

Checklist for Full IRB Application

To apply for IRB approval, the principal investigator must submit the appropriate completed application, finalized Subject Informed Consent form, and any questionnaire(s) to be distributed or appropriate release forms for biological or diagnostic specimens (if applicable). THE IRB APPLICATION CHECKLIST MUST BE COMPLETED AND SUBMITTED TO THE IRB CHAIR WITH THE APPLICATION. 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.

IRB Chair contact information:

IRB Chair contact information:

David Dedo, Ph.D.

BROOK 225

Howard College of Arts & Sciences/Communication Studies

(205) 726-2310

drdedo@samford.edu

Checklist:

- A contact number and e-mail address of the principal investigator must be provided below for the IRB Chair to inform the principal investigator of the next IRB meeting. The principal investigator will be required to attend this meeting to answer any questions regarding the research project. For meeting days, time, and place, see Meeting Schedule at <http://www.samford.edu/IRB/schedule.html>.
- This IRB application and materials must be submitted to the IRB Chair **at least 2-3 weeks** prior to the next IRB meeting.
- Complete the IRB FULL Review application and Human Subjects Protocol (HSP) (available at: <http://www.samford.edu/IRB/full.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/consentexample.pdf>. Once the Subject Informed Consent form has obtained approval of the IRB and is stamped with the official Samford University IRB stamp, the form can NOT be changed. Information to include on the Patient 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, 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 a signature line for the subject to sign and 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.

- Propose a panel of three appropriate persons not involved with the research project to serve as a Project Review Panel. The panel should include at least one member with specific professional competence pertinent to the area of study.
 - After ascertaining their willingness to serve, send a letter requesting approval of the panel to the IRB Chair listing the names of the proposed panel members with a brief statement of their qualifications. An example of this memo is located on the website listed above.
 - After approval of the panel by the IRB Chair, the investigator must meet face-to-face with this panel to critically review the protocol plus Subject Informed Consent form and complete the "Report of the Project Review Panel". This report is located on the website listed above.
 - Project Review Panel members must complete and sign the review form.
- 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 13 copies (collated into 14 separate large envelopes) of the following materials to the office of the IRB Chair:
 - Human subjects protocol signed by the investigator
 - Report of the Project Review Panel with Panel members' signatures
 - Detailed methodology (as per items 11-14 of protocol form)
 - Finalized** Subject Informed Consent form
 - Finalized** questionnaires or other project material to be used (if applicable)
 - Any special approvals (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.