SHSU IRB Process Checklist for Faculty & Students

Step 1: Request Access to Cayuse Human Ethics

New faculty or students must request access to **Cayuse Human Ethics** to submit IRB applications.

- Complete the New User Request Form.
- **Select the second option** to request access to IRB.
- For **SHSU ID**, enter your **9-digit SAM ID #** (provided during the hiring or registration process).
- For **SHSU email**, use your formal SHSU email (e.g., **username@shsu.edu**).

Step 2: Complete Required CITI Training

- All researchers must complete the CITI Training in Human Subjects Research (HSR).
  - Select the course based on your discipline (e.g., Biomedical, Social/Behavioral/Educational, or Criminal Justice research).
  - Achieve a minimum score of 80% per module of the course.
  - Save the completion report (the one containing the modular scores for your records; internal SHSU personnel will not be asked to upload into Cayuse Human Ethics; however, if you need to add an external collaborator to your application, you will be required to provide their CITI or other ethics training).

Step 3: Prepare Your IRB Submission

1. Research Protocol*: Write a clear and detailed description of your study, including:
   - Research objectives
   - Study design and methodology
   - Data collection methods
   - Plans for recruitment of participants

*Essentially address all required questions within the application (here is guidance for getting started [link to resource].

2. Informed Consent**: Draft consent forms that explain:
   - The study's purpose
   - Procedures
   - Potential risks/benefits
   - Confidentiality measures

**Here is guidance [linked here] and working SOP [linked here] for reference when preparing your consent form.

3. Other Documents:
- Recruitment materials (e.g., flyers, emails)
- Surveys, interview guides, or other data collection tools
- Any necessary permissions from cooperating institutions (if applicable)

Step 4: Submit Your Application via Cayuse Human Ethics

- Log in to the Cayuse Human Ethics System using your SHSU credentials.
- Complete the IRB application form, ensuring:
  - All research team members are listed.
  - All research team members are up to date on their CITI training
  - Attach all necessary study documents (protocol, consent forms, recruitment materials, data collection instructions, site permission, etc.).

Step 5: Select the Type of IRB Review

The IRB will determine the type of review based on the nature and risk level of your study. Below are the different review categories:

1. **Exempt Review**:
   - **Risk Level**: Minimal risk.
   - Applies to research that fits into one of the federal exemption categories (e.g., research on educational practices, anonymous surveys, or studies involving publicly available data).
   - **Limited IRB Review**: For certain exempt studies that involve the collection of identifiable private information or biospecimens, a **Limited IRB Review** is required. This ensures that adequate privacy and confidentiality protections are in place, though it is still considered minimal risk.
2. **Expedited Review**:
   - **Risk Level**: Minimal risk but does not qualify for exempt review.
   - Includes research involving activities such as blood samples, non-invasive data collection, or studies using existing identifiable data (e.g., data originally coming from participants who meet the definition of a prisoner).
3. **Full Board Review**:
   - **Risk Level**: More than minimal risk or involves vulnerable populations (e.g., children, prisoners).
   - Required for studies that involve significant interaction or intervention with participants, especially when there is potential for physical, psychological, or social risks.

The IRB will assess your study and assign it to the appropriate review type, but you should recommend the review type based on your understanding of the study's risk level and category.

Step 6: Respond to IRB Feedback

- Once submitted, your application will be pre-screened for completion by the IRB office and then it will be reviewed by the IRB.

- The IRB may request clarifications or revisions. **Respond promptly** to any requests in the Cayuse Human Ethics system to avoid delays.

Step 7: Await IRB Approval

- Do not begin research involving human subjects until you receive written IRB approval via Cayuse. The notification will come to your SHSU email Inbox. A follow-up email will be sent to you by the IRB office. The email will contain a pdf copy of your IRB approval and a stamped copy of your consent form. If any recruitment flyers are approved for use, you will be asked to use the stamped version of your flyer during recruitment.
- IRB approval is typically granted for one year. Longer projects may require continuing review.***

*** "**Longer projects may require continuing review**" refers to the process where research studies, particularly those involving human subjects, must undergo periodic IRB review to ensure they continue to meet ethical and regulatory standards.

Here's what it means:

1. **IRB Approval Period**: When your study is approved by the IRB, it is typically for a fixed period, usually **one year**. At the end of this period, the IRB needs to reassess the study to ensure:
    - The research is progressing as planned.
    - Risks to participants are being appropriately managed.
    - No new ethical concerns have arisen.
2. **Continuing Review**:
    - If your study is ongoing beyond the initial approval period, you are required to submit a **continuing review** (in Cayuse, this is your Renewal submissions) application.
    - This involves providing updates on the study's progress, including:
        - Number of participants enrolled.
        - Any adverse events or unexpected outcomes.
        - Modifications or changes to the research.
        - Withdrawals and/or Complaints
    - The IRB then reviews the submission and, if everything is in compliance, grants permission for the study to continue.
3. **When it Applies**: Continuing review is generally required for studies that are more than minimal risk or if they are initially approved under full board review. Studies approved under expedited review procedures are assigned a 3-year Administrative Check-in IRB approval. In this case, while you will still submit a Renewal in Cayuse Human Ethics, within the submission, you would select the admin check-in option. Some low-risk studies (classified as **exempt**) do not require annual continuing review.

In summary, for longer research projects that extend beyond one year or involve certain levels of risk, the continuing review process ensures ongoing oversight by the IRB to protect participants and maintain ethical standards.

Step 8: Post-Approval Requirements

- Modifications: Submit modifications to the IRB if there are changes in the study protocol, recruitment, or consent process. Here is a guide for getting started (link to resource).
- Annual Review: Submit a Renewal for ongoing research if required (e.g., full board reviews require continuing review, while expedited and some exempt/limited reviews require an Administrative Check-in report). Here is a guide for getting started (link to resource).
- Report Issues: Promptly report any adverse events or unexpected problems that arise during the study by creating and submitting an Incident report. Contact the IRB office at the email listed below for questions related to issues that occur during the conduct of your study.

Step 9: Closeout

- When your study is completed, submit a Closure to close your project with the IRB. Here is a guide for getting started (link to resource).

Useful Links:

- CITI Training Portal
- Cayuse Registration Form
- SHSU IRB Homepage
- SHSU IRB Guidance
- SHSU IRB Standard Operating Procedures
- SHSU IRB Cayuse Human Ethics Resources

For assistance, contact the SHSU IRB Office at irb@shsu.edu. If you wish to meet with Ms. Sharla Miles for project specific questions, feel free to click here to put some time on her calendar.