Terracotta IRB Questionnaire Template

The following are the responses to core items that comprise the narrative of the IRB questionnaire at Indiana University. Responses have been edited slightly for clarity and to remove extraneous details of the study's local implementation.

Describe the purpose of this study in lay terms, including research question(s) and hypothesis

> Introductory statistics is usually taught as mathematical theory, with strange symbols and complex equations full with unfamiliar Greek letters. However, the last 25 years have been full with mounting efforts to reform statistics courses with increased emphasis on empirical thinking, tangible examples, and active learning. A new and promising approach toward improving undergraduate statistics education involves a shift away from conventional algebra-based instruction and toward teaching methods that incorporate simulation and randomization. The purpose of this study is to carry out an experimental comparison between these two alternative approaches: simulation-based, and algebra-based instruction for Introductory Statistics.

List and describe all research interactions and/or interventions, including the frequency and duration of procedures, and length of participation for individual subjects.

> OVERVIEW: This study will be carried out in the Canvas course sites of up to three different sections of {course number, department, campus}. The experiment will manipulate the homework assignments that enrolled students receive in this course: either simulation-based or algebra-based. The experiment will employ a within-subject crossover design -- students who consent to participate will be randomly assigned to receive simulation-then-algebra (henceforth: Condition A), or algebra-then-simulation (henceforth: Condition B) -- so that all students will receive the same experimental treatments, just staggered in time. The primary outcome measure will be students' performance on course exams, reported by course instructors, as administered in the normal conduct of the course.

> INFORMED CONSENT: Within the first two weeks of the semester, students will be asked to respond to an informed consent "assignment" in Canvas. The informed consent assignment is graded, but all students will receive credit for responding, no matter what response they provide (consent or no consent). Potential participants will see an abbreviated ICS within the Canvas assignment (uploaded as an SIS to this submission), and will have an opportunity to click to download a complete ICS. Students' responses will be hidden from the instructor, managed by an emerging research tool called "Terracotta" (https://terracotta.education). Terracotta will record which students have consented and have not consented. The consent process will occur within a Canvas login session, where students have already authenticated with their official university ID number. The informed consent statement (ICS) is in the "Notes and Attachments" section.

RANDOM ASSIGNMENT: Students who consent to participate in the study will be randomly assigned to one of two different treatment conditions, A or B, as described above. Students who do not consent will be assigned to a "default" treatment condition, as selected by the instructor, which will not change during the semester. That is, students who DO consent will have the format of their course assignments switch in the middle of the semester, but students who DO NOT consent will have one constant (unchanging) format of these assignments, as would have been the default preference of their instructor if this study was not being conducted. Random assignment to conditions A or B, or to the "default" (non-experimental) treatment, will be automatically managed by Terracotta, with no human involvement whatsoever. The instructor will not be shown whether students were randomly assigned to A or B, or were instead assigned to "default" (non-experimental) treatment. When grading submissions, students' identities will be hidden.

MANIPULATED LEARNING ACTIVITIES and ASSESSMENTS: This study will manipulate the format of at least two different homework assignments in the participating Canvas sites. The first experimental homework assignment will be simulation-based for students in Condition A, and will be algebra-based for students in Condition B. Then students will have a midterm exam, as in the normal conduct of the course, which measures student learning from these first experimental assignments. After the midterm, the second homework assignment will be algebra-based for students in Condition A, and will be simulation-based for students in Condition B. Then students will have a final exam, as in the normal conduct of the course, which measures student learning from these second experimental assignments. Students who did not consent to participate in the study will be administered the "default" treatment (whichever version of the assignment is selected by the instructor), for both experimental assignments. The exposure of different versions of these assignments is managed by Terracotta, with no human involvement whatsoever. Example contents of these assignments are in the "Notes and Attachments" section.

DATA EXPORT: The study will conclude at the end of the academic semester. At that time, after grades have been submitted, Terracotta will allow the instructor to download a deidentified data export package. This export package will only contain data from students who consented to participate at the start of the semester; data from students who did not consent will be excluded from any data export. The export package will not include any personally-identifiable information; instead, participants will be identified using unique random identifiers. The export package will include (1) condition assignment for each anonymized participant; (2) participants' interactions (timestamped clicks, answers, scores) on the manipulated learning activities; and (3) participants' outcome scores on the midterm and final exams.

List inclusion criteria (all eligibility criteria for subjects)

All students who are enrolled in participating sections of {course number, department, campus} will be eligible to be included in the study, provided that they are over 18 at the time of consent. Students who are not 18 will be instructed to *not* provide consent.

List exclusion criteria (any criteria which would exclude otherwise acceptable subjects)

All eligible participants who provide consent will be included.

Describe how potential participants will initially be identified.

Potential participants will initially be identified because they will have enrolled in a participating section of {course number, department, campus}. All enrolled students will be added to Canvas sites automatically as in the normal conduct of the course.

Describe how potential participants will initially be contacted.

Potential participants will be initially contacted by their instructor, who will assign enrolled students to indicate (online, in a Canvas assignment) their consent to participate in the study. All students will receive credit for this assignment, regardless of whether they consent or not. When announcing the study, the teacher will emphasize that by participating in the study, students may experience different kinds of assignments than what they would otherwise receive, and that any student, regardless of whether they consent or do not, is encouraged to contact the teacher if they have any confusion or challenges with the learning activities. The teacher will emphasize that the study will not involve any manipulation of support provided to individual students, and that all students may request and receive assistance at any time, as in the normal conduct of the course.

The assignment itself will not include any recruitment materials. It will only include the informed consent statement, as approved by the IRB.

Describe the plan to ensure that the course instructor(s) will not know whether their students participated in the research until after course grades are final.

The research study is being conducted using an emerging educational research tool called "Terracotta" (https://terracotta.education/). Terracotta will collect and store informed consent responses and will withhold these data from the Instructor. At no point (not even after course grades are final) will Terracotta reveal which students have consented to participate -- when the data from participating students are available for export at the end of the semester, these data will be deidentified.

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research.

As in any research study, participants have a risk of potential loss of confidentiality.

All students who volunteer to participate in this study will receive two different kinds of instructional experiences ("simulation" and "algebra", as described above) but in different orders (some students will receive simulation-then-algebra, and other students will receive algebra-then-simulation). For this reason, all students who consent to participate in the study will receive all treatments (full parity of overall treatment), and there will be no risk that some consenting participants might receive inferior instructional experiences compared with other consenting participants.

However, consenting participants will obviously receive different treatment than non-consenting participants, who will only be exposed to the default treatment as selected by the instructor. It may be the case that some aspect of the experimental treatment will be inferior than the default treatment (or alternatively, that some aspect of the experimental treatment will be superior to the default treatment). Thus, there is a risk that students who consent to participate may be exposed to new instructional materials that might not "work" as well as established ones.

Describe procedures for protecting against, or minimizing, the potential risks listed above. Include any procedures that are already being performed on subjects for diagnostic, treatment, or standard purposes.

The research study is being conducted in an emerging educational research platform, Terracotta, that is designed specifically to protect against potential loss of confidentiality. The platform is developed by a team that is well-experienced in developing secure enterprise-scale learning technologies. Terracotta keeps track of who has and hasn't consented to participate, and never reveals this identifiable information -- it is kept encrypted in Terracotta's secure database. When Terracotta exports data, the export dataset includes no personally-identifiable information.

To mitigate the risk that consenting participants may be exposed to new instructional materials that might not "work" as well as established ones, there are a few things that will be done. First, when announcing the study at the start of the semester (inviting students to provide informed consent), the teacher will emphasize that all students, regardless of their participation in the experiment, will be able to request and receive assistance from the instructor as in the normal conduct of the course. In this way, participation in the experiment is not substantively different from other forms of voluntary alternative or make-up assignments offered in normal educational practice. Second, the informed consent statement clearly mentions the risk of exposure to inferior instructional materials, so participants who consent to participate will do so understanding this possible risk. Third, the current study is designed to experimentally manipulate a relatively minor aspect of course design in order to minimize the possible impacts of experimental treatment on class-level educational outcomes. Fourth, *all* materials in the study, both the new and the default instructional materials, represent instructors' best designs for effective learning materials in these conditions. None of the instructional

materials are "placebo" nor represent intentionally depleted treatments, instead these represent the teachers' best renderings of competing instructional strategies.

Given the above procedures, there will not be any adjustment of students' grades as a result of study findings. Students who opt to participate in the study are different students from those who do not consent, and making adjustments to one or the others' grade outcomes would not represent equitable protection against risk. Additionally, we will not be investigating the performance of students who do not consent to participate, so such adjustments would be made blindly, which is not appropriate.

Explain how research data will be protected so that only approved persons have access to subjects' identifiable data (i.e. confidentiality of data).

No person, not even the researchers, will have access to subjects' identifiable data. These data are kept encrypted in Terracotta's secure database.

Explain how subjects' physical privacy will be protected, both during recruitment/screening and during participation in the research.

Participation in this study will be conducted entirely online, where informed consent and experimental treatment are online homework assignments within the Canvas learning management system. Participants will be able to complete these assignments in whatever physical environment they so choose.

Is there a potential for subjects to benefit directly from participation in the study?

No.

State the potential benefits or information which may accrue to SCIENCE or SOCIETY in general as a result of this work.

This work will contribute to an expanded evidence base of successful instructional strategies, and improved contextual understanding of where these strategies confer the greatest benefits. As a consequence, improved undergraduate training in STEM fields will address critical societal needs for workforce development and STEM literacy.

Describe the provisions for monitoring the data to ensure the safety of subjects.

Terracotta will be managing condition assignment and learning activity deployment, but the teachers of participating BL-PSY-K300 sections will also be monitoring grades as assigned during these activities, ensuring that participating subjects are receiving their K300 assignments safely and appropriately.

For those subjects who will consent to participate, explain how subjects (or subjects' legally authorized representative) will be presented with the information needed to decide to participate, including all elements of informed consent.

> [Copied from previous question:] INFORMED CONSENT: Within the first two weeks of the semester, students will be asked to respond to an informed consent "assignment" in Canvas. The informed consent assignment is graded, but all students will receive credit for responding, no matter what response they provide (consent or no consent). Potential participants will see an abbreviated ICS within the Canvas assignment, and will have an opportunity to click to download a complete ICS. Students' responses will be hidden from the instructor, managed by an emerging research tool called "Terracotta" (https://terracotta.education). Terracotta will record which students have consented and have not consented. This will be recorded within Canvas, where students have already authenticated with their official university ID number. The informed consent statement (ICS) is in the "Notes and Attachments" section.

Describe any informed consent tools which will be used to present information to potential subjects (i.e. consent documents, videos, brochure, drug/device information, etc) and how they will be used.

> The Canvas assignment that serves as an informed consent tool will present a short, abbreviated ICS, and will include a link for potential participants to download a full complete ICS.

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

> Informed consent will be available for a two week period, during which participants will have the opportunity to read the informed consent statement fully and to respond at their convenience.