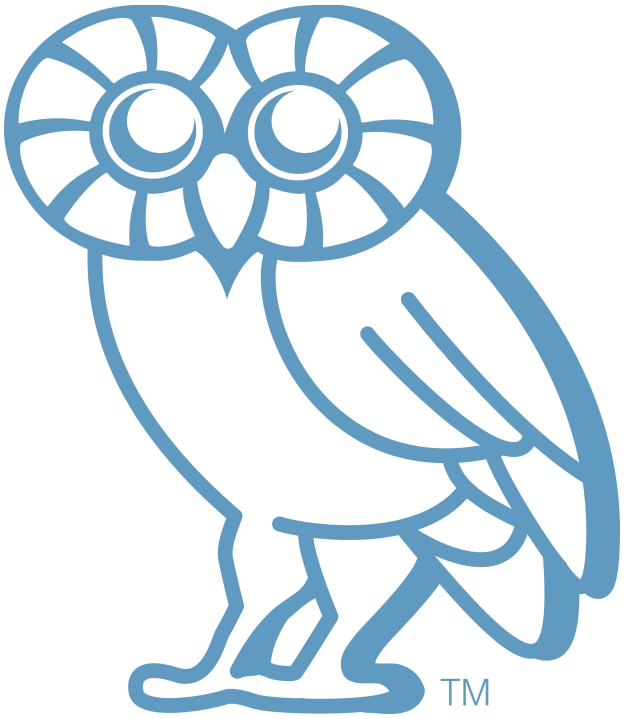

README (IRB)

Key Contact Information

- IRB related questions: IRB-IO@rice.edu
- IRBNet related questions: ERA@rice.edu
- **Stephanie Thomas**, IRB Compliance Administrator (sdt3@rice.edu | 713-348-3586)
- **John Cornwell, PhD**, IRB Chair (cornwell@rice.edu | 713-348-3227)
- **Hope Grant**, ERA Training Specialist (hcg1@rice.edu | 713-348-3801)
- **Elle Ristow**, ERA Administrator (elle.ristow@rice.edu | 713-348-3329)

SUBMISSION REQUIREMENTS

All research involving the use of human research subjects (participants) must be reviewed and approved by the Rice University Institutional Review Board (IRB) before the research can be initiated.

- Research means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; (see 45 CFR 46.102(d)).
- Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (see 45 CFR 46.102(f)).

The primary responsibility of the IRB is to assure that appropriate steps are taken to protect the rights and welfare of humans participating in research. The IRB functions according to the guidelines of the Office of Human Research Protection (OHRP) and other federal regulatory agencies. The IRB is a committee with representation from Rice University faculty and the community. With few exceptions, the Rice University IRB meets on the third Wednesday of every month during the academic year to review projects that require Full Board Review. Meeting dates are posted on the Research Compliance website, http://comp.rice.edu. Protocols that are eligible for Exempt and Expedited Review are processed on an ongoing basis.

Project Applications should be submitted in IRBNet for New Protocols, Modifications, Annual Renewals, and Unanticipated Events.
INCOMPLETE SUBMISSIONS CAN RESULT IN DELAYS IN THE COMMITTEE REVIEW PROCESS.

Informed Consent
When submitting a new protocol, please use the current Rice University Consent Form Template as a guide for your document. Refer to the instructions on customizing the template to your study. If your study involves fMRI, please use the fMRI Consent Form Template.
If you are requesting a Waiver of Informed Consent or a Waiver of Documentation of Informed Consent, you will be asked to justify this in the IRB Core Data Form in IRBNet.

Information for Students and Faculty Advisors
A faculty member or equivalent must serve as the Principal Investigator and sign the new project package in IRBNet before the project can be reviewed.

GENERAL PROTOCOL SUBMISSION PROCESS

All submissions must be complete prior to review and approval. (Note: incomplete submissions cannot be processed and may result in significant delays for the researcher). It is strongly recommended that applications be submitted at least three – four (3-4) weeks prior to the date the research is scheduled to begin.

Exempt and Expedited Studies

There is no receipt deadline for studies that qualify for exempt or expedited review. For complete applications that require no revisions, review and approval may be granted within 2 weeks. This timeframe can vary.

Full Board

For projects requiring full Board review, submissions must be received by the submission deadline date in order to be reviewed at the respected Full Board Meeting date. Please note that complete and ready applications will only be reviewed at the meetings. Please refer to the IRB compliance website for specific dates, comp.rice.edu.

The following items are necessary for a complete submission for all New IRB Reviews (projects that have not been reviewed and approved by the IRB):

- A complete protocol application form submitted electronically via IRBNet by the Principal Investigator and signed by all applicable study personnel
- Informed Consent for all applicable study populations
- All recruiting materials (i.e. flyers, radio scripts, etc)
- All questionnaires and/or surveys
- Students may not serve as Principal Investigators on protocol applications, but may be listed as
- Co-investigators with their faculty advisor serving as the Principal Investigator.
  Some studies may require other items such as documentation of permission to work in a school,
- IRB approval from a collaborating institution, etc.
  All applications and forms must be submitted electronically via IRBNet to Rice University IRB Board

TYPE OF IRB REVIEW

There are three types of review that new projects can be reviewed under. The IRB will determine the appropriate review in accordance with the determined risk to the participants.

Exempt Review
Some studies may qualify as exempt if they qualify under specific categories for exempt review . If this is selected, the IRB will ultimately determine if the project qualifies for exempt review.

Expedited Review
Protocols that do not meet the criteria for exemption may qualify for Expedited Review. These are minimal risk studies that that fall into one of eight categories set forth in federal regulations (45 CFR 46.110).

Full-Board Review
Protocols that are greater than minimal risk research or do not meet the exemption or expedited criteria discussed above must go to the Full Board for review. Annual Reviews will be reviewed by the Full Board as well. Some modifications, if they do not pose greater risk to participants, may be reviewed by expedited review.

TYPE OF APPLICATIONS

For all IRB Projects, the process involves the below:

STEP 1: Download all necessary applications, appendices and templates from IRBNet

- Please refer to the website for specific format instructions and refer to the IRBNet Resources for more information about the electronic submission process
- Complete all necessary documents and save them for attaching later.

STEP 2: Prepare application in IRBNet

- Complete the online document "Rice IRB Core Data Form"
- Upload all completed supporting documents, templates and appendices to the protocol or registration in IRBNet

A. New Projects

New Projects must be submitted via IRBNet. Select Create New Project and complete the applicable sections.

B. Modifications to an Approved Protocol

Any changes to a current approved project must be reviewed and approved by the IRB before the can be implemented, except where necessary to prevent apparent immediate hazards to study participants. Changes to the project will need to be submitted via IRBNet. If you have a question about the need to submit a modification, please contact the IRB Compliance Administrator.

Modifications that require IRB review and approval:

- New location for conduct of the study
- A change in investigators
- Changes to questionnaires
- Changes to recruiting materials
- Changes in study design (e.g. adding a new type of study activity or change in participant population)

Items that need to be submitted for a modification:

- Revised IRB Application (smart form)
- Modification form (can be found in Document Library in IRBNet)
- Any supporting materials that are changed such as:
  - Updated consent form
  - Updated and/or new questionnaires, surveys
  - Updated and/or new recruiting materials

C. Continuing Review / Annual Renewal

Federal regulations require that IRB approved protocols be reviewed and approved no less than once every 12 months. IRBNet will send out automatic reminder notices 90/60/30/14/1 day(s) prior to and the

date of expiration. The Principal Investigator is responsible for a timely renewal application submission in order for the IRB to complete an adequate review and approval.

D. Unanticipated Event

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants participation in the research, whether or not considered related to the participant's participation in the research. Adverse events can be both physical and psychological harms and however they occur most commonly in the context of biomedical research, occasionally, they can occur in the context of social and behavioral research.

IRB APPLICATION REQUIREMENT MATRIX

R = Required | **O** = Optional (depending on type of change)

STUDY TYPE >>>	A. New Projects	B. Modifications to an approved protocol	C. Continuing Review / Annual Review	D. Unanticipated Event
Rice IRB Application (Smart Form)	R	O[1]	O[2]	
IRB Modification Request Form		R		
IRB Annual Review Form			R	
IRB Unanticipated Event Form				R

O[1]: If all the changes that you plan to make cannot be captured in the IRB Modification Request Form, which can be found in the IRB Document Library, you must create a new project package, clone the previous package, make appropriate changes, and submit it.

O[2]: If all the changes that you plan to make cannot be captured in the IRB Annual Review Form, which can be found in the IRB Document Library, you must create a new project package, clone the previous package, make appropriate changes, and submit it.

CHECKLIST

- Did you share your project with all personnel listed on the project?
- Did everyone sign the package?
- Are all training credentials and records linked for all personnel?

TRAINING REQUIREMENTS

All personnel involved in Human Subjects Research that is under the purview of the Rice University IRB must demonstrate completion of an education program on the use of human participants in research. This training is completed through the Collaborative Institutional Training Initiative (CITI). This program is includes material for both social and behavioral researchers; biomedical researchers; and student researchers and is recognized and transferable among numerous institutions.

As of September 1, 2011, anyone from Rice University who will be involved in human subject's research must complete the appropriate CITI course. People who have previously completed the NIH human subjects training or the earlier version of the online Rice training are not required to complete the CITI training modules.

To complete the required education go to CITI's website.

- Select Rice University as your "participating institution" and create an account.
- When you have created an account you will be directed to a page titled "Select Curriculum" which displays a list of courses on Human Subjects Research: Biomedical Research Investigators; Social & Behavioral Investigators; Student Researchers; Data or Specimens Research Only; and IRB Members. Choose the human subject research module most appropriate to the type of research you conduct.
- The course may take a few hours to complete but can be done over a period of time. When you complete the course, CITI will e-mail your completion record to the Rice University IRB.

If you have done CITI education for another organization, add Rice University to your profile. You will be given credit for your previous courses to the extent that they overlap with Rice University's requirements. CITI Training will also need to be linked to your profile in IRBNet.