AUSTIN COLLEGE

INSTITUTIONAL REVIEW BOARD

### Human Subjects Request for Approval of a NEW Project

IRB applications should be submitted electronically to IRBChair@austincollege.edu. In addition you must submit electronic versions of all materials that will be seen by/used with participants. This includes but is not limited to consent forms, measures (surveys, interview questions, etc.), stimuli, recruitment materials (emails, flyers etc.). Ancillary materials may be submitted as separate attachments. Please note that you project cannot be reviewed until final copies of all materials are received by the committee.

# List the names of all investigators (primary members of your research team):

Date this application and all ancillary materials (including but not limited to the following: consent forms, human subjects or other required training certificates, recruitment material, surveys or other data collection protocols) were submitted to the IRB:

Austin College mailbox number of primary investigator (first author):

Phone number for first author:

Email address for first author:

In making this application, I certify that I have read and understand College policies and procedures governing human subject research and agree to abide by them. I certify that the attached information accurately describes the proposed research project.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Signature of Primary Investigator (First Author) Date

Electronic signature is acceptable

General Information

Project title:

Estimated start date:

Is this a multiyear project? \_\_\_ Y \_\_\_ N

If Y, approximately how many years will your project run?

If N, please list estimated completion date:

Note for multiyear projects you will need to submit a renewal form no later than one month before your renewal date to ensure that your IRB approval does not lapse which could result in an interruption of your research.

Types of Committee Review Requested (check one)

\_\_ Exempt

\_\_ Expedited

\_\_ Full Committee

If you have questions about which type of review matches your project, please see the guidelines for exempt, expedited, and full committee reviews. Also, note that the committee may ultimately decide another type of review is necessary based on the characteristics of your project.

Category of Project (check one)

\_\_ Faculty or staff research project

 Department:

 Funding agency (if receiving outside funding):

\_\_ Independent student research project\*

 Name of faculty or staff sponsor (required):

\_\_ Class project\*

 Course name/number and faculty sponsor:

\* Students may not submit research directly to the IRB. Student projects should be submitted to the supervising faculty member. The supervising faculty member is responsible for ensuring all of the IRB guidelines have been met and that the application and all supporting materials are complete and ready for review. This means that the faculty supervisor must read an edit the project before submitting it to the IRB. Student projects with significant errors or missing information will be returned without being reviewed.

Faculty Certification of Independent or Class-Based Student Projects.

When a faculty member submits a student project they are agreeing to the following:

*I have read and edited this proposal and all related documents. In my opinion, the proposed research project is accurately described and all materials are ready to be reviewed by the committee. I accept responsibility for supervising the student’s conduct of the research, ethical treatment of human participants involved in the student project, and will take steps to ensure the students comply with College policies and procedures governing human subject research.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Faculty Signature (if this is a student or class project) Date

Electronic signature is acceptable

## Human Subjects Training

Members of the Primary Research Team: Please list the date that each member of your research team completed the CITI human subjects training:

If you have not yet completed your training, please submit your anticipated completion date. Projects will be reviewed before CITI training is complete, but they will not be approved.

Faculty Supervisors: If this is a student project, the faculty supervisor must have current human subjects training. For student projects include the date of your faculty supervisors most recent CITI training:

## Research Project Information

## (Note: Err on the side of ambition in filling out the following information. The IRB will need as much information as possible about your research project – and adequate information will assist us in avoiding any unnecessary delays.)

1. Please type a description of your project below that includes your general project design (for example: descriptive, case study, experimental, quasi-experimental, correlational, or other), major hypotheses or research questions, variables, rationale for the project, and goals for the project. Please minimize your use of jargon; the IRB members may not be specialists in your academic discipline.

Participants

1. Please describe your participant populations(s). (Check all that apply)

 \_\_ Adults other than college students (age 18 and over)

 \_\_ College students – adult only (age 18 and over)

 \_\_ College students – any age (this would include any person who has graduated from high school and is enrolled in college even if they are under 18). If you check this box you need to explain either 1) how you will get parental consent or 2) why you want to use student consent only and waive parental consent

Special Populations (only select if you are targeting these populations primarily or exclusively for your study)

 \_\_ Minors (under the age of 18) other than college students

 \_\_ People with reduced or impaired mental capacity

 \_\_ Minority groups (for example ethnicity, sexual orientation)

 \_\_ Prisoners (defined as people who are incarcerated by the court, regardless of the facility)

 Here are the guidelines: <http://www.hhs.gov/ohrp/policy/faq/prisoner-research/regulations-define-prisoner.html>

 \_\_ Women who are pregnant

 \_\_ International participants (people from any country outside of USA and its territories)

 \_\_ People with limited English proficiency

\_\_ Other vulnerable populations – please specify (anyone who may be at greater risk due to their individual characteristics or circumstances such as economic status, health condition, etc., for more information see the CDC’s definitions at <http://www.cdc.gov/minorityhealth/populations/atrisk.html>)

If you checked “Yes” to recruiting participants from a special population, please describe that population and your purpose for including them in your research.

If you checked “Yes” to recruiting participants from a special population, make sure to identify the risks (for example language barriers, cultural differences, etc.) or vulnerabilities that exist in that population and describe how those risks will be addressed/mitigated in question #8.

1. Please list all exclusion criteria for participants in your study and explain why those people will not be allowed to participate.
2. Are there any special characteristics of your participants that the committee needs to be aware of that were not addressed in the questions above? (specify)
3. Provide a detailed description of your procedures from the point of initial recruitment of participants through collecting your data. Err on the side of providing more details about your process. Make sure to identify at what point you will obtain consent from participants.

Recruitment

1. How will participants be selected, recruited, or enlisted?

\_\_ On campus using the psychology department participant pool

\_\_ On campus using something other than the participant pool (explain recruitment procedures)

\_\_ Off campus (explain recruitment procedures and include letter of support from partner organization, if applicable)

1. Attach a copy of any and all recruitment materials (email, flyers, etc.) that will be distributed to participants. Make sure to include the words “recruitment materials” in your file name so that these can be identified by the committee. Once you have been assigned an IRB#, you must add that number to any recruitment materials sent out to participants. Submitted materials should indicate where on the document the IRB# will be located.

Risks and Deception

1. Will subjects be asked to identify themselves or provide any type of information that could allow them to be identified by someone with access to your research materials (e.g. SSN, unique characteristics, any type of identity coding, images, audio recordings, box number, email address, etc…)? \_\_\_ Y \_\_\_ N

If Y, please describe all measures that will be taken to protect the confidentiality of information provided. Please note that this question pertains to all research notes and raw data, not just to published products of the study.

1. Please describe all foreseeable risks (physical, mental, and social) to the participants including risks that electronic data could be compromised in some way. Describe any distress that might be caused by the study, such as probing for information that might be considered personal or sensitive to the participant or that might be considered offensive, threatening or degrading. If you are using solely electronic means to collect your data make sure to address how you will take extra steps to monitor your participants for stress and provide them with opportunities to ask questions or seek out additional support. Note, just saying they can contact the campus counseling center is not sufficient if you believe there is a risk of significant and specific distress.
2. Will you be using deception? \_\_\_ Y \_\_\_ N

If Y, describe the nature of the deception and the rationale for its use. If distress is a possible outcome or if deception will be employed, describe the planned procedures for debriefing the participants after the research is conducted.

1. Attach a copy of debriefing materials or provide a rationale for not providing debriefing materials. These should be submitted to the IRB in the same form as they will be viewed by participants.
2. What procedure will you use for addressing and reporting unanticipated problems to the IRB? For example, if you find out someone is in danger. For student projects, you should also describe possible situations that you would immediately report to your faculty supervisor.

Benefits and Compensation

1. Please describe any benefits participants will receive by participating in your research. (Note this does not include any compensation for participation. That is covered in Question 10.)
2. Will participants be paid or compensated in some other fashion (extra credit, food, prizes, money, academic grades, etc.)? \_\_\_ Y \_\_\_ N

If Y, please specify what compensation you will provide and how that compensation will be delivered to participants. How, if at all, will compensation be affected by withdrawal from your study?

Informed Consent

Note: Once your receive an IRB#, add it to your informed consent statement. Submitted materials should indicate where on the document the IRB# will be located. Once you have been assigned an IRB#, please include that number in all communications with the IRB committee (e.g., subject line of emails).

1. Please describe the consent process by explaining when and how the participant’s consent will be solicited. Describe additional steps that will be taken to ensure the participant’s right to withdraw without penalty at any time and to guarantee their privacy and to ensure confidentiality. If participants include minors or other populations who may not be able to give consent for themselves, describe how parents/guardians will be informed of the study and give their consent. If the research is part of an in-school or institutional study, what will teachers, officials, or administrators be told about the study, and how will their permission be obtained?
2. Are there any conditions under which you may violate confidentiality? \_\_\_ Y \_\_\_ N

If Y, then describe those conditions and how they would be handled.

1. Attach a copy of your consent form in the same form as it will be viewed by participants.
2. How and where will the written, signed consent forms be stored? If these will be destroyed later, specify who will be responsible for destroying the material and how and when that will occur. (We recommend that consent forms be retained for at least seven years following the completion of the research.)

Data

Note: If you are using electronic data, then make sure to address how you will address data security in the questions below by clearly describing your procedures for handling, securing, storing, and destroying electronic data, materials, voice recordings, or images.

1. Select below all methods you will use to collect data:

Observation: Will you be collecting observational data? (choose one) \_\_\_ Y \_\_\_ N If Y then answer the following questions:

Will you be observing in a public or private (for example a school) location? \_\_\_ Y \_\_\_ N

If Y, (you are observing in a private location) please attach a letter from the location owner confirming you have their permission to observe at that location. If the owner of the location is a partner in your research, you can submit a single letter that covers observation permission and other components of your partnership.

Will your observation involve audio or video recording of participants? \_\_\_ Y \_\_\_ N

If Y, then make sure to address how you will protect confidentiality and securely store electronic recordings in questions #6 and #7 and in your informed consent document.

Make sure to attach your data recording protocols (this should include information on where you will be observing and who will you be observing as well as your exact process for recording data) or describe your data collection procedures here.

Survey: Will you be collecting questionnaire, test, or survey data? (choose one) \_\_\_ Y \_\_\_ N

If Y, briefly describe your measures. If the measure has been used in previous research please provide at least one citation for the measure using the format: Survey 1: Title, Author, and Citation

If Y, will you collect data electronically? (choose one) \_\_\_ Y \_\_\_ N

If Y, will you be collecting IP addresses? (choose one) \_\_\_ Y \_\_\_ N

If Y, provide a rationale as to why you need IP addresses. Also this must be noted in your consent statement.

Interview: Will you be collecting interview data? (choose one) \_\_\_ Y \_\_\_ N If Y please answer the following questions:

If Y, briefly describe the interview format you plan to use (for example, structured, semi-structured, or unstructured). If some form of the interview has been used in previous research please provide at least one citation for the measure using the format: Survey 1: Title, Author, and Citation

If Y, will the interview be conducted face-to-face, via telephone, over email/chatroom, or through online video? For any method other than face to face, please address how you will protect confidentiality and securely store electronic recordings in questions #7 and #8 and in your informed consent document.

Other: Will you be using another method of data collection that is not covered by the previous questions? (choose one) \_\_\_ Y \_\_\_ N

If Y, please describe.

1. Please attach a copy of any surveys, interviews, etc… as well as detailed description of the written or oral materials, stimuli, or experimental procedures to which participants will be asked to respond. Failure to include this information may delay approval of your request. If you are using Survey Monkey or some other electronic means of data collection submit a PDF (preferred) or screenshots of all online materials that participants will be exposed to along with your application.

Additionally, make sure to clearly identify which questions are required (meaning that participants may not continue without answering them) and which questions are optional.

1. Who will be responsible for securing and destroying the data, and exactly when and how the data will be destroyed. For student projects (in particular class projects), the supervising faculty member should have a role in ensuring data are secured/destroyed.

The following are general guidelines for storing and destroying data. These are just guidelines, if your field has higher standards, then those are the standards you should follow.

* For class projects materials/data should be stored for 1 year after the end of the semester. For projects that use an online methods of data collection (for example, Survey Monkey), the data should be deleted off of the online (external) server before the end of the semester or the supervising faculty member should be the person identified as responsible for deleting the data (as students may not have access to the account after the course ends).
* For class projects where the results will be presented to an external audience or independent student projects the data should be stored for 3 years after the conclusion date of the research.
* For faculty research or student research that has the potential for publication the data should be stored for 7 years.

Projects Involving Biological or Medical Material/Information

1. Are you using any medical procedures with humans? (choose one) \_\_\_ Y \_\_\_ N

If Y, please describe any medical procedures to be used (for example, blood pressure or temperature monitoring, heart rate monitoring, EKG, blood drawing, etc.) and describe the safeguards to be employed. Justify the necessity of employing invasive or noninvasive medical procedures.

1. Are you collecting biological material from a living human? (choose one) \_\_\_ Y \_\_\_ N

If Y, please submit a copy of your procedures for handling biological material and a copy of completion certificates for any relevant biosafety training related to your project.

If Y, does your project require review by the Institutional Biosafety Committee (IBC)? Note you must be approved by the IBC before the IRB will review your proposal and you must submit a copy of your IBC approval letter with your IRB application.

1. Will you be accessing HIPPA protected health documents? (choose one) \_\_\_ Y \_\_\_ N

If Y, then you must submit a description of the procedures you will take to be HIPPA compliant and provide a copy of your HIPPA training completion certificate.

Other Information

1. Are you receiving funding to support your research (this includes on and off campus awards)?

(choose one) \_\_\_ Y \_\_\_ N

If Y, is the funding source internal (provided by or award through Austin College) or External (funding from any entity outside of Austin College)? (choose one) \_\_\_ Internal \_\_\_\_ External \_\_\_\_ Both

Identify the funding source(s) and the purpose for which the funding was given:.

If you are receiving any part of your funding from an off-campus/external source please complete the Conflict of Interest Form and attach it with your application.

1. Are partnered or collaborating with one or more agencies, groups, colleagues, etc. outside of Austin College? (choose one) \_\_\_ Y \_\_\_ N

If Y, please list all contact information (names, addresses, phone numbers) for those who have engaged in this relationship for the purposes of this project. Additionally, the IRB will want a signed statement on organization letterhead from those contacts that describes in detail the nature of that relationship, including specific information pertaining to prospective responsibilities, payments, expectations, limitations, deadlines, etc. Note: If your partner organization or individual in a foreign country, then you must also identify the human subjects requirements they operate under and describe, if any, additional procedures that are required to meet those foreign policies.

1. Are there any other potential conflicts of interest or involvement of any groups not addressed elsewhere in the form that the IRB needs to be aware of when reviewing your project? (choose one) \_\_\_ Y \_\_\_ N

If Y, please describe.

Submit this application and any other relevant materials electronically to the current IRB Chair at IRBChair@austincollege.edu

Rev March 2016

IRB Checklist

This checklist is for your information only. It does not need to be completed or submitted to the IRB.

The following items need to be submitted to IRBChair@austincollege.edu as part of the IRB process:

\_\_\_ IRB Form

\_\_\_ Consent Form

 Consent forms should contain the following information:

* Description of the purpose and procedures included in the study (here it should be clear what you are asking participants to do as part of participating in your research).
* Duration – How long will they be involved in research activities
* Risks/benefits – What are the risks/benefits to participants if they participate in your research? It is ok to say no know risks if none exist. The benefit can be our students learning about the research process.
* Compensation – If compensation is offered, describe how it will be awarded (drawings, extra credit, money, etc.)
* Confidentiality – How will you collects, store, and destroy information you are collecting? Will there be any identifying information collected? If so, what steps will you take to protect that information. Are there any circumstances under which you would violate confidentiality?
* Statement about voluntary nature of the study and right to withdraw
* Contact information for researchers and the IRB chair and what to do if they have any questions about the study – Here include the contact information for researchers (and if it is a student project, include information for faculty supervisor). Additionally, include space for adding your IRB#, which will be assigned once your project is submitted to the IRB. All consent forms/statement should include an IRB# for study tracking purposes.
* Statement of Consent – a final statement of what participants are agreeing to. If you have multiple activities or assessment that participants are agreeing to, separate them out into separate statements that participants can agree to or not (usually by checking Y/N next to the statement describing each activity)
* Conflicts of Interest, Alternative Treatments, and Funding – If any of these issues apply to your research make sure to clearly describe them somewhere in your consent statement.

\_\_\_ Recruiting Materials (emails, flyers, etc.) – Make sure to include your IRB# on each recruiting statement

\_\_\_ Copies of Study Materials (stimuli, surveys, debriefing materials, etc.) – Note: These materials need to be submitted in the format they will be given to participants. For published materials under copyright, you do not need to submit copies of the materials, references for the original source material is sufficient though the IRB may request the actual material for review.

\_\_\_ Conflict of Interest Form (only if required – see question #25)

\_\_\_ When submitting the form all members of the project (including faculty supervisors) must be included on the original email. Once an IRB# is assigned, that number should be in the subject line on all subsequence communications with the IRB.

\_\_\_ Complete CITI Human Subjects Training (required modules only unless you are directed to complete supplementary modules by the IRB) at <https://www.citiprogram.org/> Begin by registering to create and account, then choose Human Subjects Training only (you do not need to register for CE or any of the other courses, Austin College uses CITI for several different types of ethics training). The IRB chair can log on to see that the training has been completed, so you do not need to submit proof of training, just report the date you completed the training. For students training should be completed yearly.