**Response to IRB Reviewer Comments, Round 1**

*I have not submitted revised documents for review, but instead am addressing the reviewer’s concerns in this document by providing additional information. I hope that I am providing enough additional detail for the reviewers to be satisfied that this research design presents minimal risk to student participants and incorporates the ethical concepts of respect for persons, beneficence and justice in a manner consistent with federal regulations and accepted educational research practices.*

**Reviewer comments received:**

Comment 1: The consent form should conform to the requirements as outlined on the IRB webpage (<http://www.txstate.edu/research/orc/humans-in-research/checklist.html>); otherwise, approved. Good luck with your research.

Comment 2: The consent form is insufficient because it doesn't meet the requirements set forth by the IRB. Perhaps the Texas State researchers might consider devising their own research consent form and exclude under 18 year old students so they won't have to get parental consent. Researchers’ access to student's private information and the possibility of children (under 18 years old) among the participants negates any possibility of waiving the proper consent form.

**Researcher’s responses:**

In response to comments regarding the format of the consent form (“The consent form should conform to the requirements as outlined on the IRB webpage” by Reviewer 1, and “The consent form is insufficient because it doesn't meet the requirements set forth by the IRB” by Reviewer 2, I submit the following:

According to the federal regulations as specified in 45 CFR 46, the following information must be provided during the informed consent process:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

This is addressed by both the script to be read by the researcher (as described in the response to question #3 in the synopsis submitted previously) and the consent form that will be distributed with each survey. While the word “research” does not appear in either document, it is clearly discussed as a “study.” According to www.thesaurus.com, “research” and “study” are synonymous.

Details are also provided during the consent process about the topic of the survey, what the results will be used for, and how the survey will be administered in the group setting. No experimental procedures are involved.

2. A description of any reasonably foreseeable risks or discomforts to the subject;

There are no anticipated risks or discomforts, so this is not addressed.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

Benefits are addressed in both the script and consent form. In the script, “Information … is used by Texas State faculty and administrators and by other higher education leaders to improve the collegiate experiences of undergraduates,”, and in the consent form, “Completing the … BCSSE will provide me and other administrators with information directly from our new students to help us improve our curriculum and general campus life.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

There are no alternative procedures.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

This is addressed by the consent form: “…your responses will be kept confidential.”

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

This research does not involve more than minimal risk. No compensation will be given.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

This is addressed in the consent form: “For more information about the survey, email the Center for Postsecondary Research at [bcsse@indiana.edu](mailto:bcsse@indiana.edu) or call 812-856-5824. For information about the project on this campus or our interest in using the results, please contact Susan Thompson in Texas State’s Office of Institutional Research at [st03@txstate.edu](mailto:st03@txstate.edu) or 512-245-2386. With questions or concerns about your rights as a participant in this research project, contact the Indiana University Office of Human Subjects Committee at 812-855-3067 or [iub\_hsc@indiana.edu](mailto:iub_hsc@indiana.edu).”

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

This is addressed by both the script (“The Informed Consent Statement … describes the voluntary nature of the survey … If you do not wish to participate in the survey, you may turn in the blank survey without any penalty”) and the consent form (“Your participation in this study is voluntary…”).

The federal requirements for consent documents have been met in the information that will read aloud to students prior to survey administration and the consent form that will be distributed with the surveys. According to Robert Amdur in the Institutional Review Board Member Handbook provided as a reference to IRB members at Texas State, “After the consent document explains the important implications of a decision to participate in research, the wording of the consent document does little to protect the rights and welfare of research participants” (pp. 49-50). In this case, lengthening the consent document may increase the likelihood that students will not read it, hence having the unintended effect of decreasing the information they use to make their decision to participate or not participate.

A longer and more complication version of the consent form as specified by our local IRB requirements would adversely affect this research project. The survey is being administered in a large group setting, with approximately 400 students in the room, and it is important to keep the documents simple and clear. These students are incoming freshmen, excited about starting college and overwhelmed by orientation activities, and they will be less likely to read and comprehend a document of greater length. By announcing the important information to the group and providing only the basic information in written form for them to keep as a reference, it is more likely that students will absorb the important message about the implications of their decision to participate in the research.

In response to comments regarding the waiver of parental consent for children participants (“Perhaps the Texas State researchers might consider devising their own research consent form and exclude under 18 year old students so they won't have to get parental consent. Researchers’ access to student's private information and the possibility of children (under 18 years old) among the participants negates any possibility of waiving the proper consent form” by Reviewer 2, I submit the following:

Although the students do meet the definition of “children” in terms of age, they are also entering college, where they will be treated just as the other freshmen who are 18 or older in terms of where they live, what classes they take, what experiences they will have on campus, and so on. In fact, their parents have already consented to their children taking part in college activities, events, and programs by permitting their enrollment in college. The students’ exposure to this research survey designed to improve educational practices can be viewed as a part of attending college; just as they will be asked to participate in other research studies used for quality improvement purposes during their enrollment at Texas State. The BCSSE survey contains no sensitive items that would put under-18 years of age students at a greater risk than older students.

Last fall (2008), only 32 of the 3,336 entering freshmen were under the age of 18. Two were 16 years of age and 30 were 17 as of September 1, 2008. There is no reason to expect this fall’s entering class to differ with respect to age, so this issue will affect a small number of students, and they will be nearly 18 years of age. The survey will be administered to entering freshmen in large groups at orientation, where it will be impossible to separate out the under-18 year old students. PAWS Preview orientation organizes students into groups based on the University Seminar 1100 section in which they are enrolled, so the under-18 year olds will be distributed across the groups based on their class sections.

With regard to the reviewer’s comment specifically about “Researchers’ access to student's private information…negates any possibility of waiving the proper consent form”, it is true that the Texas State researcher will have access to the students’ private information. Institutional Research staff at Texas State has access to all students’ private information that is stored as data in the university’s data bases and use that information routinely for university business, subject to federal law, the Federal Educational Rights and Privacy Act (FERPA). Students are informed about FERPA and their rights by the Registrar’s Office, so in essence they have indicated their permission for the university to use their private information by their enrollment. In this study, we are only requesting consent to provide data collected by the survey and to permit linkage of that survey data to private information to which they have already given consent.

The BCSSE survey is a national study developed by the Center for Postsecondary Research at Indiana University. The Center has an excellent reputation among higher education institutions for conducting quality research on the undergraduate student experience, most notably the National Survey of Student Engagement (NSSE) that is used extensively and considered to be one of the best commercial surveys for quality improvement research in higher education. More than 1,300 institutions in the U.S. and Canada have administered these surveys, *using the same consent process outlined in this application*, to students since 2000, without a breach in data security or any adverse affect on students. Instead, the information collected from these surveys has been used to identify aspects of the undergraduate experience inside and outside the classroom that can be improved through changes in policies and practices more consistent with good practices in undergraduate education. The information is also used by prospective college students, their parents, college counselors, academic advisers, institutional research officers, and researchers in learning more about how students spend their time at different colleges and universities and what they gain from their experiences.