IRB Short List
(CliffsNotes)

The following information is provided in the interest of simplifying the IRB submission process for Chairs and students while maintaining the integrity of the **federally regulated Institutional Review Board (IRB)** of TCSPP (45 CFR 46).

These notes are meant only to be a quick reference/reminder to guide the process. The IRB website (https://my.thechicagoschool.edu/community/academicresource/irb/Pages/default.aspx) provides a thorough explanation for almost any question that arises during the submission process, and this document is definitely not a substitute.

The **Role of the IRB**: Approve research applications for **human subject*** research to ensure that the following federal requirements are satisfied (45 CFR §46.111):

1. All precautions have been taken to **minimize any risk to participants** by
    a. Exhibiting "sound research design"
        - The IRB must be able to know from the application what and how the research will be conducted.
        - Providing a **step by step methodology**, **references**, and **how the data will be ultimately used** (for what scientific purpose), written **in clear and direct language** to help eliminate future questions.
    b. If appropriate, using procedures already being used for diagnosis or treatment.

2. **Risks** to the participants are **reasonable** in relation to **anticipated benefits**.
    a. When there are no direct benefits to the participants, describe benefits to society
    b. Remuneration is not considered a benefit.
    c. Consider individual questions on all instruments being used.
    d. For "vulnerable populations," consider additional safeguards/protection to minimize risks.

3. Participant selection is "**equitable**."
    a. Federal law requires special consideration be given to certain populations: children, prisoners, pregnant women, mentally disabled, and economically/educationally disadvantaged individuals.
    b. Consider the setting and purpose of research.

4. **Informed consent** will be obtained and documented, unless conditions for a waiver are met. (Conditions for a waiver of consent are found in the Q&A form and on the IRB website.)
    a. Participant (or legal representative) must act voluntarily with a sufficient amount of decision making time and without coercion or undue influence.
    b. The IRB template with required language must be used when obtaining consent.
    c. When in doubt about eligibility for a waiver of consent please check with the IRB office.

***Please note:** For purposes of IRB application, the use of archival data sets is considered "human subject" research. Requesting IRB "exemption" is usually quite reasonable for research that involves archival data sets; however, based on information received in the application, the IRB will make the final determination regarding "exempt" status. A complete IRB application is required for all exempt applications.

IRB Process: The ideal application will travel through the following process (with student checking status of application periodically):

Pre-submission: Student and Chair discuss:
Request status of review (after checking criteria):
(Some considerations: Archival? Redacted individual ID? In person? On-line?)
Exempt
Expedited (minimal risk)
Full Board Review

Note: **IRB makes final status determination** after pre review and reviewing

1. Student:
   - Fills out and submits for IRB profile – Review e-mailed "IRB Quick Tips for Students."
   - Awaits IRB confirmation of profile and instructions
   - Completes CITI training
   - Fills out and completes Q&A form, uploads supplemental documents including permission letters, recruitment documents, surveys, consent forms, CITI certification, etc.

2. Chair and Student review application together

3. Student:
   - Completes Chair's edits
   - Submits IRB application which will go to Chair for final review

4. Chair:
   - Receives notice of the IRB application.
   - Checks the application for completion and submits it to the IRB for review.

5. IRB Staff:
   - Reviews **completed** application (pre-review).
     - If incomplete will return without processing
   - May request further information/modifications from applicant
   - May determine application is eligible for Exempt review – an Exemption notice will be issued and student may start research.
   - May send to Reviewer who could
     - Approve as submitted
     - Request modifications/clarification/more information
     - Ask for full IRB Review which might
       - Approve as modified/written
       -Ask for further clarification/modification
       -Reject application

6. IRB Staff (after pre-review, Reviewer feedback, and/or full Board review) will send letter to applicant/copy to Chair in the form of
   - Memo requesting applicant response to specific questions
   - Rejection of application with specific reasons
   - **Written approval** of application: At this point data collection may begin

7. Student:
    - If any letter other than one of approval is received (i.e., requests for modification, requests for additional information, rejection letter) will in a timely manner:*
        -Consult with Chair
        -Respond with specificity to the IRB memo's requests
        -Follow directions (i.e., submit a memo that explains response to each IRB request)

    *Please note that student responses are often not received by the IRB for more than three weeks (24 day average) after memo is sent.

8. Student:
    - Does not start recruitment or data collection until approval letter from IRB is received
    - Upon receipt of approval letter
        - Collects data only as described in the IRB approved application
        - Includes only participants (number and description) as approved by IRB
        - Any intended changes to the approved application must be submitted as an addendum to the IRB prior to implementing the changes. **Changes may not be implemented until the IRB approves the addendum.** .
    - *If OIR permission is required, this is the time to request it.
        - If participants are being recruited from TCSPP e-mail list
        - Follow all directions on IRB website regarding OIR permission
        - <u>Any</u> changes due to OIR approval (or for any other reason after IRB approval) require IRB review and approval
            - All modifications must be sent to IRB
            - No data collection may begin until IRB approves changes

One last reminder: Please keep in mind that compliance with the IRB's regulations and guidelines is an integral part of conducting research at TCSPP and has very real application regarding

- Protecting the safety, rights, and welfare of research participants.
- The community trust in TCSPP as a research institution.