

Checklist for Expedited IRB Application

To apply for IRB approval, the principal investigator must submit the appropriate completed application, finalized Subject Informed Consent form, any questionnaire(s) to be distributed, and appropriate release forms for biological or diagnostic specimens (if applicable). The purpose of the checklist is to facilitate the application approval process by ensuring that each investigator has completed the requirements set forth by the IRB Committee. Expedited review is allowed for research activities that involve no more than minimal risk to the human subjects and can be placed in one or more of the categories listed on the application form.

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Checklist:

- Complete the IRB Expedited Review application and Human Subjects Protocol (HSP) from the web (available at: <http://www.samford.edu/IRB/expedited.pdf>).
- Develop the Subject Informed Consent form. **NOTE:** The Subject Informed Consent form should be written in lay language. Examples of the Subject Informed Consent forms available at http://www.samford.edu/IRB/ic_example.html. Once the Subject Informed Consent form has obtained approval by the IRB committee and is stamped with the official Samford University IRB stamp, the form can NOT be changed. Information to include on the Subject Informed Consent Form:
 - ___ Title on the first line
 - ___ Introductory paragraph. Occasionally the following “generic” paragraph is used; however the introduction should be tailored to fit the individual study. An example of such follows: “Before agreeing to participate in this research study, it is important that you read the following explanation of (state your study). This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the program. It also describes the alternative treatments that are available to you (if applicable), as well as your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.”
 - ___ The body of the Subject Informed Consent form must contain statements addressing the following issues (please refer to <http://www.samford.edu/IRB/consent.html> for specific details):
 - ___ Study involves research
 - ___ Foreseeable risks or discomforts to the subject
 - ___ Benefits to the subject or other individuals as a result of the research
 - ___ Alternative treatments available to the subject (if applicable)
 - ___ Confidentiality
 - ___ Compensation for any possible injuries due to the research project (if applicable)
 - ___ Contact information for questions concerning the research project and in case of injury due to the project (should NOT be the principal investigator; include faculty advisor if student is principal investigator).
 - ___ Study participation is voluntary and refusal to participate or withdrawal from the study will involve no penalty or loss of benefits to which the subject is otherwise entitled.
 - ___ Add two lines for the subject to sign plus print his/her name. If the Subject Informed Consent form exceeds one page, place the signature lines on the last page. Also include on the bottom of all other pages the phrase “Participant’s Initials:_____”.
 - ___ Each page of the Subject Informed Consent form should be numbered using the “Page X of Y” style (even if all the information is contained on only one page).
 - ___ At the bottom RIGHT hand corner of EACH page of the Subject Informed Consent form, leave at least a 2” X 2” blank space. This area is to be used for the official Samford University IRB stamp.
- If the principal investigator is a student:** The principal investigator’s faculty advisor has reviewed finalized copies of the application and all project information or materials (i.e., questionnaire/survey).

- Submit the original plus 2 copies (collated into 3 separate packages) of the following materials to the office of the **IRB Chair (A & S, Pharmacy, Divinity) or IRB Chair-Elect (Law, Nursing, Education, Arts)**:
 - Completed IRB Expedited Review application and Human Subjects Protocol
 - Finalized** Subject Informed Consent form
 - Study objective plus research methodology/description
 - Finalized** questionnaire(s) or survey(s) (if applicable)
 - Completed specimen release forms (if applicable)
 - Completed drug release forms (if applicable)
 - Other **finalized** project information or materials (if applicable)
- All Subject Informed Consent forms signed by study participants must be kept by the principal investigator. These signed forms are subject to review by an IRB committee member.

Contact Information and Signatures:

_____ (Principal Investigator) _____ e-mail
 _____ (Print) _____ phone
 _____ Date

To be completed by the faculty advisor of a research project in which the student is the principal investigator:

I have read/reviewed this IRB application and all other project materials. All information is complete, accurate, and finalized.

_____ (Advisor) _____ e-mail
 _____ (Print) _____ phone
 _____ Date

PLEASE NOTE:

Complete and submit the Closure Form (<http://www.samford.edu/IRB/closure.pdf>) to the IRB Chair.

If this research project extends beyond 12-month after the approval date, a renewal IRB application form must be submitted to the IRB Chair.