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**IRB APPLICATION**

**INSTRUCTIONS & TEMPLATES**

If a requirement or template in this document presents a problem for you or doesn’t apply to your project, please contact the Research Integrity & Compliance office first before you submit your application without them. We will make every effort to accommodate you. However, if you submit an application without a required item and without approval for the omission, it will be returned to you without being reviewed.

**Why is all this even necessary?**

If you are like most applicants to the IRB, you’re busy, you’re juggling numerous deadlines, and even if you’re familiar with IRB processes and the underlying human subjects regulations, it’s likely that you’re not exactly thrilled at the prospect of having to submit an IRB application in order to complete your research or academic project.

It’s even more likely that you’re concerned about:

1. not having enough time to prepare and submit an IRB application, and/or
2. the review process taking too long, resulting in
3. delays in, and/or unanticipated changes to, your project.

Understandably, it might seem that *reading*, much less *following*, all these requirements, and having to use our templates instead of just copying material you’ve already got on hand, is way too much work. It might also seem like the IRB is overly preoccupied with picky details, doesn’t care about how important your work is, or wants you to take time to answer questions that don’t even appear to be related to what you’re trying to accomplish. Believe it or not, these requirements were put in place to save time and make the process as efficient as possible for every applicant.

**We’re all here for the same reason**

It’s an exciting time to be at Texas State University-San Marcos. As it says on the [university website](http://www.txstate.edu/rising-stars/rising_stars_home.html)

*Whether they achieve success in the research lab, the classroom or on location around the world, it is the people who make Texas State a university that is on the move. Their excellence helps Texas State shine.*

Helping maintain that level of excellence as the University’s research and academic communities continue to grow is central to the IRB’s mission. At any institution where research with human subjects is conducted, IRBs are charged with the responsibility of ensuring that research meets the standard required by federal regulations.

**Consistency is the key**

The IRB reviews more than 200 applications every year. Reviewers are faculty, staff, students, and community members, all of them volunteers donating their time to serve on the IRB. They’ve undergone hours of training and meetings, and at any given moment, are reviewing multiple applications, some for the second or third time.

Because no two research or academic projects are exactly alike, every IRB application is inherently unique. One application might contain the bare minimum of documents, the research presents minimal risks to subjects, and the methodology is familiar and easy to understand. The next application may concern a project that presents significant risks, involves highly experimental methodologies, and require the inclusion of non-standard documentation. In addition, while the research being reviewed involves human subjects, the researcher’s point of view is most likely focused on issues central to the goal of the research, and may not coincide directly with the specific facts the IRB is required to assess in order to conduct a review.

Requiring all applicants to follow the same basic requirements, answer the same core questions, and use the same templates establishes a level of consistency across differing applications and points of view. Reviewers have the information they need to assess, and they can quickly find it because it’s in the same place in every application. This in turn, enables them to finish reviews faster, without having to ask the applicant for more information or clarification. When more applications can be approved on the first review, reviewers can move on to new applications faster, and more applications can move through the process in a timely manner.

**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](http://www.tr.txstate.edu/itac/netid.html) 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.

 **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](http://www.txstate.edu/effective/upps/upps-04-01-02.html), you must follow the review and approval procedures outlined in [UPPS No. 01.03.05, Administrative Surveys](http://www.txstate.edu/effective/upps/upps-01-03-05.html), 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.

**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 [IRB Chair or the Director of Research Integrity & Compliance](https://www.osp.txstate.edu/irb/irb_inquiry.html). 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

**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 all of the following. If you feel a question does not apply, explain why you believe it doesn’t rather than omitting it or answering “N/A.” Provide detailed and specific information, and use explanations rather than declarative close-ended statements. Example: “I feel this project poses no more than minimal risk to subjects because etc., etc., etc.,” rather than “This project poses no risks to subjects.”

1. The following statement must appear prominently on all **Consent Forms**:

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) and to Becky Northcut, Director, Research Integrity & Compliance (512-245-2314 - bnorthcut@txstate.edu).

1. “**Consent Form**” must be the title of the document, not “Informed Consent”. Informed consent is considered an action or an ongoing process of communication between the participant and the researcher.
2. 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](http://www.google.com/search?q=How+to+determine+reading+level+of+documents&ie=utf-8&oe=utf-8&aq=t&rls) for assessing reading levels.
3. Depending on the target population, the **Consent Form** (and other relevant documents) may be required to be written in a language other than English. Translating documents (into Spanish, for example) is typically accomplished by having a qualified individual translate the document(s) from English to Spanish, then having a second qualified person translate the resulting Spanish version back to English. This is done to ensure that the meaning embodied in the document is retained and that the document(s) was not merely translated “word-for-word.” Also, the researcher should consider whether an interpreter familiar with the study (do not depend on ad hoc interpreters being present] should be present during data collection. If not, justification should be provided.
4. Give the researcher(s)’ name(s), contact information and affiliation(s) in the very first paragraph.
5. A statement that the study involves research should be included in one of the first few sentences of the **Consent Form**.
6. A statement that identifies the funding source of the research project. If the project is not funded, state so.
7. Near the beginning, clearly state the purpose(s) of the research project.
8. Provide the reason(s) why the participant has been chosen/asked to participate.
9. Describe procedures (including length of time assessment/participation will require, number of questions included in a survey, etc.) that will be used to collect data in easily understandable terms and language.
10. For questionnaires/surveys/instruments that may be sensitive in nature, include in the **Consent Form** a sample question(s) from the questionnaire/survey/instrument so that each participant is fully informed prior to giving consent.
11. Clearly identify any procedures that are experimental.
12. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant, must be included.
13. List the benefits to the participants. Be specific and do not answer, “There are no benefits.” If you feel there are not benefits, explain why, and explain why you feel it’s still necessary that you’ve chosen to do the project.
14. List the physical and/or psychological risks to participants. Be specific and do not answer, “There are no risks to subjects.” If you feel there are not risks, explain why you believe so, considering all risks from the point of view of any subject, not just your own. If risks are more than minimal, explain why it’s still important that you’ve chosen to do the project.
15. 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 TxState Counseling Center is listed as a referral, and if your participants are registered TxState students, please state that mental health services at the Counseling Center are free to registered students, though the number of sessions allowed may be limited.
16. A protocol for the implementation of emergency 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.
17. Give the 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.
18. A statement that participation is voluntary and participants may withdraw from the study at any time without prejudice or jeopardy to their standing with the University and any other relevant organization/entity with which the participant is associated.
19. A statement that participants may choose not to answer any question(s) for any reason.
20. Regarding the data collection procedures, the **Consent Form** must include a statement of confidentiality or anonymity. Understand the difference between those two terms. If the data collection is conducted in such a fashion that participants are known to the researcher and the participants’ ID can be matched to his/her data, the data collection procedure can be described as *confidential*, provided you take the measure to keep it so. If not, then the data collection procedure is *anonymous*, provided you take the measures to keep it that way.
21. Regarding data records and record keeping, include a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, and how and where they will be secured. Be specific, including location, dates, persons who will have access. Do not make promises you cannot keep. The IRB includes a data security expert who will be assessing your security information you provide.
22. The location and length of time the survey data, videotapes, audio recordings etc. will be kept must be explicitly stated.
23. The **Consent Form** must state that a summary of the findings will be provided to participants upon completion of the study, if requested. Researcher should include instructions for participant with regard to how to access results of study.
24. In most circumstances, participants (or parent/guardian) and researchers must sign the **Consent Form**. If the data collection is to be conducted anonymously, then signed **Consent Form** must be collected separately from other data (e.g. surveys, experimental behavior, etc.). In some instances, a signed **Consent Form** might not be required/desired, but such instances must be approved by the IRB, requiring that the applicant provide the IRB with sufficient rationale for the complete omission of a signed **Consent Form**. The IRB may waive the requirement for a signed **Consent Form** for some or all participants if it finds either of the following:
	1. That the only record linking the participant and the research would be the **Consent Form**, and the principal risk associated with the study is the potential harm resulting from a breach of confidentiality. In that event, each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
	2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

However, in cases in which the requirement to have signed **Consent Form** is waived, the researcher must still provide participants with a written statement describing the research. This document is often a **Consent Form** with the signature lines removed.

1. If the data is collected via an internet-based survey, the **Consent Form** must be included for the respondent to review before starting the online survey. Furthermore, each participant must indicate that he/she fully understands the **Consent Form** and its contents before participation is allowed. This is typically done by including a “check box” or some similar “field” that would allow the participant to consent/agree to participate simply by clicking on the field/box.
2. Research that involves children must include documentation of “Assent.” This can be achieved by including a separate document that is intended to meet the federal mandates that require researchers to seek and obtain assent from minors for their participation in research when those minors are capable of providing assent (typically those who are 8 years old and older). Assent may also be acquired by including a signature line on the parental **Consent Form** for the minor to sign.
3. Participants must receive a copy of the **Consent Form** for all data collection protocols. For internet-based surveys, participants should be instructed to print the consent document for their records.
4. The **Consent Form** should contain signature lines for both the participant and the researcher.
5. The **Consent Form** must neither ask nor imply that subjects are waiving any rights or releasing you from liability. You are responsible for what happens to your subjects as a result of participating in your study.

**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
1. **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.

1. **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.

**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.]

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) and to Becky Northcut, Director, Research Integrity & Compliance (512-245-2314 - bnorthcut@txstate.edu).

Questions about this research should be addressed to [insert your name, phone number and email address.]

**MONITOR YOUR APPLICATION STATUS, LOGS, AND EMAIL**

**RESPONDING TO REQUESTS FOR REVISIONS**

**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:**

* 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 @ tx.state.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.

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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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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. Reviewer comments or requests will be sent to the IRB Chair, who in turn, will send you an email explaining what you need to do next.

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, and 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.”