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ITEMS REQUIRED FOR EVERY IRB APPLICATION

The following items are required on every Expedited or Full IRB application. They do NOT apply to Exemption Requests or Continuation/Change applications, both of which are self-contained forms in the Online IRB Application System that don’t require training or additional documentation.

1. Up-to-date (not expired) completion of CITI Training (or approved alternative training) in the protection of Human Subjects for applicants and faculty supervising student applicants. Take care to register for the correct course, as there are a number of other courses available on the CITI website. Hint: if the training you are taking doesn’t mention human subjects or IRB, you have likely registered for the wrong course. Include training completion in the Synopsis.

2. Synopsis – use the template in this document. At a minimum, each application must have a Synopsis, but additional documents (consent forms, surveys, etc.) should be included as necessary.

3. All uploaded documents, including Synopsis, should follow a naming schema that includes First Name or Initial, Last Name, and one-word description, with no extra spaces or special characters other than underscores. Acceptable examples: JohnSmithSynopsis, J_Smith_synopsis.doc, JohnSmith_consentformEnglish.pdf, JSmithconsentformSpanish.doc

4. Student applicants must provide accurate Texas State NetID for supervising faculty in the online form. Do not use any other type of information or ID number derived from a non-Texas State email address. If you do not know your faculty member’s NetID, look it up or ask them before guessing or submitting the wrong information. Failure to provide the correct information will prevent your faculty member from completing the next step and will keep the application from being reviewed.

5. Supervising faculty member must log in and approve submission for student applications. If you cannot access the application, make sure your student provided your correct Texas State NetID on their application.

6. Make sure finished application is SUBMITTED, not just SAVED. Look for the dialog box that confirms your submission and check to see the application status has changed. Applications that are simply saved as In Process and not submitted cannot be accessed by the IRB or Compliance staff, and will remain hidden in the system.

7. Monitor your application closely after submission via email updates and status log in application. All status changes, including reviewers’ request for modifications, are logged and emails are sent to applicants as well.

8. If reviewers request revisions, respond promptly and follow instructions provided for submission of modifications. If you disagree with, or do not understand, the comments or request for revisions, contact the IRB Chair or the Director of Research Integrity & Compliance for clarification rather than challenging or ignoring the reviewers’ request.
Download an editable version of the Synopsis Template

SYNOPSIS TEMPLATE

Replace the red and bracketed [ ] text below, with text appropriate for your approved research.

Cut and paste or use the “Save As” command to use this template for your Synopsis document. All documents including the Synopsis should be titled with naming schema that uses First Name or Initial, Last Name, and one-word description, with no blanks spaces and no special characters other than underscores. Acceptable examples: JohnSmithSynopsis, J_Smith_synopsis.doc, JohnSmith_consentformEnglish.pdf, JSmithconsentformSpanish.doc

Every application submitted for review and approval must include a Synopsis organized in numerical brief paragraph form as outlined below. Do not omit or substitute another document for the Synopsis. You may add items but do not omit any. If you feel a question below does not apply, explain why rather than omitting it.

[Insert the Title of Your Study or Project at top of your document]

1. Identify the sources of the potential subjects, derived materials or data. Describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.

2. Describe the procedures for recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects, and the methods of documenting consent. (Include applicable Consent Form(s) for review.) If written consent is not to be obtained, this should be clearly stated and justified.

3. If your planned recruitment process involves emailing Texas State students, staff, faculty or other individuals using their active Texas State email address, provide details in the Synopsis. (In addition, the IRB will require a draft of your recruitment email, using the enclosed template and formatted as illustrated in the example in this document, submitted in addition to other required documents.

4. If you plan to distribute a survey to collect information directly from individuals who comprise a significant proportion of one or more Texas State affiliation groups, as defined in Section 04 of UPPS No. 04.01.02, Information Resources Identity and Access Management, you must follow the review and approval procedures outlined in UPPS No. 01.03.05, Administrative Surveys, and provide information in your Synopsis regarding review and approval.

5. Describe the project’s methodology in detail. If applicable, detail the data collection procedures, the testing instruments, the intervention(s), etc. If using a survey, questionnaire, or interview, please provide a copy of the items or questions.

6. Describe any potential risks — physical, psychological, social, legal or other — and state their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used.

7. Describe the procedures for protecting against or minimizing any potential risks and include an assessment of the likely effectiveness of those procedures. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing mental health or medical treatment, if needed.

8. Describe and assess the potential benefits to be gained by the subjects, as well as the benefits that may accrue to society in general as a result of the proposed study.

9. Clearly describe any compensation to be offered/provided to the participants. If extra credit is provided as an incentive, include the percentage of extra credit in relation to the total points offered in the class. Also, if extra credit is provided, describe alternatives to participation in your research for earning extra credit.
10. Discuss the risks in relation to the anticipated benefits to the subjects and society.

11. Identify the specific sites/agencies to be used as well as approval status. Include copies of approval letters from agencies to be used (note: these are required for final approval). If they are not available at the time of IRB review, approval of the proposal will be contingent upon their receipt.

12. If you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member.

13. In the case of student projects, pilot studies, theses, or dissertations, evidence of approval of Supervising Professor or Faculty Sponsor should be included. Thesis and dissertation proposals must be approved by the student’s committee before proceeding to the IRB for review.

14. If the proposed study has been approved by another IRB, attach a copy of the letter verifying approval/disapproval and any related correspondence. If the proposed study has not been reviewed/approved by another IRB, please state this explicitly.

15. Identify all individuals who will have access, during or after completion, to the results of this study, whether they be published or unpublished.

16. Provide date of completion of the required CITI training on the protection of human subjects. Applicants must provide training dates for themselves and for supervising faculty member. All training must be current and not expired.

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OTHER TYPES OF DOCUMENTATION SUBMITTED

In addition to a Synopsis, required for every IRB application, you are required to submit all documentation that is relevant for review by the IRB. Sometimes, it’s hard to know what those might be. This list is intended to give you an idea of the most typical additions to applications.

The other types of documentation required for the IRB to make an accurate assessment will vary, depending on the nature of your project, your methodology, collaborations, and other factors. If you aren’t certain what to include, contact the Office of Research Integrity & Compliance at 512.245.2314. After they read your submission, the IRB may require additional information or certain types of documents.

Typical documentation submitted with an IRB application may include, but is not limited to:

1) recruiting documents (e.g., flyers, letter, e-mails, brochures, etc.)
2) a consent form
3) an assent form
4) letters of approval from relevant organization(s)
5) surveys/instruments/questionnaires, esp. those created by the researcher
6) a list of questions that the researcher may ask (e.g., focus groups questions, questions for qualitative studies, etc.)
7) all documents in translated versions
8) data use agreement
9) data security plan

All documents including the Synopsis should be titled with naming schema using First Name or Initial, Last Name, and one-word description, with no blank spaces and no special characters other than underscores. Acceptable examples: JohnSmithSynopsis, J_Smith_synopsis.doc, JohnSmith_consentformEnglish.pdf, JSmithconsentformSpanish.doc
Download an editable version of the Consent Form checklist

CHECKLIST FOR CONSENT FORMS

Replace the red and bracketed [ ] text below, with text appropriate for your approved research. You may cut and paste or “Save As” to use this as a template for your Consent Form document as long as the final document is formatted and titled as a Consent Form rather than simply this checklist of items.

The Consent Form submitted to the IRB for approval MUST address/include information according to the following eight items:

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.
   - Include details about the length of time assessment/participation required, number of questions included in a survey, etc. that will be used to collect data in easily understandable terms and language.

2. A description of any reasonably foreseeable risks or discomforts to the subject.
   - For questionnaires/surveys/instruments that may be sensitive in nature, include a sample question(s) from the questionnaire/survey/instrument so that each participant is fully informed prior to giving consent.
   - Clearly identify any procedures that are experimental.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
   - Include details of any compensation offered to participants (e.g., the amount of money on a gift card, the amount of extra credit, etc.). If extra credit is provided to students who choose to participate, it must be stated that an alternative form of extra credit will be made available to students who choose not to participate. This alternative form of extra credit must be clearly described. Researcher should ensure that the alternative form of extra credit is comparable to the requirements of the study.

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.
   - Be specific, including details about the storage location, length of time, and persons who will have access.

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 and, if so, what they consist of, or where further information may be obtained.
   - For studies that have the potential of being psychologically/emotionally distressful, a resource list of at least three mental health providers must be given to all participants. It must be stated who is responsible for covering expenses incurred in the event that the participant requires attention from a mental health provider. If the Texas State University Counseling Center is listed as a referral, and if your participants are registered Texas State students, please state that mental health services at the Counseling Center are free to registered students, although the number of sessions allowed may be limited.
   - A protocol for the implementation of medical procedures must be listed for studies with any risk of physical harm/medical complications to participants. It must be stated who is responsible for covering medical expenses incurred in the event that the participant requires medical attention.

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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.
   - Give the researcher(s)’ name(s), contact information and affiliation(s) in the very first paragraph.
   - This statement MUST appear in the consent form:

   This project [insert IRB Reference Number] was approved by the Texas State IRB on [insert IRB approval date]. Pertinent questions or concerns about the research, research participants’ rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser 512-245-3413 - (lasser@txstate.edu) or to Monica Gonzales,IRB Administrator 512-245-2314 - (Meg201@txstate.edu).

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.
   - For surveys/interviews, include a statement that participants may choose not to answer any question(s) for any reason.

The following suggestions for consent forms are not required by the IRB but instead are presented as best practices to be adopted when applicable to the research study:

The Consent Form should be written in language that is easily understood by prospective subjects. Many consider it most appropriate to write the Consent Form between 5th and 8th grade reading levels. There are numerous online tools for assessing reading levels.

Depending on the target population, the Consent Form (and other relevant documents) may be required to be written in a language other than English.

The Consent Form should include the reason(s) why the participant has been chosen/asked to participate.

The Consent Form should state that a summary of the findings will be provided to participants upon completion of the study, if requested. The researcher should include instructions for accessing results of the study.
Download an editable version of the Email Recruitment Template

EMAIL RECRUITMENT MESSAGE FORMATTING REQUIREMENTS AND TEMPLATE

Formatting Requirements

1. **Address Line.** The Principal Investigator (PI) should employ measures to avoid disclosing the email addresses of potential research subjects to others. Common techniques include the use of:
   - Individually targeted messages (only one address in ‘TO:’ line) per message
   - Group targeted messages with all recipient addresses in the ‘BCC:’ line

2. **Subject Line.** The PI shall use a standard subject line formatted as follows:
   
   `Subject: Research Participation Invitation: <Project Topic or Key Words>`
   
   Thus, the ‘Subject:’ line always begins with the phrase ‘Research Participation Invitation’ and ends with a phrase or key words describing the nature of the research.

3. **Email Message Body.** The email message body should be free of special font effects such as color, bolding, or highlighting. The PI should include all pertinent information in the message body, but if supplemental information is necessary, hyperlinks (to the supplemental information) are preferred over attachments.

   The first sentence of the message body must affirm that the Texas State Institutional Review Board (IRB) has either approved the project or declared it exempt from IRB oversight. The bulk of the message body should describe the purpose of the research project and the anticipated value of the findings. To enhance the likelihood of recipient participation, the PI may also wish to address other topics, such as the reason for the recipient’s selection, a statement of anonymity or confidentiality, the anticipated time required for participation, the voluntary nature of participation, and any incentives for participating.

   The body must close with the following information:
   - The IRB Approval or Exemption Number.
   - A statement directing questions about research, research participants’ rights, or research-related harm to participants, to both the current IRB chair and the director of Research Compliance, and including their current contact information.
   - A statement directing questions about the research project itself to the PI, and including the PI’s telephone and email contact information.

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Recruitment Email Message Template

Replace the red and bracketed [ ] text below, with text appropriate for your approved research.

To: [Use this line for individual addresses or your own address if BCC line is used]
From: [Principal Investigator]
BCC: [Use this line when sending the same email message to multiple addresses]
Subject: Research Participation Invitation: [Research project title, topic or key words]

This email message is an approved request for participation in research that has been approved or declared exempt by the Texas State Institutional Review Board (IRB).

[Text of recruitment email message goes here. To enhance the likelihood of recipient participation, the PI may wish to include the purpose and anticipated value of the research project, the reason for the recipient’s selection, a statement of anonymity or confidentiality, the anticipated time required for participation, the voluntary nature of participation, and any incentives for participating.]

To participate in this research or ask questions about this research please contact me at [insert your name, phone number and email address.]

This project [insert IRB Reference Number or Exemption Number] was approved by the Texas State IRB on [insert IRB approval date or date of Exemption].

Pertinent questions or concerns about the research, research participants’ rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser 512-245-3413 - (lasser@txstate.edu) or to Monica Gonzales, IRB Administrator 512-245-2314 - (Meg201@txstate.edu).

Questions about this research should be addressed to [insert your name, phone number and email address.]
Application Status
As soon as you initiate an IRB application in the system, it is assigned a STATUS. The initial status of all applications is Application in Process. At that stage, applicants can still log out of the application, log back in, make changes, and upload documents as many times as they need to. Theoretically, an application can remain at the Application in Process step for months.

NOTE: In Process applications cannot be accessed by anyone other than the applicant. The compliance staff can see the application in the system but cannot modify it or access the contents. That’s why it’s important to make sure that, when you’re ready to submit the application for review, you click the “Submit” button, confirm your application has been submitted (not just saved), and finally, check to make sure the application status has changed to Application Submitted. If it doesn’t, your application will remain In Process and won’t move forward.

IRB Applications will cycle through a number of status changes between creation and final approval. Below is a list of all possible status changes. Your application will have a minimum of 7 status changes.

- Application in Process
- Application Submitted
- IRB Admin Requests Applicant and/or Supervising Faculty Complete HSP Training
- Human Subject Protection Training Finished
- IRB Admin Requests Revision
- Application Revision Received (In Response to Request Made by IRB Admin)
- IRB Chair Requests Revision
- Application Revision Received (In Response to Request Made by IRB Chair)
- Application Certified by Faculty Member
- Approve Application On Behalf of Faculty Member
- Application Submitted to IRB Chairs for Review
- Application Approved
- Application Approved - Exempt
- Application Discontinued
- Applicant Requested Continuation
- Applicant Requested Change

Keep an Eye on Things
Every time someone makes a change to your application, the status will change. Monitoring your application status will let
you know what’s happening as it makes its way through the cycle. There are two ways to do this:

- An automatic email is sent to the email address you provided every time the status changes. The online system email address is ospirb@txstate.edu, so keep an eye out for those emails. If you don’t see them, check your junk mail folder or spam filter to make sure your email client is allowing them through.

- The same information is noted on your application’s Status, Evaluation, and Action Log in the online system. At any time, you can log in and see the progress in the log.

**SUMMARY OF APPLICATION STATUS, EVALUATIONS AND ACTION LOGS**

**Application Title:** Working with Pre-K Children in Caldwell County Foster Care  
**Application Number:** 2008N8589  
**Status:** IRB Chair Requests Revision  
**Last Approval Date:**  
**Faculty Approved Submission?**

<table>
<thead>
<tr>
<th>Application Submitted Date</th>
<th>IRB Administrator Sent Request for HSP Training Date</th>
<th>Application Sent to IRB Chairs for Review Date</th>
<th>Application Sent to Reviewers for Review Date</th>
<th>Last Request for Revision Date</th>
<th>Last Application Revision/Update Received Date</th>
<th>Date of Application Approved by IRB Chairs</th>
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<td>10/02/08 11:04:20</td>
<td>12/05/08 11:08:39</td>
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**Reviewer Actions - Read Carefully**
The majority of IRB applications receive expedited review. In an expedited review, your application is assigned to two reviewers.

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<th>Reviewers’ Evaluation Log</th>
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<td>Yes</td>
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<td>Yes</td>
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You will not know the identity of the reviewers but you can see what action they’ve taken on your application. When they both finish, if they’ve both approved, you will receive an email notifying you the application has been approved. If a reviewer has not **YET** approved, you’ll see a “No” in the evaluation log. **Only if the log indicates that the reviewer is FINISHED does that “No” mean they did not approve.** Otherwise, it just means they have not yet approved.
Requests for Revisions – Don’t Worry, it Happens to Everyone

No IRB application is ever just disapproved and returned. If one or both reviewers don’t approve on the first review round, they will request changes or ask for more information. Often, reviewers will both ask for the same thing. Sometimes their requests may conflict with each other. So that you can easily understand what is required of you, reviewer comments or requests are first sent to the IRB Chair, who in turn, creates a summary of the revisions requested or questions you’ll need to answer. You’ll get that summary in an email from ospirb@txstate.edu, which will also include instructions on how to submit your revisions.

If you get a request for revisions, you’re in the majority of applicants. More than half the applications submitted are returned for modifications, corrections, or clarifications. However, pay close attention to what’s being asked and respond with thoughtful, complete corrections or clarifications.

The email will explain how to upload your modifications into the system, and how your modifications should be formatted. You’ll be asked to use the “Track Changes” feature in Microsoft Word so the reviewers can easily make sense of your revisions. Because your original documents cannot be deleted from the application, you’ll be instructed to change the title of the document you’re modifying so it can be distinguished from the original. For example, if the reviewers have requested you to modify your consent form, originally entitled “JSmithConsent.doc,” you would upload a revised version entitled “revisionJSmithConsent.doc,” or “JSmithConsent_Rev1.doc.”
ACCESSING AND PRINTING THE IRB APPROVAL CERTIFICATE

1. LOG INTO THE ONLINE IRB APPLICATION MODULE

2. CLICK ON THE TOPMOST LINK IN THE RIGHT COLUMN

3. CONFIRM YOUR APPLICATION STATUS IS “APPROVED”

4. CLICK ON “PRINT OUT CERTIFICATE”

5. FROM WITHIN THE NEXT WINDOW, PRINT THE CERTIFICATE, OR SAVE IT AS A PDF