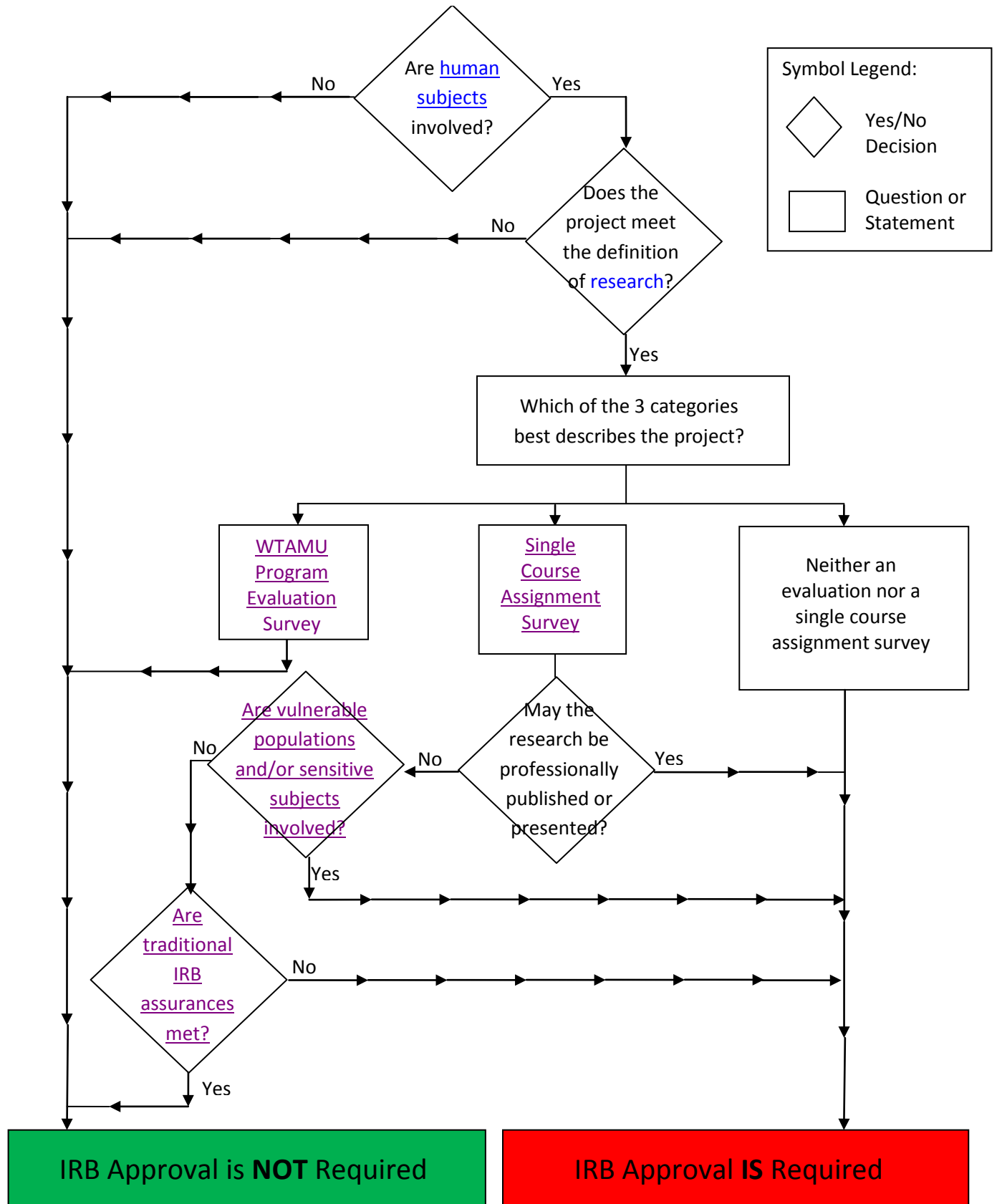


Flow Chart for Determining if a Research Proposal Requires Submission to the WTAMU IRB for Approval



Flow chart designed for West Texas A&M University by Dr. Gary Bigham

[Return to IRB Home](#)

Definitions

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

[Return to IRB Flowchart](#)

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 includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *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, a medical record). 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.

[Return to IRB Flowchart](#)

IRB EXEMPTION FOR SURVEYS

Surveys that are conducted by students as a single course assignment under the supervision of the course instructor are exempt from IRB review under the following conditions: (a) Participation is voluntary, confidential, and without penalty or reward; (b) the survey does not involve vulnerable populations (e.g., children, mentally disabled, institutionalized elderly, disadvantages persons, or prisoners; (c) the survey does not deal with sensitive aspects of the respondents behavior such as illegal conduct, drug use, or sexual behavior.

Surveys conducted by WTAMU and its colleges, divisions or departments for the purpose of program evaluation and institutional effectiveness are exempt from IRB review.

To help determine if your survey is exempt from IRB review, we suggest you answer the following questions:

If any of questions 1-3 are answered "YES," the survey must be submitted to the IRB for approval.

QUESTIONS:

1. Does the survey involve any of the following?

- Children under the age of eighteen.
- Mentally disabled persons.
- Institutionalized elderly.
- Economically or educationally disadvantages persons.
- Persons with limited civil freedoms such as prisoners, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline

2. Does the survey require disclosure of any of the following?

- Illegal conduct.
- Drug use.
- Sexual behavior/sexually transmitted diseases

3. Could the subject's responses, if made public, place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability?

If any of questions 4-9 are answered NO," the survey must be submitted to the IRB for approval.

QUESTIONS:

4. Do you assume responsibility for the survey?

5. Do you assume responsibility for the preparation and training of students or staff administering the survey?

6. Is participation voluntary?

7. Is the confidentiality of the participants preserved?

8. Is there a written statement accompanying the survey informing participants of the following?

- A statement of the nature, purpose, procedures, risks, and benefits of the survey.
- A statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.
- A statement assuring the subjects their participation is voluntary and does not carry any rewards or penalties.
- A statement assuring the subjects their participation is confidential and their participation will not be used in determining grades, employment, promotions, etc, as warranted by the situation.
- A means by which the investigator(s) may be contacted (e.g. phone number, P.O. box number, address).

9. If the survey involves another agency or institution, has agency approval been obtained?

[Return to IRB Flowchart](#)