Institutional Review Board Workshop - Dallas

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https://twu.edu/institutional-review-board-irb/

Institutional Review Board (IRB)

- It is the policy of Texas Woman's University (TWU) that all research conducted by any TWU faculty member, staff member, or student using human subjects must have prior approval from a TWU Institutional Review Board (IRB) before the research is initiated.

- The purpose of the IRB is to protect the rights and welfare of research subjects and to ensure that such research is conducted in full compliance with both the letter and the spirit of applicable regulations.

- The TWU IRB operates under the following governances: Federalwide Project Assurance # FWA00000178, TWU University Policy 1.15 Human Subjects in Research, and TWU IRB Procedures – December 2014.

Does my study/activity require IRB review?

https://www.twu.edu/institutional-review-board-irb/irb-review-process/irb---does-this-activity-require-irb-review/

Only RESEARCH involving HUMAN SUBJECTS must be reviewed by the IRB.

- **Research** is a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge.

- **Human subjects** in research are living individuals about whom investigators (professionals or students) conducting research obtain (1) data through intervention or interaction with individuals, or (2) identifiable private information.

Which level of IRB Review does my study require?

https://www.twu.edu/institutional-review-board-irb/irb-review-process/determining-level-of-irb-review/

Categories of Review

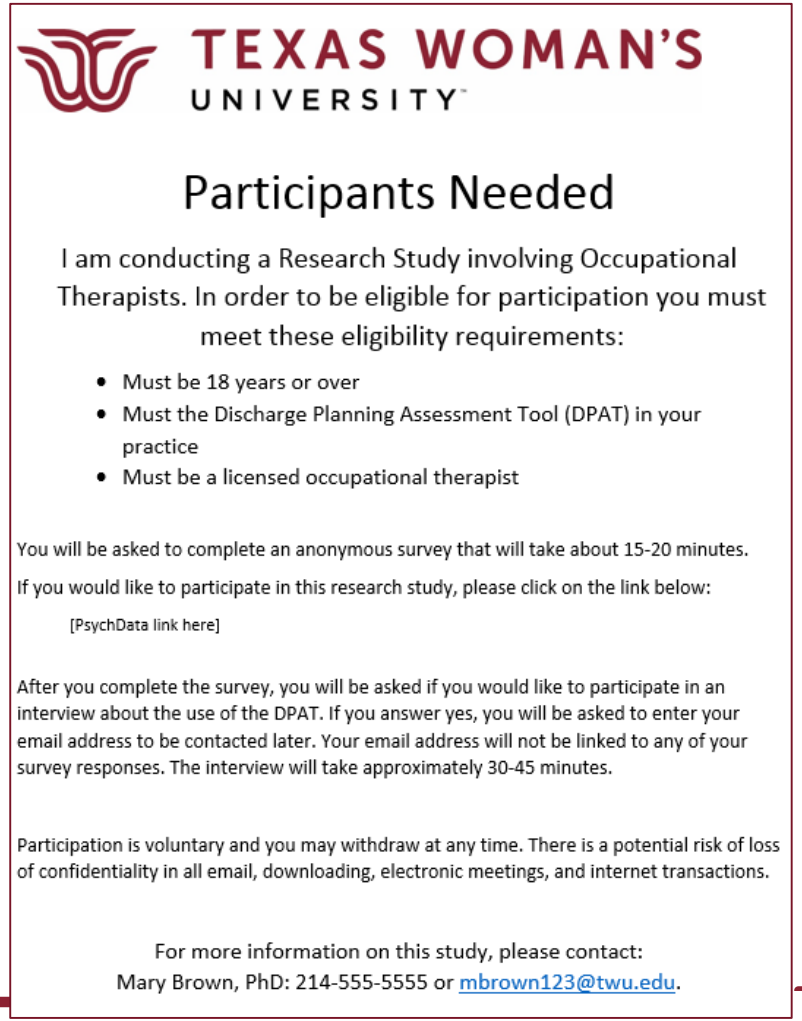
- **Exempt** – little-to-no risks; e.g., online and anonymous surveys
- **Expedited** – minimal risks; e.g., interviews, low-risk interventions
- **Full Review** – more than minimal risks; e.g.: studies involve sensitive topic, vulnerable population, and high-risk interventions

What should I include with my IRB application?

https://www.twu.edu/institutional-review-board-irb/forms-and-requests/

- Appropriate IRB Application: Exempt or Expedited/Full
- Recruitment Materials: Flyer, Email, or Phone Scripts
  - Needs to state that it is a research study and participation is voluntary
  - Good to Include primary inclusion and exclusion criteria
- Consent Form
  - Detailed procedures
  - Detailed steps to minimize risks
- Study Measures
  - Surveys/Questionnaires
  - Interview Questions
- Current Human Subjects Training
  - For all research team members

Sample Flyer



TEXAS WOMAN'S UNIVERSITY

Participants Needed

I am conducting a Research Study involving Occupational Therapists. In order to be eligible for participation you must meet these eligibility requirements:

- Must be 18 years or over
- Must the Discharge Planning Assessment Tool (DPAT) in your practice
- Must be a licensed occupational therapist

You will be asked to complete an anonymous survey that will take about 15-20 minutes.

If you would like to participate in this research study, please click on the link below:

[PsychData link here]

After you complete the survey, you will be asked if you would like to participate in an interview about the use of the DPAT. If you answer yes, you will be asked to enter your email address to be contacted later. Your email address will not be linked to any of your survey responses. The interview will take approximately 30-45 minutes.

Participation is voluntary and you may withdraw at any time. There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings, and internet transactions.

For more information on this study, please contact:
Mary Brown, PhD: 214-555-5555 or mbrown123@twu.edu.

TEXAS WOMAN'S UNIVERSITY

Sample Email Script

Dear_____,

My name is Mary Brown, and I am conducting a research study at Texas Woman's University. You are being contacted because you are an occupational therapist using the Discharge Planning Assessment Tool (DPAT) in your practice. We are interested in your feedback on the use of the tool and ways to improve the tool.

Your responses to the survey are anonymous. The survey does not collect identifying information and all responses will be kept confidential. Please provide honest feedback on this survey. Your participation is completely voluntary. You may quit the survey at any time. The survey is comprised of 10 questions and should take about 15-20 minutes.

If you would like to participate in this survey you can click on the link below.
[PsychData link here]

At the end of the survey you will be asked to participate in an interview at a later date. Participating in the interview is voluntary. The interview is to further capture your opinion and recommendations about the clinical use of the DPAT. If you are interested you will be asked to contact the principal investigator at mbrown123@twu.edu. The interview will take approximately 30-45 minutes.

If you have any questions please contact me by email or telephone. Please note that there is a potential risk of loss of confidentiality in all email, downloading and internet transactions.

Thank you,

Mary Brown,
Occupational Therapy
Texas Woman's University
mbrown123@twu.edu
214-555-5555

How do I write a consent form?

- Consent forms and instructions/examples
  - https://www.twu.edu/institutional-review-board-irb/forms-and-requests/
- Guide to Writing a Consent Form

  All consent form requirements are found here!
  - https://twu.edu/media/documents/orsp/irb-guide-to-writing-a-consent.docx
  - Must be written in second person and in an appropriate reading level (6-8th grade)
    - You are writing this TO the participant, not about them
    - Consider your population when writing your
  - Shorter sentences make for lower reading level
  - Spell out all acronyms at first use
  - Provide all information necessary for participants to make an informed decision on whether or not they want to participate

How do I write a consent form?

- Explanation and Purpose
  - Who are you, and why are you conducting this research?
  - Explain the inclusion/exclusion criteria section here.
- Description of the Research Study
  - Detailed Research Procedures,
  - Time commitment for each participant (per session & total time)
- Potential Risks and steps to minimize the risks
  - Loss of confidentiality, “Confidentiality will be protected to the extent that is allowed by law”.
  - Coercion
  - Emotional Discomfort
  - Loss of Time
- TWU Disclaimer (see Guide for entire statement)
- Benefits & Participation
- Questions Regarding the Study

Common Risks & Steps to minimize them

- **Loss of Confidentiality** – Confidentiality will be protected to the extent that is allowed by law. There is a potential risk of loss of confidentiality in all email downloading and internet transactions. Audio recordings may use names, however in the transcriptions, only codes will be used. The recordings will be permanently deleted after transcription. The master list linking codes with names will be stored separately from all data. All other forms will be coded and will not use identifiable information. All data will be stored in a locked cabinet in the researcher's office.
- **Coercion** – Participation is completely voluntary and participants may withdraw from the study at any time. Students' decision on whether or not to participate will not affect their relationship with the Principal Investigator, the department, or TWU.
- **Emotional Discomfort** – Participants may take breaks as needed. They may also stop the study at any time. (For some studies: Participants will be given a list of counseling resources at the time of consent. If they experience emotional discomfort, they may use the resource list to contact a counseling service.)
- **Loss of Time** – Participants will be informed of the time commitment, and will be able to choose a time that is convenient for them. They may withdraw from the study at any time.

Human Subjects Training Requirements

https://www.twu.edu/institutional-review-board-irb/training-requirements/

- CITI Program Training
  https://about.citiprogram.org/en/homepage/
  - Training must be updated every 3 years
  - Social & Behavioral Research *OR* Biomedical Research
  - IRB does not accept *Responsible Conduct of Research (RCRs)* as human subjects research
  - IRB will accept NIH certificates that are less than 3 years old

What happens after you submit an IRB application?

- Sandy Processes your application
  - You will receive a Receipt Notification Email
    - Protocol number is issued for that specific study.
    - Time frame for review provided. This is subject to change due to holidays or high volume of submissions. Please be patient; there is only one person handling all applications for Dallas and Denton.
  - Application under review
    - By IRB committee chair and/or committee members
    - Committee members are TWU faculty, staff, or community members.
    - Comments are sent back to Sandy to compile

What happens after you submit an IRB application?

- More Information Request
  - Most PIs will get a letter; even IRB members. It is not a big deal!
  - The committee may need you to clarify or explain some of your responses
  - The committee might ask you to submit some more items
  - The letter will tell you exactly what to change to make and where to make that change
  - If you do not understand the request, email or call Sandy
  - If you do not agree with a certain request, you are welcome to respond in writing. Sometimes the IRB's request might not make sense the way your study is set up. If you cannot make the requested change, explain it in writing and provide a rationale. It could just be a simple misunderstanding.
  - Highlighted and numbered revisions should be emailed back to Sandy at irb@twu.edu
  - Revisions will go to the chair or co-chair unless specified
- Approval or Exemption Letter

We are here to help you!

Office of Research & Sponsored Programs

Institutional Review Board (IRB)

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Dallas & Denton IRB Coordinator:
Sandy Owens: irb@twu.edu | 940-898-3378

Questions for the Chair or Co-chair:

swang@twu.edu or mneville1@twu.edu