

**SHORTER UNIVERSITY
INSTITUTIONAL REVIEW BOARD
REVIEW PROCEDURE**

New Research involving human participants

1. After determining that the research involves gathering data from living human beings, the Principal Investigator (P.I.) must complete the "Application to the Institutional Review Board" available from the Shorter University IRB chair and return it to the Board chair. The P.I. may seek review under one of the following categories, which are fully defined in Appendix 1:
 - a. Exempt Review: research that involves no risk to the participants
 - b. Expedited Review: research that involves no more than minimal risk to participants, or that involves minimal changes to previously approved research during the period of one year or less from the approval date.
 - c. Full Review: research that involves more than minimal risk to participants, including research that uses deception of participants.

Exceptions: The only exceptions to the review procedure are "minor" research studies conducted by students as part of class work. (See Appendix 2 for the criteria for this type of research). Student projects that fulfill a thesis or senior seminar requirement are not considered "minor" research studies; these research projects must go through the review process.

2. Applications are distributed to the Board members for individual review. Applications are considered to be confidential documents and are not to be openly discussed by Board members with others outside the Board, with the exception of the Provost.
3. The Board completes its review within fourteen (14) days of the date the application was submitted. The chair of the Board communicates this decision to the P.I. within seven (7) days.
 - a. For Exempt or Expedited review, Board members submit their written comments to the chair, who then determines Board action. The chair may consult Board members for clarification of their comments or further discussion. Board comments and discussion can occur over email.
 - b. For Full review, the Board will convene to discuss the application. Any action must be passed by a majority vote of the members present. Research proposals may be disapproved only after a Full Review.
4. The P.I. may request clarification of the Board's decision or submit the modifications requested by the Board at any time following the initial Board decision. Modified proposals will be acted upon by the Board and the decision communicated to the P.I. within fourteen (14) days of receipt.

Please note: The Board will make every attempt to deliver timely reviews. However, the 14 and 7 day time limits are only applicable when the College is in regular session for fall and spring semesters and excludes official College holidays, spring and fall breaks, intersession and summer session.

Ongoing Research

Review Board approval lasts for one calendar year from the date on the approval form.

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Research that is not completed in that year must undergo review before the approval expiration date. If there have been no changes to the original research protocol, the P.I. should fill out a new application form, request Expedited Review, and submit the requested number of copies to the IRB chair. If changes have been made in the research protocol, the P.I. must treat the application as a new request.

ETHICAL GUIDELINES

Research should follow the American Psychological Association's ethical principles which can be found in Ethical Principles In the Conduct of Research With Human Participants, published by the APA, 1982. The Review Board requires adherence to these guidelines in each of the following areas:

Informed Consent

1. Informed consent must be documented by use of a written/scripted consent form approved by the Review Board. Researchers must use language that is reasonably understandable to participants in obtaining their informed consent.

- a. For Exempt Review, informed consent may be oral but a written copy of the oral script must be approved by the Board. A statement must be placed at the head of any questionnaires or written materials that will be completed by participants that informs participants that by filling out the materials, she or he is consenting to participation.
- b. Expedited or Full Review requires written informed consent. The consent form must be signed by the participant or the participant's legal representative and a copy of the form must be given to the person signing that form. The P.I. is responsible for keeping the original document in a secure file separate from any data collected from the participant.

2. Elements of informed consent:

- a. Purpose, Duration, & Procedures: a statement that the study involves research, a fair explanation of the purposes of the research and the expected duration of participation, a description of the procedures to be followed and identification of any procedures which are experimental;
- b. Discomforts & Risks: A description of any reasonable foreseeable discomforts and risks to the participant;
- c. Potential Benefits: A description of any benefits to the participant which reasonably might be expected as a result of doing the study;
- d. Alternative Procedures: A disclosure of any appropriate alternative procedures to course of treatment which might be advantageous for the participant;
- e. Confidentiality of Records: A statement describing the extent to which confidentiality of records identifying the participant will be maintained;
- f. Compensation and Treatment: For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so, what they consist of and where further information may be obtained.

- g. Contact Person on Research, Rights, & Treatment: An explanation of whom to contact for answers to pertinent questions about the research, procedures and research participant's rights, and whom to contact in the event of a research-related injury.
- h. Voluntary Nature of Participation & Withdrawal: A statement that participation is voluntary and that the participant is free to withdraw from the study at any time without penalty or loss of benefits.
- i. Anonymity: a statement regarding the expectation that participants' names will not be attached to their data.

Post-Participation Debriefing/Feedback

Investigators must provide a prompt opportunity for participants to obtain appropriate information about the purpose, results, and conclusions of the research study, and to attempt to correct any misconceptions that participants may have about their responses during the study. It is recommended that feedback be provided to participants immediately following their participation. In cases where the design of the study prevents immediate feedback, delayed feedback must be provided as soon as practical, and within six (6) months of completion of the study. If scientific or humane values justify delaying or withholding feedback, the researcher must take reasonable measures to reduce the risk of harm to participants.

For Exempt or Expedited Review, debriefing may be incorporated into the informed consent form or script. Full Review requires a written debriefing statement that is also presented orally to participants.

The Use of Deception in Research

Research involving deception may not be conducted unless the P.I. provides adequate rationale that the use of deceptive techniques is justified by the study's prospective educational, scientific, or applied value and that equally effective alternative procedures that do not use deception are not feasible. The P.I. must complete Attachment 1 and submit it with the Application for Review.

Researchers may not deceive participants about significant aspects that would affect their willingness to take part in the study, such as physical risks, discomfort, or unpleasant emotional experiences.

Any deception that is an integral feature of the research design or procedure must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research study.

**SHORTER UNIVERSITY
RESEARCH APPLICATION TO THE INSTITUTIONAL REVIEW BOARD**

Primary Investigator (P.I.) _____

Faculty Advisor (if student P.I.) _____

Program _____ Phone _____ Email _____

Title of Project _____

Project start date _____ Expected end date _____

Submission date _____ The project is: New _____ Continuing _____

* To maintain continuous approval for projects that last more than one year, submit a continuing application at least one month prior to the yearly expiration date.

Review requested (select one) Exempt _____ Expedited _____ Full _____

* See Appendix 1 for full definitions of the review categories.

* See Appendix 2: if research is a minor part of course requirements IRB approval is not required.

Project type: Non-funded/Student research _____ Externally funded _____

Supporting agency (if any) _____

* The P.I. will receive written notification of the Review Board's decision within three (3) weeks of receipt of this application.

Signature of Primary Investigator

Date

Signature of Faculty Advisor (if applicable)

Date

Application to Institutional Review Board for research approval: Provide a narrative for each section listed below, attaching required documentation as needed.

- 1. Purpose and objectives of the research:** Give enough background information to support the importance of the project, its expected contribution, and the hypothesis under study.
- 2. Participants:** Include a discussion of the characteristics, number and any payment of participants. Explain the participant selection process and how you will initially contact potential participants. If you will be working with participants from another institution or organization, attach documentation of that agency's permission for you to do so and any pertinent regulations from those agencies. If minor children are to take part in the research, attach a parent information letter.
- 3. Method or Procedure:** Describe the way in which data will be collected, including where the study will take place, who will collect data, length of participation, what data will be recorded and how. List and describe any apparatus that will be used. Attach copies of any survey or interview questions to be used. If deception is used, provide a rationale.
- 4. Assessment of risk:** Determine if participants are at more than minimal risk for physical, psychological, social, financial, legal, or political harm. (This includes research involving DECEPTION of participants). Describe procedures (such as informed consent) that will be used to minimize potential risks to participants. If participants are at greater than minimal risk, responses to Attachment 1 must be included in this application.
- 5. Risk-benefit ratio:** Research involving human participants can be approved only if expected benefits outweigh potential risks. Describe possible benefits to the participants, a class of participants, society in general, or the advancement of science. State your reasons for believing that the benefits of the proposed study outweigh potential risks.
- 6. Methods of obtaining informed consent from participants:** Who will obtain informed consent? If signed consent is needed, where will consent forms be stored? Attach a copy of the script for oral informed consent (Exempt Review) or the full written informed consent form (Expedited or Full Review). Please see the guidelines for informed consent to be sure you include all elements of consent (i.e., assurances of anonymity and confidentiality, voluntary nature of participation, etc.).
- 7. Confidentiality:** Describe procedures to be used to maintain confidentiality including who will have access to identifying information, where data will be stored, when data will be destroyed, and in the event that findings are published or made public, how participants' identities will be masked.

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Appendix 1: Definitions of Review Categories

Exempt Review: Research involving no or minimal risk and in which the only involvement of human participants will be in one or more of the following categories:

1. Research conducted in established educational settings, such as that measuring the effectiveness of teaching techniques or involving educational tests (cognitive, aptitude, diagnostic, achievement) if the information cannot be linked to the participant.
2. Research using survey or questionnaire procedures providing the responses are not linked to the participant, and responses do not place the participant at risk of criminal or civil liability or constitute damage to the participant's reputation or employability.
3. Research involving observation of public behavior, provided that the participant's behavior is not linked to their identity, and that these observations do not place the participant at risk of criminal or civil liability or constitute damage to the participant's reputation or employability.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, provided these sources are publicly available and the data is recorded in such a manner that the participants cannot be identified.

Expedited Review: Research involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the following categories:

1. Voice, video, digital, or image recordings made for research purposes such as investigations of speech defects.
2. Research on group or individual behavior or characteristics (including, but not limited to research on perception, cognition, motivation, communication, cultural beliefs, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at the time of exfoliation, or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing; (j) sputum collected after saline mist nebulization.
4. Recording of data from participants 18 years or older using noninvasive procedures (not

involving general anesthesia or sedation) routinely used 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 participant or an invasion of the participant'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. Collection of blood samples by finger stick, ear stick, heel stick, or venipuncture from a) healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amount drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or b) other adults and children under the age of legal consent, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these participants, 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.
6. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
7. Study of existing data, documents, records, pathological specimens, or diagnostic specimens that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
8. Continuing review of research previously approved by the convened RERB where a) the research is permanently closed to the enrollment of new participants or all participants have completed all research-related interventions or the research remains active only for long-term follow-up of participants; b) where no participants have been enrolled and no additional risks have been identified; or c) where the remaining research activities are limited to data analysis.
9. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
10. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
11. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the two previously listed categories do not apply but the RERB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Review: Any research that involves more than minimal risk to participants.

1. Research that utilizes deception of participants.
2. Research that involves the manipulation of participants' behavior, with or without the participants' knowledge.
3. Research that involves new and/or untested procedures

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Appendix 2: "Minor" Studies Conducted by Students as a Part of Class Work

In some courses, students collect data individually or in groups, as part of course requirements or to facilitate class discussion. In such courses, the carrying out of the research process makes up a small portion of actual class work. **The instructor in such a course has the responsibility to discuss ethics of research with the students who will be engaging in the research and must judge that the potential educational benefits from such research outweigh any risks to the participants. If, in the instructor's judgment, such research follows ethical guidelines for human participants, IRB approval is not required.**

This category **does not** include senior seminar or thesis courses in which the focus of the course is on original research designed and carried out by individual students. With these considerations in mind, research is considered "minor" if all of the following conditions are met:

1. There is no expectation that data from the study will be included in any publication or presentation outside of class;
2. All participants are age 18 years or older;
3. The research does not involve participants from clinically or otherwise sensitive populations (e.g., delinquents);
4. Participants are not recruited through any agency or school, publication (including the student newspaper), public posting, or departmental research participant pool;
5. Funding is not sought for the research;
6. Participation in the research takes less than 30 minutes of the participant's time;
7. The research does not involve deception;
8. No physically invasive procedures are used;
9. Privacy of participants is respected. No potentially self-incriminating, sensitive, or highly personal questions are asked, and participants' identities are kept anonymous; and
10. Contact with participants is well scripted or standardized.

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Appendix 3: Sample Informed Consent Form

(Sample) Informed Consent Form

This study is concerned with individual differences in perception. With other participants, in a lab setting, you will be asked to watch a projection screen in a darkened room while a series of slides is briefly flashed on the screen. After each slide you will be asked to describe what you saw. This is an evaluation of what is called "preperceptual storage" and is not a test of intelligence or personality. There are no standards against which your responses will be measured. A tape recorder will be used to record your responses. The task requires considerable concentration on your part but should cause no physical, psychological or emotional discomfort. The task will take between 30 and 60 minutes.

Your responses will be identified with a code number and your anonymity is guaranteed both in responding and in later analysis of your responses. If you agree to participate, this form, with your signature, will be stored separately from your responses in (department/program/faculty member's office).

You are not required to participate in this study. If you elect to participate, you are free to change your mind and withdraw from the study at any time during the experiment. If you are receiving course credit for participating, please fill out the participation slip prior to the start of the study. You will receive the credit even if you withdraw before the end of the study. After you have completed the task, a complete description of this research will be given to you. If you desire, you may receive the results of this study when it is completed.

Any inquiries concerning the procedures of this study can be discussed with the experimenter (insert name of P.I.). This study has been reviewed and approved by Shorter University IRB as in compliance with ethical guidelines. Questions, reservations, or appeals regarding the procedures can be referred to (insert instructor's name).

The results of this study are expected to be of considerable importance to psychologists and educators. Your cooperation is invaluable and greatly appreciated.

(insert name of P.I.)

I have read and understand the above statement and give my voluntary consent for participation in the study entitled: (insert name of study).

Signature of Participant

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Appendix 4: Sample Debriefing (Study Involving Deception)

This experiment was designed to study the ways in which people evaluate themselves and others on the basis of their cognitive abilities. It is a study of social comparison theory, a theory that states everyone wants to evaluate himself or herself on important personal qualities. This happens frequently in school, when students compare themselves according to the grades they receive. If we evaluate ourselves favorably compared to our classmates (for example, if we are at the top of the grade curve) then our self-esteem will be boosted. On the other hand, if we are at the bottom of the grading curve, then we will suffer from lowered self-esteem. In the experiment you just completed, we wanted to see how experiencing success or failure affected self-esteem and willingness to compare yourself to others.

It was necessary to withhold the true purpose of this experiment until after you had completed your participation so that you would not second-guess our goals and perhaps change your responses to our questions. Thus, the "Spatial-Verbal Manipulation Test" you took in which you unscrambled letters to make words (an anagram problem) did not measure any kind of cognitive ability. In fact, your score on that test was determined ahead of time. One half of you received a test in which 12 of the 15 word puzzles were solvable and 3 were impossible to solve (they did not form real words). The other half of you received a test which contained only 3 solvable and 12 unsolvable puzzles. It was impossible for you to score any better than you actually did, and everyone in your group scored exactly as you did. Therefore, your score is not related to any ability on your part.

We included this anagram task so that one-half of the participants would be successful and one-half would be unsuccessful on this task. We will analyze your answers to our questionnaires and then study the effect of the test feedback on your responses. We predict that people who feel they have performed poorly will attempt to boost their self-esteem by comparing themselves against a group of people who are worse off.

It is important that you understand that the "Spatial-Verbal Manipulation Test" was created specifically for this study and is not related to your grades or to any cognitive ability. Since most college students think learning is important, we linked our fake test to cognitive abilities so that you would become personally involved in the task and try your best. But please be aware that your score on the test was determined by random chance at the start of the study and in no way reflects on your intelligence or abilities.

We ask that you please not discuss this experiment with anyone on campus, since other students may participate during the remainder of the semester. Study results will be made available during (insert Spring/Fall) semester; you may call (insert P.I./ faculty sponsor name) at (insert phone number) if you would like to know the outcome or would like to talk more about your participation in this study. Do you have any questions about the study that haven't been answered?

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Attachment 1: Additional Information Required for Full Review
of Research Involving More Than Minimal Risk to Participants

Please answer the following questions for all appropriate categories involved in your research.

Risk

For research in which the possibility of injury is greater than minimal:

1. Identify and describe in detail the possible risks, including physiological, psychological, or social injury, to which participants may be exposed.
2. Explain why you believe the risks to the participant are so outweighed by the combined benefit to the participant or society at large and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept these risks. Discuss any alternative ways of conducting this research that would present fewer risks to the participant, and explain why the method you have chosen is superior.
3. Explain fully how the rights and welfare of participants at risk will be protected (e.g., equipment closely monitored, medical exam given prior to procedures, psychological screening of participants, etc.)

Equipment

For research in which the participants will be in contact with any mechanical, electronic, electrical, or other equipment which might put him/her at risk of accidental harm or injury, should there be a mechanical failure in the equipment.

1. Identify and describe in detail the equipment to be utilized and the exact location. Use manufacturer's name and serial numbers, and submit copies of manufacturer's literature on the equipment when available.
2. Identify and describe in detail how the participant will interact with the equipment.
3. Indicate the names and qualifications (with regard to the safe use of the equipment) for all individuals authorized to use the equipment.
4. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the equipment.

Psychological or Physiological Intervention

For research in which the participants will be exposed to any psychological intervention such as deception, contrived social situations, manipulation of the participant's attitudes, opinion or self-esteem, psychotherapeutic procedures, or other psychological influences, or in which the

participant(s) will be exposed to any physiological treatments or interventions upon the body by mechanical, electronic, chemical, biological or any other means.

1. Identify and describe in detail the psychological intervention (or manipulation) and the means used to administer the intervention.
2. Identify and describe in detail the behavior expected of participant(s) and the behavior of the investigator during the administration of the intervention.
3. Describe how data resulting from this procedure will be gathered and recorded.
4. Identify anticipated and possible psychological, physiological, or social consequences of this procedure for the participant(s).
5. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the means used to administer the intervention. For all equipment used, the questions regarding equipment above must be answered.
6. For research involving DECEPTION, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator.
7. For research involving psychological intervention, describe in detail the plan for debriefing participants.
8. Indicate the investigator's competence and identify her/his qualifications, by training and experience, to conduct this procedure. Give name, title, academic affiliation and program, an address, and telephone number of the individual(s) who will supervise this procedure.