prisoners (incarcerated)
- Research interaction with Children

Human Exempt Research must be one or more of the following:

- Conducted in established or commonly accepted educational settings, involving normal education practices
- Only including interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior
- Involving benign behavioral interventions and collection of information from adults with their agreement
- Secondary research use of identifiable private information or identifiable bio-specimens
- Studying, evaluating or examining public benefit or service programs
- Taste and food quality evaluation of consumer acceptance studies
- Storage or maintenance of identifiable private information or biospecimens for secondary research use

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Best practices for quick approvals

- Read the application forms carefully and answer all of the questions completely
  - Give the IRB the information they need to make the 7 determinations
- Have ethics training completed
  - www.citiprogram.org
- Don’t reuse forms from prior studies
- Ask for help if you have any questions
After approval, what are your responsibilities?

- Always protect the participants’ rights, safety, and welfare
- Follow your approved protocol
  - Amend it with the IRB before you change anything
- Principal investigators are directly responsible for all aspects of their studies
  - know your responsibilities and supervise other team members
- Promptly report any unexpected problems involving risks to subjects or others to the IRB
- Submit updates as required to maintain approvals, and submit final reports when research is completed
- Maintain research records that are attributable, legible, contemporaneous, original, and accurate
Still have questions?

Contact Us
Questions about research & regulations?
Our experts are here for you.

https://www.uthscsa.edu/vpr/services
Self-Service Learning is available in the Research Learning Library

https://ce.uthscsa.edu/browse/research