## Steps to Obtain Institutional Review Board (IRB) Approval of a Research Study

**STEP 1:** Determine if your study is research requiring IRB review. See <u>Does My Project Require IRB</u> Review? on the IRB website.

**STEP 2:** CITI Training – You must complete CITI Human Subject training before you submit your protocol to the IRB. Once you have completed the training, a certificate will be issued, which you should save for your records. Notification of completion will automatically be sent by CITI to the GSRD Office.

Note: All members of the research team must complete training, including co-investigators, research assistants, and/or faculty advisors.

**STEP 3:** Prepare for submission to the GSRD Office your protocol package, which should include the following as applicable to your research:

- 1. Request for Review of Research Involving Human Subjects
- 2. Informed Consent, Parental Permission and/or Subject Assent forms
- 3. Copies of recruitment materials, including emails, flyers, letters, etc.
- 4. Copies of surveys to be used in the study
- 5. Copies of interview questions to be used in the study
- 6. List of variables that will be observed if biospecimens/biomarkers are to be collected
- 7. Debriefing Form (Required for studies involving deception)
- 8. Copies of all other materials to be used in the study, such as pictures, videos, and website URLs, etc.

NOTE: The Request for Review form and templates for Informed Consent, Parental Permission, Subject Assent and Debriefing form are available on the GSRD Forms webpage.

**STEP 4:** Sign your Request for Review form, then obtain the approval of your Department Chair or College Dean. If you are a student, your faculty advisor must also sign.

**STEP 5:** Submit your complete protocol package to the IRB Administrator (Michele Smith, Administrative Assistant of GSRD) for processing via email (smithmr@winthrop.edu).

Consult the IRB <u>webpage</u> for meeting dates of the IRB and when protocol packages must be submitted for consideration at those meetings.

**STEP 6:** IRB Communications – You will receive a "receipt" via email once your protocol package is received. This receipt will note whether additional information is needed or if CITI training is not complete. If everything is complete, the receipt will state that your protocol has been forwarded to the IRB Chair for review.

You will be notified via email of the IRB action on your protocol as either Approved, Exempted, Declined or if additional information is needed.