DOES YOUR RESEARCH PROJECT REQUIRE IRB APPROVAL?

A Guide for Investigators

West Texas A&M UNIVERSITY

INSTITUTIONAL REVIEW BOARD

www.wtamu.edu/irb

This booklet provides guidance to WTAMU investigators who may be uncertain if their study meets the definitions of human subjects research as stated in the federal regulations (45 CFR § 46.102). The WTAMU IRB recognizes that the definition may not always provide a straightforward answer. ***Does Your Research Project Require IRB Approval? A Guide for Investigators*** offers researchers an explanation of the definitions as well as examples of studies that do or do not qualify as human subjects research. For further information, please refer to the WTAMU IRB website at www.wtamu.edu/irb.

HUMAN SUBJECTS RESEARCH

Research projects involving human subjects require **review and approval** by an Institutional Review Board (IRB). An IRB is an ethics committee composed of scientists and non-scientists who serve as advocates for human subjects involved in research. The IRB is charged with the responsibility of reviewing and overseeing human subjects research conducted under the aegis of West Texas A&M University. The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of human subjects research. In light of the mission to protect human subjects, and the potential regulatory consequences of not obtaining IRB review and approval, **the investigator should choose to err on the side of caution and consult with the IRB when he/she is uncertain whether the study is human subjects research or not.**

DEFINING RESEARCH

Federal Regulations define **research** as **"a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"** (45 CFR § 46.102(d)). As described in the Belmont Report "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn (quantitative methods) or to generate hypotheses by describing extant phenomena (qualitative methods)... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective."

"Research" generally does **not** include operational activities such as defined practice activities

in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. It generally does not include journalism or political polls. **However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.**

DEFINING HUMAN SUBJECTS

A **human subject** is defined by Federal Regulations as **"a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information"** (45 CFR § 46.102(f)(1-2)).

Living individual – The specimen(s) / data / information must be collected from live subjects.

"About whom" – a human subjects research project requires the data received from the living individual to be about the person.

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.

Interaction includes communication between the investigator and the subject. This includes face-to-face, mail, email, and phone interaction as well as other modes of communication.

Identifiable private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom) "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 health care record)" (45 CFR § 46.102(f)(2)). **"Identifiable" means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual** (e.g. Social Security #).

Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may **not** constitute human subjects research if individuals are not identified (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

However, **the prudent investigator will check with the IRB before making any assumptions.**

Studies based on data that are individually identifiable, but are also publicly available, may **not** constitute human subjects research. However, the term "publicly available" is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

IDENTIFYING HUMAN RESEARCH STUDIES

Certain studies may have the characteristics of human subjects research but may not meet the regulatory definition.
There are three categories to be considered:

- **studies that are human subjects research**
- **studies that may be considered human subjects research (gray area)**
- **studies that do not qualify as human subjects research**

An IRB determination flowchart is provided at the end of this document and available on the WTAMU IRB website at www.wtamu.edu/irb to assist you in determining whether your study qualifies as human subjects research. Any investigator who is unsure of whether his/her proposal constitutes "human subjects research" **should contact** the WTAMU IRB. The IRB staff, chair and/or designee will assist you in determining if the study is human subjects research.

If a study does not qualify as human subjects research, the IRB can issue a written notification (email or letter) stating that the project does not require IRB review or approval. *Note: Grant offices, faculty advisors, or publications may require a determination letter from the IRB.*

Once the determination has been made that a study **is** human subjects research, the investigator must choose the appropriate type of review to request of the IRB.

The Exempt Review is used in research that exposes human subjects to very little to no risk beyond that of everyday life. Although these studies may be exempt from the requirements set forth under 45 CFR § 46 (CFR § 46.101(b)), the Office of Human Research Protections (OHRP) recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt. Accordingly, the WTAMU IRB policy requires that **ALL** human subjects research be approved by the IRB.

The investigator may determine if his/her study is exempt **from review** by establishing that the research does not include human subjects. However, if human subjects are used in research in any way—even those studies meeting the definition of an exempt review—approval must be granted by the IRB **before** data collection may commence.

The Expedited Review is used when human subjects in research are exposed to no more than minimal risk (CFR § 46.110(b)). For this type of review, risks to human subjects must be minimized and must be reasonable in relation to anticipated benefits and knowledge gained from the research. Human subject selection must be equitable, and informed consent must be obtained and documented (CFR § 46.111(a)).

The Full Board Review is required when risks to human subjects used in research exceed those identified in exempt and expedited reviews. In short, when a proposal fails to qualify for either an exempt or expedited review, a full board review must be conducted.

EXAMPLES OF HUMAN SUBJECTS ACTIVITIES QUALIFYING FOR AN EXEMPT REVIEW

1. Research conducted only in established or commonly accepted educational settings (like classrooms) **AND** involving normal educational practices such as research on regular and special educational instructional strategies, or research on the effectiveness of, or the comparison among, instructional techniques, curricula or classroom management methods.
2. Research that involves the use of only educational tests (cognitive, diagnostic, aptitude, achievement); or survey or interview procedures; or observation of public behavior so long as the information obtained will be recorded in such a manner that subjects *cannot* be identified *directly or through identifiers linked to the subjects*; or any disclosure of the subjects' responses outside the research could not reasonably place the subject at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation (e.g., information regarding illegal or immoral conduct, drug or alcohol use, sexual behavior, mental illness, or other possibly personally embarrassing subjects); or the subjects are elected officials or candidates for public office.
3. Research that is limited to the collection or study of existing data, documents, records, pathological, or diagnostic specimens if they are available to the public; or they are recorded *by the investigator* in such a manner that subjects *cannot* be identified, *directly or indirectly*, through identifiers linked with the subjects.
4. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed; or a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXAMPLES OF HUMAN SUBJECTS ACTIVITIES QUALIFYING FOR AN EXPEDITED REVIEW

Expedited reviews may be conducted on projects involving no more than minimal risk, where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples include the following:

1. Clinical studies of drugs and medical devices only when certain conditions are met.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) excreta and external secretions (including sweat); (c) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (d) placenta removed at delivery; (e) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (f) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (g) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes *(such as medical treatment or diagnosis)*.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

EXAMPLES OF ACTIVITIES REQUIRING A FULL BOARD REVIEW

When the risks to the human subject are elevated beyond minimal, a full board review is required. Examples include:

1. Studies intended to evaluate the safety and effectiveness of the medical device, including studies of cleared medical devices for new indications.
2. Studies that involve human subjects for testing new devices, products, drugs, or materials.
3. Prospective collection of biological specimens for research purposes by invasive means.
4. Studies that collect data through intervention or interaction with individuals. Examples: drug trials, studies requiring alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, studies requiring strenuous exercise, and open-ended interviews with minors that contribute to generalizable knowledge.
5. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
6. Studies that use human subjects to evaluate environmental alterations. For example, making changes to a living or working space (e.g. changing the temperature).

Essentially any human subjects research that does not qualify for an expedited review requires a full board review before any data may be collected.

EXAMPLES OF ACTIVITIES THAT ARE NOT HUMAN SUBJECTS RESEARCH

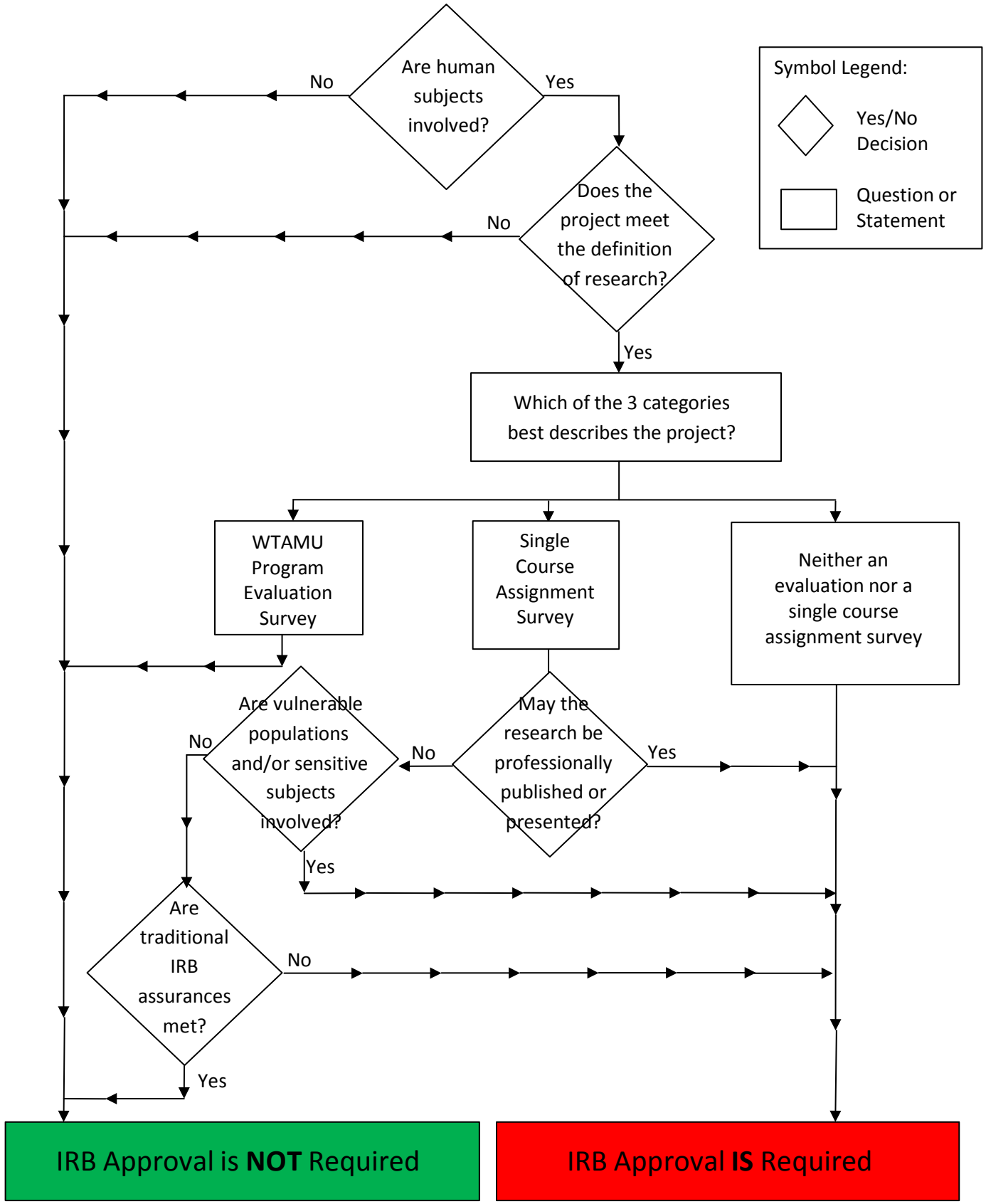
Activities that fit any of the categories below **do not** need IRB review.

1. **Data collection** for internal departmental, college, or other university administrative purposes. Examples: teaching evaluations, customer service surveys. However, in the event that the data are later used for purposes of research, IRB review **IS** required.
2. **Service surveys** issued or completed by university personnel for the intent and purposes of improving services and programs of the university or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or university consortia. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.*
3. **Information-gathering interviews** (through interviews, surveys, etc.) where questions focus on things, products, or policies rather than people or their thoughts. Example: asking company officers to provide data about company facts (such as number of employees) or to provide copies of company policies. *Note: If the study involves collecting the officers' opinions of company policies (e.g. in your opinion, is the policy effective?), then the study will need IRB review.*
4. **Single course assignment surveys** administered by students, where data are collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom (professionally published or presented) **only if** no vulnerable populations and/or sensitive subject are involved **and if** traditional IRB assurances are met.
5. **Publicly available data** may not require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as "publicly available." An investigator should **not** assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.*

For more information, visit the West Texas A&M University IRB website

www.wtamu.edu/irb

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