Research Compliance for Graduate Proposals that involve Human Subjects

Institutional Review Board

Human Research Protection Program

Director - Aliese Seawright, M.S., CIP

When is IRB Review Required?

- *First, the project has to be research:*

  Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- Second, it has to involve human subjects:

  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.

Intervention or Interaction

- *Intervention* includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

  (examples: research on new educational tests or techniques, new treatments or new products on humans; varying behavior modification techniques; exposing humans to a physical or chemical stimulus; manipulating public or private spaces including websites;)

- Interaction includes communication or interpersonal contact between investigator and subject.

  (examples: surveys, focus groups, interviews, online or remote communications;)

Private Information

- *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; and

- Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, health records; educational records; employee records).

- Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects

HRPP Guidance

A detailed guide that includes list of activities and whether or not they generally require IRB review can be found in HRP SOP-093 posted on the HRPP website:

http://rcb.tamu.edu/humansubjects/forms/HRP093SOPActivitiesthatRequireIRBReview.pdf

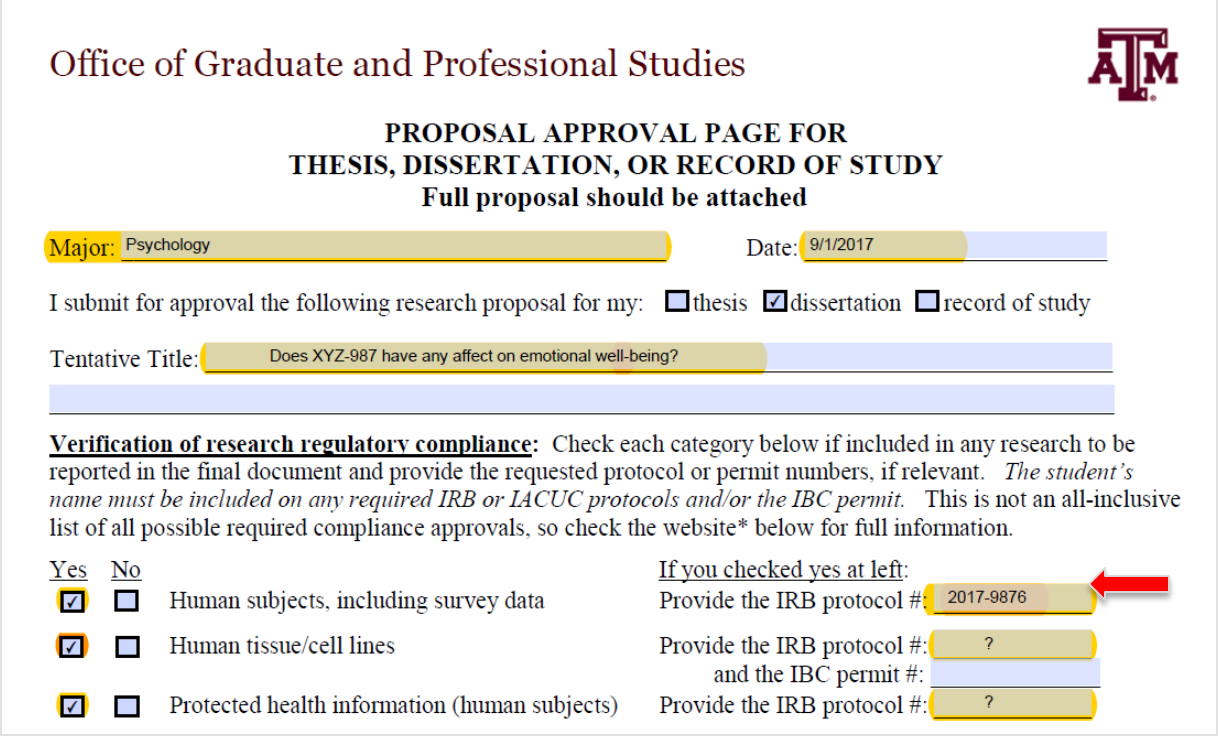
If unsure whether or not an activity is human subjects research and requires an IRB application, please contact the IRB staff at:

979.458.4067

irb@tamu.edu

Process for Compliance

- Identify whether or not the proposal involves research with human subjects.
- If yes, human subjects research is involved, the student must be listed on an active IRB study that is congruent with the student's proposal.



Office of Graduate and Professional Studies

PROPOSAL APPROVAL PAGE FOR
THESIS, DISSERTATION, OR RECORD OF STUDY
Full proposal should be attached

Major: Psychology Date: 9/1/2017

I submit for approval the following research proposal for my: ☐ thesis ☑ dissertation ☐ record of study

Tentative Title: Does XYZ-987 have any affect on emotional well-being?

Verification of research regulatory compliance: Check each category below if included in any research to be reported in the final document and provide the requested protocol or permit numbers, if relevant. *The student's name must be included on any required IRB or IACUC protocols and/or the IBC permit.* This is not an all-inclusive list of all possible required compliance approvals, so check the website* below for full information.

Yes	No		If you checked yes at left:
☑	☐	Human subjects, including survey data	Provide the IRB protocol #: 2017-9876
☑	☐	Human tissue/cell lines	Provide the IRB protocol #: ? and the IBC permit #:
☑	☐	Protected health information (human subjects)	Provide the IRB protocol #: ?

Process for Compliance

The OGAPS Proposal Approval Page can be stamped '**Approved**' by the HRPP when:

- The form is complete and has the required signatures
- The IRB number for an active study has been provided
- The student is listed as a member of the study team
- The study information and the student's proposal are congruent
- The proposal has been reviewed by all three compliance groups:

  - ✓ Human Research Protection Program – IRB
  - ✓ Animal Welfare Office
  - ✓ BioSafety Office

Process for Compliance

If an IRB project has not been identified on the proposal approval page, the student will be contacted to let them know that one of the following actions must occur to meet the compliance requirements for human subjects:

1) The student can be added to a current IRB study that is congruent with their proposal through a '**Personnel Change Request**'. This request is initiated by the study's principal investigator and processed through **iRIS**.

2) A new IRB study application must be open through **iRIS**.

Process for Compliance

When creating a new IRB application:

- The student must include a faculty member as the principal investigator of their projects even though the student may carry-out many of the protocol related functions as a 'protocol director'.

- Students will be required to complete human subjects training in **CITI** and sometimes **TRAINTRAQ** modules prior to submitting the IRB application. The number and type of modules required depends upon the type of research being proposed.

- Students should refer to the guidance on the HRPP website posted under FAQs or the HRPP Investigator Manual for complete information. http://rcb.tamu.edu/humansubjects/faqhumansubjects

Tips for Success

Do not wait till the proposal is completely written to start an IRB application. Students often comment that creating the IRB application helped them write a better proposal.

Clearly define in detail the origin or source of any human materials (specimens, cells or data).

Clearly define the method of obtaining any human materials or data and all entities involved in the process.

Do not participate in human subjects research prior to receiving IRB approval. This will be considered non-compliance with federal and institutional rules.

Remember, a delay in the IRB application may jeopardize defense dates and graduation plans.

HRPP Contact Information

email: irb@tamu.edu

Phone: 979.458.4067

http://rcb.tamu.edu/humansubjects

HRPP liaison for OGAPS – Denise Puga, PhD.

denisepuga@tamu.edu

979.458.5590