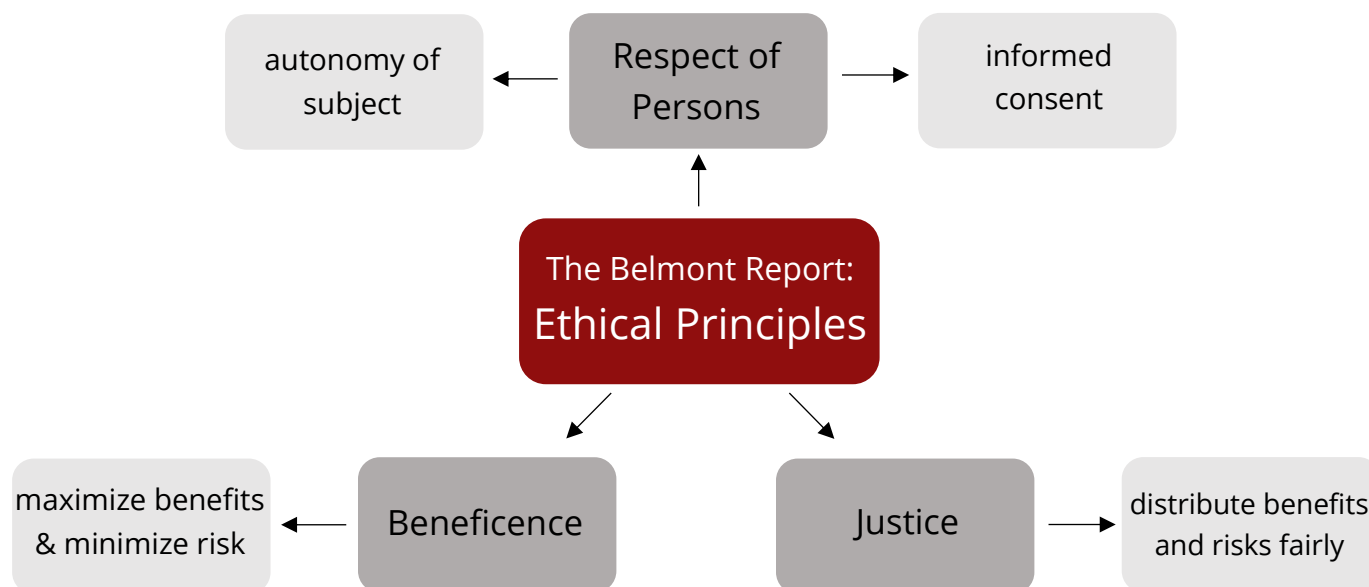


# Tips for TAMU Institutional Review Board Research Application

The IRB Office is registered with the U.S. Department of Health and Human Services.

*"The Institutional Review Board of Texas A&M University is charged ... to protect the rights and welfare of human subjects and support the institution's research mission"<sup>1</sup>.*



**Figure 1.** Principles of the Belmont Report

## 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".<sup>2</sup>

## Is it a Human Subject?

"A living individual about whom an investigator (whether professional or student) conducting research obtains (i) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies analyzes, or generates identifiable private information or identifiable biospecimens"<sup>3</sup>.

<sup>1</sup> Institutional Review Board. (2019, October 3). Retrieved from <https://www.tamuct.edu/research/irb.html>

<sup>2</sup> 45 CFR 46.102(d)

<sup>3</sup> 45 CFR 46.102(e)(1),(2)

## Where do I start?

### Ethics Training:

- CITI Program Training @ [www.citiprogram.org](http://www.citiprogram.org)
  - What training do I need?
    - **Human Subject Protection (HSP)** - *Required of everyone participating in research.*
    - **Good Clinical Practice (GCP)** - *Required for those participating in NIH funded studies and highly suggested for those participating in industry sponsored research.*
    - **Conflict of Interest Training** - *Required for those participating in NIH funded studies.*
  - Register and create a new account
    - Institution affiliated with Texas A&M University
  - Must be renewed every five years
- HIPAA Training: TAMU TrainTraq  
<https://apps7.system.tamus.edu/TrainTraq/web/default.aspx>
- More information available at:  
<http://rcb.tamu.edu/humansubjects/training>
- Create an iRIS account and complete a conflict of interest disclosure (COID).
  - Access the URL <https://iris.tamu.edu>
  - Log into iRIS using your NetID or UIN/SSO login and password.
  - From the 'Study Assistant' menu click 'Add a New Study'.
  - Then select 'IRB Application' (Human Subjects) from the 'New Study Application' list.
  - Complete each section of the online IRB Application, as needed.
  - Click 'Save and Continue to the Next Section' after each page is complete.
  - Upload the consent form to the 'Informed Consent' page, as applicable.
  - Upload all other supporting documents to the 'Study Documents' page, as applicable.
- Create an IRB Research Proposal<sup>4</sup>

<sup>4</sup> Division of Research. (2018). *Investigator Manual*. Pg. 6-7. College Station, TX: Texas A&M University. Retrieved from <https://rcb.tamu.edu/humansubjects/resources/HRP103INVESTIGATORMANUAL.6.15.2017.pdf>

Investigator and Research Staff involved in <b>Clinical Studies</b> (drugs, devices, biologics, invasive procedures) Required Training		
	Course	Timeline
Initial Training	CITI Biomedical Research Basic	Prior to IRB submission of research
	*CITI Good Clinical Practice	Prior to IRB submission of research
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Prior to IRB submission of research
	***TRAINTRAQ Financial Conflicts of Interest in Research - 211716	Prior to IRB submission of research
Refresher Courses	CITI Biomedical Research Refresher	Every 5 years
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required
	***TRAINTRAQ Financial Conflicts of Interest in Research - 211716	Every 4 years or upon change

**Figure 2.** Investigator and Site Research Staff Required Training

Investigator and Research Staff involved in <b>Social &amp; Behavioral Studies</b> Group 2 (Surveys, Qualitative, Educational, Record Reviews) Required Training		
	Course	Timeline
Initial Training	CITI Social and Behavioral Research Basic	Prior to IRB submission of research
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Prior to IRB submission of research
	***TRAINTRAQ Financial Conflicts of Interest in Research - 211716	Prior to IRB submission of research
Refresher Courses	CITI Social and Behavioral Research Refresher	Every 5 years
	**TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required
	***TRAINTRAQ Financial Conflicts of Interest in Research - 211716	Every 4 years or upon change

**Figure 3.** Investigator and Site Research Staff Required Training

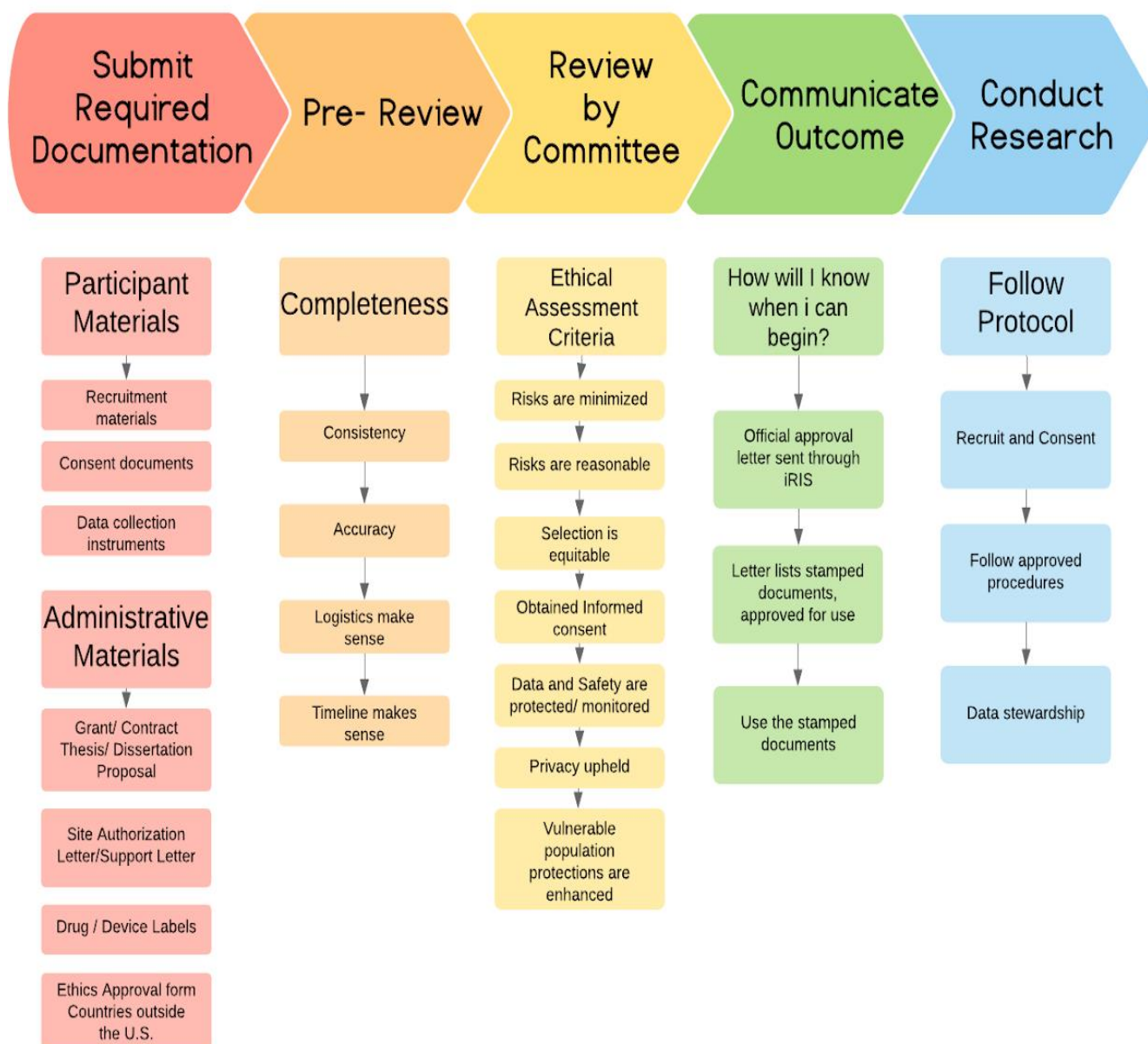
## Submit an IRB research proposal

To submit a new project for approval, follow these steps:

1. One important thing to remember is that the student participating in research does not submit the IRB proposal the board themselves. The Principle Investigator is responsible for the research project and is responsible to submit the proposal.
2. Complete an IRB Protocol Worksheet found under "What to submit?":  
<https://rcb.tamu.edu/humansubjects/step-2-what-to-submit>
3. The IRB website has specific protocol templates for you to select depending upon the type of research you are proposing, social and behavioral, biomedical or retrospective data or specimen review.
  - a. Key points to remember when developing an Investigator Protocol<sup>5</sup>
    - The italicized bullet points in the protocol templates serve as guidance and are meant to be deleted prior to submission.
    - For any items described in the sponsor's protocol or other support document submitted with the application, investigators may simply reference the page numbers of these documents within the application rather than repeat information.
    - Always keep an electronic copy to making changes.
    - Depending on the nature of your research, certain sections of the template may not be applicable.
    - You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications.
      - Adults unable to provide legally effective consent
      - Individuals who are not yet adults (infants, children, teenagers)
      - Pregnant women
      - Prisoners
    - If you are conducting community-based participatory research, you may contact the IRB Office for information about:
      - Research studies using a community-based participatory research design
      - Use of community advisory boards
      - Use of participant advocates
      - Partnerships with community-based organizations
4. Obtain all researchers signatures on the protocol form and forward it to the *Department Chair* for review, approval, and digital signature.

<sup>5</sup> Division of Research. (2018). *Investigator Manual*. Pg. 10-11. College Station, TX: Texas A&M University. Retrieved from <https://rcb.tamu.edu/humansubjects/resources/HRP103INVESTIGATORMANUAL.6.15.2017.pdf>

5. Once all required digital signatures have been completed, submit the IRB Protocol to the IRB Chair ([irb@tamuct.edu](mailto:irb@tamuct.edu)). If you have any difficulties with the form, email the IRB Chair for assistance.
6. Attach copies of any consent forms, information sheets, surveys, and other relevant documents as well as all materials that the protocol form says to attach. Finally, include a copy of the certificate for CITI training for each investigator on the project. To assure consideration at the next IRB meeting, all materials MUST be submitted to the IRB Chair at least 5 business days prior to that meeting. Allow for up to 2-4 weeks for the IRB to process your application.



**Figure 4.** Submission Process for Research with Human Subjects

## Who may be a principal investigator for human Research?

Every research study requires a Principal Investigator (PI). This person takes full responsibility for the conduct of the study including the eligibility and training of the research staff.<sup>6</sup>

Eligible to be a Principal Investigator	With Permission of Dean or Department Head on Case by Case Basis	Not Eligible to be a Principal Investigator
<ul style="list-style-type: none"> <li>• Tenure-track faculty (full, associate, and assistant professors);</li> <li>• Non-tenure-track faculty (full, associate, and assistant professors);</li> <li>• Instructors</li> <li>• Librarians</li> <li>• Faculty Equivalent Research Scientists</li> </ul>	<ul style="list-style-type: none"> <li>• Lecturers</li> <li>• Adjuncts</li> <li>• Visiting faculty</li> <li>• Visiting scholars</li> <li>• Retired faculty</li> <li>• Senior Research Fellow</li> <li>• Senior Staff</li> </ul>	<ul style="list-style-type: none"> <li>• Undergraduate students</li> <li>• Graduate Students</li> <li>• Residents</li> <li>• Post-Doctoral Fellows</li> <li>• Research Assistants</li> <li>• Research Associates</li> <li>• Research Coordinators</li> </ul>

**Figure 5.** Lists of Principle Investigators

### Protocol Considerations Process

- Funding
- Personnel
- Background & Rationale complete
- Objectives & Study Design
- Study Population
- Recruitment
- Consent & Waivers
- Procedures
- Risks & Benefits
- Data & Safety Monitoring
- Costs & Compensation
- Privacy & Confidentiality
- Data & Safety Monitoring

### Informed Consent

- It is a process
- Starts at recruitment
- Ends when study is
  - Different Forms:
    - \* Written Documentation of Consent
    - \* Waiver Documentation of Consent
    - \* Alteration of Consent
    - \* Waiver of Consent

<sup>6</sup> Division of Research. (2018). *Investigator Manual*. Pg. 5. College Station, TX: Texas A&M University. Retrieved from <https://rcb.tamu.edu/humansubjects/resources/HRP103INVESTIGATORMANUAL.6.15.2017.pdf>



## How do I create consent or assent documents?

A participant or their Legally Authorized Representative must sign a consent document if the IRB has not waived the requirement to obtain written documentation of informed consent. Include information about consent documentation in your application or protocol.

Use the Consent/Assent document templates posted on the IRB website to create consent/assent documents: <https://rcb.tamu.edu/humansubjects/forms/templates> Each different template contains information that is generally relevant for each type of research in each of these categories, social and behavioral, biomedical or simple survey research. You may ultimately need to edit sections to fit the type of research proposed.

## Required Elements of Consent

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Federally supported research

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - (a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future

research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility

- (b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research

## Should I obtain a Certificate of Confidentiality for my research?

A Certificate of Confidentiality (CoC) is a tool for protecting certain information from forced or compelled disclosure, e.g., to oppose a subpoena. The certificate helps researchers protect the privacy of participants enrolled in biomedical, behavioral, clinical and other forms of sensitive health related research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant<sup>7</sup>.

Read the CoC policy to learn more: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html> and <https://humansubjects.nih.gov/coc/index>

## What is an appropriate recruitment method?

The following methods of recruiting subjects at TAMU are generally acceptable: Advertisements, flyers, information sheets, notices, TAMU email, internet postings and/or media. Referrals may come from outside professionals that were provided general information letters or through snowball sampling methods for minimal risk social and behavioral research. You must include a description of your recruitment methods in the application, or in the protocol, you upload in iRIS. The IRB must approve the recruitment plan and the text of the recruitment materials<sup>8</sup>.

## Vulnerable Populations

Additional safeguards must be implemented for populations in which research may pose additional and/or unknown risks.

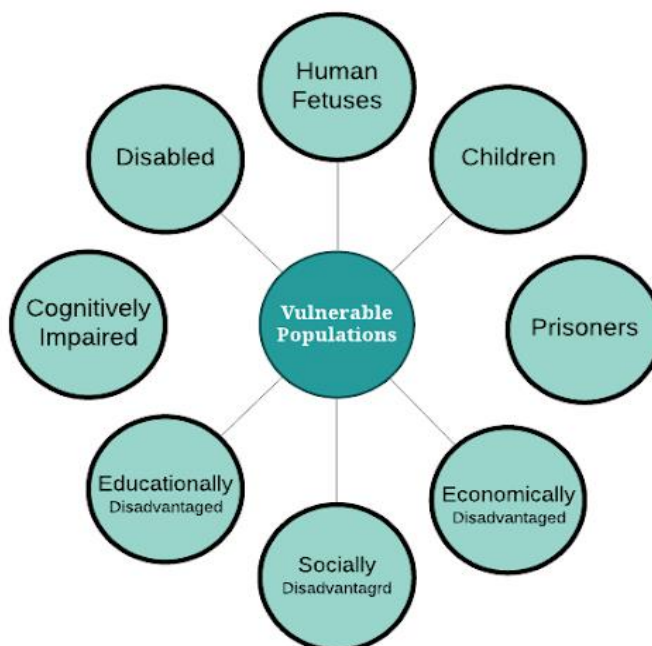
## Research with Children

- Consent Process must include the parent(s)/ guardian(s) and the child
  - Whether one or two parents must consent depends on the risk level of the study.

<sup>7</sup> Division of Research. (2018). *Investigator Manual*. Pg. 11. College Station, TX: Texas A&M University. Retrieved from <https://rcb.tamu.edu/humansubjects/resources/HRP103INVESTIGATORMANUAL.6.15.2017.pdf>

<sup>8</sup> Ibid. Pg.19





**Figure 6.** *Vulnerable Populations*

## How can I use or disclose Protected Health Information for Research and Comply with the Privacy Rule?

The Privacy Rule describes the ways in which covered entities can use or disclose PHI, including for research purposes. In general, the Rule allows covered entities to use and disclose PHI for research if authorized to do so by the subject in accordance with the Privacy Rule. In addition, in certain circumstances, the Rule permits covered entities to use and disclose PHI without Authorization for certain types of research activities. For example, PHI can be used or disclosed for research if a covered entity obtains documentation that an Institutional Review Board (IRB) or Privacy Board has waived the requirement for Authorization or allowed an alteration. The Rule also allows a covered entity to enter into a Data Use Agreement for sharing a Limited Data Set. There are also separate provisions for how PHI can be used or disclosed for activities preparatory to research and for research on decedents' information<sup>9</sup>.

## How do I De-identify Protected Health Information under the Privacy Rule?

Covered entities may use or disclose health information that is de-identified without restriction under the Privacy Rule. Covered entities seeking to release this health

<sup>9</sup> Division of Research. (2018). *Investigator Manual*. Pg. 21. College Station, TX: Texas A&M University. Retrieved from <https://rcb.tamu.edu/humansubjects/resources/HRP103INVESTIGATORMANUAL.6.15.2017.pdf>

information must determine that the information has been de-identified using either statistical verification of de-identification or by removing certain pieces of information from each record as specified in the Rule. The simplest way of de-identifying data under The Privacy Rule is by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members; Find these numbered in the investigator manual<sup>10</sup>.

## Am I done with the IRB?

*Not quite! Keep us informed!*

- Amendments
  - Submit any desired project changes to the protocol or study documents for review
- Yearly Continuing Review for Expedited and Full Board projects
- Report any adverse events or deviations
- Apply good record keeping
- Store consent and study documents
- Keep track of participation numbers, reasons for withdrawals, complaints, unanticipated problems. Be audit ready at all times.
- Submit a completion report when all study procedures and data analysis are complete

## Resources and Templates

- Website: <https://rcb.tamu.edu/humansubjects>
- IRB liaison: <http://rcb.tamu.edu/humansubjects/resources/hssp-staff-contacts>
- Investigator Manual:  
<https://rcb.tamu.edu/humansubjects/resources/HRP103INVESTIGATORMANUAL.6.15.2017.pdf>
- Protocol Templates: <https://rcb.tamu.edu/humansubjects/forms>
- Toolkit: <https://rcb.tamu.edu/humansubjects/forms>

## FAQ's?

*Do I need to submit an IRB application?*

[Activities that Require IRB Review](#)

*How do I submit an application?*

Online system – iRIS, <http://iris.tamu.edu>

iRIS Support Team: [outreachrcb@tamu.edu](mailto:outreachrcb@tamu.edu), 979.845.4969

*What do I put in my IRB?*

<https://rcb.tamu.edu/humansubjects>, 979.458.4067

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<sup>10</sup> Ibid. Pg. 22.

## First Point of Contact:

### TAMU-IRB

<https://rcb.tamu.edu/humansubjects>

**Heather Cline, MPA, CIP**

IRB Coordinator – Human Research Protection Program

Division of Research Texas A&M University

[hcline@tamu.edu](mailto:hcline@tamu.edu)

979-862-3653

### CHI-St Joseph's

**Debbie Lewis, RN, Clinical Trials**

[DLewis@st-joseph.org](mailto:DLewis@st-joseph.org)

### Houston Methodist IRB website:

<https://www.houstonmethodist.org/research/research-toolbox/morti/>

Contact: [IRBstaff@houstonmethodist.org](mailto:IRBstaff@houstonmethodist.org)

**Kimberly N. Claiborne, MPH**

Research Protection Analyst, Office of Research Protections

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7550 Greenbriar Dr., JR4 | Houston, TX 77030, Ph 346-356-1404

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