1. **Who serves on the IRB?**

IRB members are appointed for one-year terms, and may be reappointed for successive periods. In accordance with applicable federal regulations, the Board must have a minimum of five members, including at least one individual who would be considered a non-scientist. Members are selected from faculty, staff, students, and community members. Considerable effort is expended to recruit individuals who have expertise in different areas. This diversity helps to ensure that protocols are evaluated fairly by knowledgeable individuals. If necessary, non-voting consultants may be enlisted to review specific protocols for which there is no IRB member with sufficient knowledge of the research method or scientific discipline to conduct a substantive review. The current composition of the board (October 2013) is:

- Jeff Dennis Ph.D (Chair) Assistant professor of Sociology
- Lewis Busbee MA, LPC - SAS counselor ECISD, prn Crisis for Oceans Behavioral Health
- Janet Carter Ph.D - Assistant professor of Education Counseling
- Rachel Harlow Ph.D - Assistant Professor of Communication
- Jamie Hughes Ph.D - Assistant Professor of Psychology
- Dorothy Jackson Ph.D, RN - Director of Nursing
- Jim Olson Ph.D - Professor of Psychology
- Joe Stauffer Ph.D - Associate Professor of Management
- Brandon Walker-Price - MPA, Graduate Student

2. **Upon what federal regulations is IRB policy based?**

The primary regulation that pertains to human subjects research Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). This statute defines relevant terms and describes all aspects of human subject protection, including the composition of review boards, criteria for protocol review, guidelines for informed consent, requirements for record-keeping, special protections for vulnerable populations, types of review, and procedures for dealing with non-compliance. It is based on the ethical principles identified in the Belmont Report. As written, 45 CFR 46 applies only to federally funded research, however, UT Dallas maintains an agreement with the federal Department of Health and Human Services (DHHS) that extends the protections of 45 CFR 46 to all research conducted by University personnel, regardless of the source of funding, or lack thereof. This agreement is the Multiple Project Assurance (MPA) and is required before the institution may receive federal research funds.

If a protocol includes the use of FDA-regulated drugs, devices, or biologics, then Title 21 of the Code of Federal Regulations (21 CFR) is applicable. The terms described in 21 CFR and 45 CFR 46 are similar in many ways, but there are important differences that investigators should be aware of (comparison of regulations).
3. **What is the Belmont Report and how has it influenced federal regulations regarding the protection of human subjects?**

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (I) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (II) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (III) appropriate guidelines for the selection of human subjects for participation in such research and (IV) the nature and definition of informed consent in various research settings. The Belmont Report attempts to summarize the basic ethical principles (respect for persons, beneficence, and justice) identified by the Commission in the course of its deliberations. Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of the Department of Health and Human Services (formerly the Department of Health, Education, and Welfare). Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy.

4. **How do the ethical principles identified in the Belmont Report relate to human subjects protection?**

*Respect for persons:* Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information (informed consent). Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated (e.g., assent of the subject, permission from a parent/guardian).

*Beneficence:* Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the
improvement of knowledge and from the development of novel medical, psycho-
therapeutic, and social procedures.

**Justice:**
Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

5. **What are the criteria for IRB review of a protocol?**

When reviewing a protocol, the IRB must make the following determinations:

1. **Risks to subjects are minimized:** (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable in relation to anticipated benefits,** if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. **Selection of subjects is equitable.** In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant
women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6. When is an IRB review required?

IRB review is required whenever an investigator who is affiliated with the institution conducts research with human subjects. Research is defined in 45 CFR 46 as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Student projects are considered to be research whether or not there is intent to disseminate study results, if all other conditions are met. A human subject is defined in 45 CFR 46 as "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". Individuals who provide information for research that is not about themselves are not considered to be human subjects in this context. While researchers should take steps to ensure that these individuals are not placed at risk, it is not necessary for the IRB to approve their participation.

7. Once the board reviews my study, when can I start enrolling subjects?

If the board has asked for revisions, you will receive a letter outlining the revisions that are needed. When the revisions have been completed, reviewed, and approved by the IRB, they will sign your application for approval. Once you have received the signed application, you may begin enrolling subjects.

8. What is informed consent?

Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will
understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The prospective subject should be presented with the information, and then given an opportunity to ask questions and have them answered, prior to signing the consent document.

9. What is the procedure for conducting research at a local public grade school or charter school?

The UTPB IRB welcomes research at neighboring schools, although it is imperative that we meet certain criteria to protect all individuals involved and maintain good relationships with all of these institutions.

First, you will be expected to provide approval from the district central office, either a superintendent or similar person with authority to permit research at a school. A school principal’s permission is not sufficient to authorize your research, although it is generally appropriate to provide principal’s permission as a supplement, because they should also approve of research taking place on their campus.

For private schools, a head administrator’s approval, including signature on letterhead, with full contact information should be provided.

If you will be conducting research on students, i.e., individuals under the age of 18, you will have to obtain parental consent for each participant. As such, make sure that your consent form is addressed to the parent, noting what the child will be expected to do should they consent to his/her participation. Ideally, you should also have an age appropriate script for minor participants to agree to participate. This script would be considered “assent”, since a minor cannot legally give consent.

Research at a day care or childcare facility should generally follow the same protocol as schools, providing administrator or director’s approval. Again, use parental consent/child assent forms as appropriate. Many examples of these types of permission forms exist online, but the IRB can direct you to examples should you fail to find appropriate documentation.

10. What is the protocol for conducting research at a community organization or business?

Each case will be different, depending on the risk or nature of the study. However, similar to school research, we request written permission from a head administrator, manager, or owner (as appropriate), with full contact information. It will be your responsibility as the researcher to detail in your IRB application whether they will have access to your data or results.

If you work at this place of business, please outline your position there. We must consider issues of coercion and data security, and your place within that organization may be relevant to the degree to which individuals feel their participation is voluntary.
Similarly, if you do not work for the organization, but are accessing it for your research because of someone you know, e.g. a friend or family member, please outline his or her position with that organization as well.

11. Do I qualify for exempt review? If my project is exempt, does that mean that I do not have to submit an application to IRB?

This is a commonly misunderstood designation. An exempt review is a designation of IRB review that meets standards as defined by 45 CFR 46.101 of the Dept. of Health & Human Services regulations. In short, an exempt review is one that is deemed to be of minimal risk and therefore does not merit a review by the full IRB. Importantly, exempt review applications are still reviewed by the IRB, but they typically take less time because they do not require a full board decision. The determination of exempt status must be made by the IRB, so all research involving human subjects still requires an application to the IRB, even if you think it qualifies as exempt. The IRB will determine exempt status based on the description in your IRB application, and we will proceed with the process based on that designation.

In some cases, the IRB chair may conclude that your proposed research activity does not qualify as human subjects research. In this case, such a project would not be deemed IRB exempt, but rather classified as being outside of IRB purview. If you are unsure if your research deals with human subjects, please contact the IRB chair for guidance.

Applications will be classified as requiring full IRB review, exempt IRB review, expedited IRB review, or not requiring IRB review.

12. Do I need to tell the IRB that my project is exempt?

All applications received by the UTPB IRB are reviewed for exempt status. As such, you do not need to indicate this on your application. However, you are welcome to mention in your submission email that you believe the project should qualify for exempt review.

13. I plan to collect data at universities/colleges other than UTPB, what is required for approval of this type of project?

Each IRB application is judged on specific elements of its research methodology and recruitment, and as such, there is no singular rule for this type of research. However, for the general case, we recommend the following:

Assuming you will collect data at UTPB, you should submit your IRB application with a primary focus upon how you will collect data at UTPB. You may mention that you eventually plan to collect data at other universities, but understand that UTPB IRB does not have jurisdiction over research carried out at other universities.
Once you have approval to collect data at UTPB, the IRB will provide you with documentation of your approved research. If your project requires a formal signed letter from the IRB chair, please request one. With that letter, you may then contact the IRB at other institutions where you want to collect data, noting your existing approval. Often you will need a faculty contact at each university who has volunteered to help you in your data collection. In some cases, other institutions may grant approval based on your existing IRB approval through UTPB. However, please note that each university IRB has the authority to govern research at their institution, and may require a full application or other documentation before approving your project.

14. I am a researcher at a university or institution other than UTPB, and I would like to survey UTPB students/faculty/staff, do I need approval from the UTPB IRB to collect my data?

Yes, although depending on the situation, procedures required for approval may differ. First, in most cases we would expect you to have a UTPB faculty or staff member who is serving as your point of contact or representative with UTPB. That is, we would expect in many cases that a faculty member at UTPB might be helping you collect data, and this relationship will aid the approval process.

If you have existing IRB approval at your own institution, you may provide that information to us, along with relevant details about your study, and from there, we will work with you to gain approval for your study. In some cases, we may ask for additional details to ensure protection of participants at UTPB.

If you do not have existing IRB approval at another institution, then you will need to have a faculty sponsor at UTPB whom you are working with, and through whom you will submit a full application to the UTPB IRB.

15. Can I waive informed consent on my study?

Yes, the UTPB IRB considers requests to waive consent in circumstances where it is justified. Please provide ample detail or documentation as relevant to demonstrate why your research necessitates a waiver of informed consent. Requests for waiver of consent will be evaluated based on regulations outlined in Dept. of Health and Human Services 45 CFR 46.117. [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117)

16. I plan to conduct a pilot study (or feasibility study) to guide a larger research project. Does this require IRB review?

Often individuals assume that pilot studies do not require IRB approval. However, as long as the pilot study uses human participants in some form, it should be reviewed by
the IRB. It is in the best interests of all involved parties that all human subjects research be reviewed by the IRB.

If you are unsure if your study or pilot study requires IRB review, please contact the IRB chair for guidance.

17. I am a professor who intends to collect data for an assessment of one of my classes. Do I need IRB?

As with many of these questions, the answer may differ depending on the situation. You may always contact the IRB chair for guidance.

However, in general, if you are doing a classroom assessment for your own pedagogical assessment, or for institutional assessment purposes, this work traditionally is not considered human subjects research, and therefore would not need approval by the IRB.

Alternatively, if you would like to present, publish, or disseminate this information beyond the above parameters, you may submit an IRB before collecting the data (this option is preferable) or you may submit an IRB after the data has already been collected, if you decide after the fact that you want to use the data for purposes beyond your original pedagogical assessment.

Again, the IRB chair may be able to work with you to help determine which category your research falls into.

18. I am a professor who has assigned a class to complete research activities that may include contact with human subjects. Do I need to complete an IRB application for the class as a whole, or must I require each student to complete one independently?

Given the spectrum of possibilities for such a project, there is no “rule” that can be applied to this question. However, we can provide some guidance.

For course projects that involve students individually performing similar human subjects research (e.g., everyone interviews a public sector worker, an entrepreneur, etc.), it may be useful for the instructor to submit a single IRB application for the class detailing what information will be gathered.

It will often be appropriate for the instructor to create an informed consent template to be used by all class members. Secondly, you should describe what instructions you will give students to guide research, including any ethics training. You may ask students to complete the NIH online training module or other appropriate training for the project.

For classes where students will be doing projects using a variety of methodological approaches, it may be most appropriate for students to submit separate IRB applications.
The IRB will be glad to work with you to decide what approach best suits your class needs.

19. Does focus group research require IRB approval?

Yes, focus group research at UTPB qualifies as human subjects’ research. You should submit a standard IRB application detailing methods, recruitment, consent, etc. A common concern of the IRB often involves how disclosures of potentially sensitive information will be handled, given that focus groups are not anonymous. You should be prepared to consider management of such instances, depending on the subject matter of your proposed focus group. For example, if a focus group among workers in an organization brings out mention of illegal activity, how will you manage that information as a researcher?