

Example of an Initial IRB Application

Please note that all study information and citations in this document are fictional and intended to be a useful tool for Boston College investigators who are working on their own research protocols.

I. Title

- A. Study title: Understanding Undergraduates' Experience in the Transition from High School to College
- B. Today's date: 11/8/18

II. Principal Investigator

- A. PI: Dr. Joe Example. Campion Hall 632, Lynch School of Education, joe.example@bc.edu, 617.552.1758
- B. Role: Faculty
- C. IRB training date: August 1, 2017
- D. *Attach CV and Human Subjects Training Certificate (CITI)*
- E. Not a student. Department chair: Dr. Lucy Dean. Email: lucy.dean@bc.edu, 617.552.4778.

III. Research Risk

- A. Does the research pose greater than minimal risk to participants? NO
- B. Does the research include prisoners? (yes/no) NO
- C. Level of review: please select a level of review and the appropriate category that corresponds to that level of IRB review: (select exempt, expedited, or full board)
EXEMPT LEVEL 2

IV. General Study Information

- A. Funding:
 - 1. None
 - 2. University funded
 - 3. External - YES: Foundation for Studies on Life Transitions, Grant #10101
 - 4. Federal
 - 5. Is BC the primary awardee for the grant? (yes/no). If no, list primary awardee. YES
 - 6. Are there subcontracts? (yes/no) If yes, list sub-contractors. NO
- B. Participant recruitment numbers: 62 males, 63 females
- C. Participant ages (check all that apply): 18-65
- D. Estimated project duration: start date and end date: January 1, 2019 – April 1, 2019
- E. Why is this project being conducted (select one): faculty/staff research
- F. Will this study involve long-term follow-up with participants NO
- G. Special study populations (check all that apply): no special study populations
- H. Does this study involve any of the following? (check all that apply): NO

V. Research Summary

- A. Introduction and background:
 - 1. State the problem and hypothesis

The problem: Students often have a difficult time transitioning from high school to college, and figuring out which aspects are most difficult, and why, may be useful in creating tools, lessons, and methods to make the transition easier.

Research Questions:

- Which aspects of transitioning from high school to college do undergraduates report as being most difficult?
- Do students who go to college far from home have the most difficult transition?
- Do female or male students have more difficulty with the transition, either academically or socially? Are there any other demographic characteristics that put students at risk for having an exceptionally difficult time with the transition, or serve as a buffer (example: status as an athlete, having a declared major vs. no declared major, participation in club sports or extracurriculars)?
- Do students find any features of their freshman experience to be helpful in the transition?

Hypotheses:

- We expect that undergraduates will identify a number of academic and social difficulties during this transition
- We expect that students who are coming to college from further away have a more difficult adjustment
- We expect that males and females will have similar difficulties in the transition
- We expect that participation in freshman seminars, freshman retreats, and interaction with academic advisors will be identified as helpful programs that aid the transition.

2. Provide the scientific or scholarly reason for this study and background on the topic

According to many scholars, the transition from high school to college is a particularly difficult time for many students, both academically and socially (Brady, 2002; Gronkowski, 2008). However, little is known about which students are most at risk for having a difficult transition. It has been suggested that liberal arts universities should identify which students are most at risk for having a difficult transition (Belichick, 2015), and to identify programs and features of the freshman experience that may aid in the transition (Edelman, 2018).

B. Specific aims/study objectives

1. List the purpose of the study

To determine characteristics of students that have a difficult transition from high school to college, and to better understand what those difficulties are. Additionally, to learn more about what might help to make this transition go more smoothly.

C. Materials, methods, and analysis

1. Describe data collection methods: There will be two types of data collection. First, an anonymous online survey through Qualtrics will be sent to freshman at Boston College. We will ask Residence Hall Advisors to forward the link to their residents. We will also recruit 25 volunteers for in-person interviews to gather richer data that the survey may not capture. We have attached the text of the online survey as well as our general interview questions to this protocol.
2. Describe the specific materials or tools that will be used to collect the data: The online survey, administered with the anonymous function through Qualtrics.

The interviews will be 1-on-1 interviews that will take place in my office with no other participants present. They will be audio recorded with a handheld audio recording device.

3. Describe timeline of the procedures and how long each procedure will last. The online surveys will be sent out in mid-January and will close on February 1st. I expect it to take 20 minutes to complete. Flyers to recruit volunteers for the survey will be hung the second week of January and interviews will be scheduled in February and March. I expect the interviews to take 30 minutes. Data analysis will last until April.
4. Describe how you will analyze your data: The survey data will be downloaded anonymously and analyzed with SPSS software. The audio recorded interview data will be transcribed by me and my graduate assistant, and the recordings will be deleted. All identifying information will be deleted from the interview transcripts. They will be analyzed with Atlas-Ti software using thematic analysis.

D. Research population and recruitment methods

1. Describe inclusion and exclusion criteria
Participants must be 18 or older and in their freshman year at Boston College. There is no exclusion criteria regarding gender or race. Freshmen who are under 18 years old will not be included in the study.
2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
We are interested in examining the transition from high school to college among students. Freshmen in college have experienced the transition most-recently, and thus are an ideal population to include in the study. We hope to recruit up to 100 participants to achieve a high statistical power for the quantitative portion of the study. Separately, we will also hang flyers around campus to recruit 25 freshman to be interviewed for the qualitative portion of the study. Students who participate in the interview may also complete the survey, but it is not required.
3. How did you choose the source of participants or data?
We chose to include Boston College freshmen as a convenience sample, as they are the most easily accessible and offer a diverse background.
4. Recruitment procedure; including who will recruit participants, and if applicable, how any conflict of interest/coercion, undue influence will be mitigated
The online survey will be sent out to freshman from Resident Assistants in freshman dorms (we have received permission from the Office of Residential

Life to do this). As the attached email text indicates, it will be made clear that this is completely voluntary and students should only participate if they are interested in doing so.

We have attached the flyer that we will hang around campus in the academic buildings to recruit freshman for the interview portion of the study.

Research assistants on the study will be in charge of hanging these, and we will receive permission from the administrators of each academic department before posting the flyers in their buildings.

5. Tools that will be used to recruit (recruitment tools should be uploaded as an attachment)

Please see the attached email text for survey recruitment, and the attached flyers for interview recruitment.

6. Research incentives and payments: please specify what form of payment you will be using and how it will be documented

As specified in the consent form, at the conclusion of the online survey, students will have the option to go to a separate webpage and enter their email address to be included in a raffle for three \$50 gift cards to the BC Bookstore. The webpage is separate so that student email addresses are not tied to the survey responses in any way (to preserve anonymity).

As specified in the consent form, participants in the in-person qualitative surveys will each receive a \$10 gift card to the BC Bookstore. Survey participants will still be able to enter the raffle even if they choose to end the study early. Participants who are interviewed will still receive the full gift card amount even if they choose to end the study early.

E. Informed consent procedure

1. Who will perform the informed consent procedure, and how will that person be trained?

For the online surveys, the consent language will appear as the first page of the survey, and participants will click either “yes” or “no” to the consent statement. Those who click “yes” will proceed to the survey, those who click no will be brought to an exit page.

For the in-person interviews, the PI and research assistants on this project will give the consent form to participants to read and sign. The PI and all research assistants have up-to-date CITI training certificates.

2. How will the prospective participant’s competence or understanding of the procedures be assessed; will participants be asked questions about the procedures, or encouraged to ask questions?

For the online consent for the survey, we have included a sentence to make it clear that participants can contact us with any questions before consenting to the survey. For the in-person interviews: after being given the consent form, we will tell participants to read it and ask us any questions before signing it. All participants in our study are adults ages 18+, so we assume that they will be able to read and understand the contents of the consent.

3. Please describe the process by which informed consent will be obtained.

For the online surveys, the consent language will appear as the first page of the survey, and participants will click either “yes” or “no” to the consent statement. Those who click “yes” will proceed to the survey, those who click no will be brought to an exit page. For the in-person interviews, the PI and

research assistants on this project will give the consent form to participants to read and sign prior to beginning the interview.

F. Confidentiality:

1. Where will the data be stored, and who will have access to the data and the area?

All data will be stored in the PI's folder on the secure Boston College departmental server. Only the PI and the research assistants on the study will have access to it.

2. How will the data be stored, and in what format?

The data will be stored electronically as Excel Files (the online survey), and as interview transcripts (in-person survey). The audio files for the interviews will also be stored on the secure server and immediately deleted from the devices used to record them.

3. Will the participants' identity be coded? Will the codes to identify participants be stored with the data?

Through the anonymous function on Qualtrics, all survey respondents will have an anonymous identifier so that the participant's identity cannot be ascertained. For the in-person interviews, each person will be assigned a random ID through a random number generator, and the list of IDs linked to the participants will be kept in a locked file in the PI's office, separate from the data which will be on the server. All identifying information in the interview will be redacted from the transcripts immediately.

4. HIPAA: Are you using protected health information or working at a HIPAA covered institution? (yes/no)

No

G. Statement of potential risks to subjects

1. Indicate the type of risk that may result from participation

It is possible that some students may feel uncomfortable discussing their feelings around the transition from high school to college, particularly if the transition was difficult.

2. Consider the likelihood and magnitude of the risks or discomforts occurring. Are they unlikely or likely to occur and what effect would the discomforts or risks have on the individual should they occur?

The risks are unlikely since we have designed the survey questions in a sensitive way, and we don't anticipate that they would have a major impact on the participants.

3. How will you minimize the risks? Some examples include informed consent, adequate staff training and experience, debriefing, and monitoring adverse effects on participants.

We will minimize the risks by making it clear in the consent form that the study is voluntary, and participants can stop at any time.

H. Statement of potential research benefits to subjects

1. Indicate the type of benefit that may result from participation.

Consider psychological or emotional benefits, learning benefits, physical benefits and discuss if participant will benefit directly or if

the benefit is largely to gather generalizable knowledge that may benefit society.

Participants may enjoy sharing their experiences of the transition from high school to college. Additionally, we are hopeful that this study can help us to identify characteristics of students who might be at particular risk for a difficult transition, and to identify supportive mechanisms that universities can provide.

2. Consider the likelihood of benefits. Will all or some participants benefit?

Although participants may not benefit directly, it is likely that they will feel satisfied in helping us to conduct research that may help other college freshmen in the future.

- I. Investigator experience: CV of the PI must be attached
The CV of the PI is attached.

VI. Informed Consent

- If the project qualifies for exempt review or if informed consent is not applicable, a box can be clicked so that you can skip to section IX.
 - Are you requesting an alteration or waiver? (yes/no). If yes, a waiver consent box will open. You will need to check whether you are asking for a partial or total waiver of consent, and whether you are asking for a waiver of the documentation of consent. A text box will allow you to describe the elements you are waiving and your rationale. In this case, the PI would choose “both” and then “yes” for partial waiver and waiver of documentation.
- J. If you are not requesting an alteration or waiver, you will be asked to attach your consent forms and check that you have included all of the standard elements of consent. Please see our [sample forms page](#) to see what should be included in your consent. You will also be asked to ensure that the consent form is written at a reading level appropriate to the population being studied.
 - K. Consent Waiver/Alteration: you will need to answer whether you are asking for a partial waiver, total waiver, or waiver of documentation of consent.
 - L. We provide links to 3 readability tools, and you will need to use one of those to generate a readability comprehension level.

VII. Research with Minors (only fill out this section if you are using minors in your research)

- M. Please provide a scientific or medical rationale for the inclusion of minors
- N. Federal regulations classify research with minors into four categories based on the degree of risk. Please pick the appropriate category for your research (check one):
 1. Research involving minimal risk to minors
 2. Research involving greater than minimal risk to minors with the prospect of direct benefit to the child
 3. Research involving greater than minimal risk with no direct benefit to the minors but it is likely to yield generalizable knowledge about the subject's disorder or condition
 4. Research not meeting the criteria for Categories 1-3 that involves greater than minimal risk to healthy minors and presents no direct benefit to them

but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare.

VIII. Research Sites *(The applicant would not fill out this section since it does not apply)*

- O. Are you conducting research at a site? (yes/no) NO
- P. If yes, do they have an IRB? (yes/no) Will IRB approval be sought from that institution? (yes/no)
- Q. Name of site

You will be asked to include a site permission/approval letter

IX. Acknowledgement

- R. You will be asked to read a statement on the definition of scientific misconduct. You will also be asked to read a statement on conflict of interest and check a box (yes/no) stating whether you or a family member derived income within the past year of \$5,000 or more in publicly-traded or non-publicly traded entities.

X. Co-PIs *(The applicant would not fill out this section since it does not apply)*

You will need to list each Co-PI's name, contact information, school, department, and IRB training date by moving them over from the "available individuals" box to the "assigned co-PI box." To have names available on your protocol, you will first need to add Co-PIs through the "My Contacts" tab. There is a button that will allow you to upload their CITI or NIH training certificates.

Research Assistant

You will need to list each research assistant's name, contact information, school, department, and IRB training date by moving them over from the "available individuals" box to the "assigned research assistant" box. To have names available on your protocol, you will first need to add Co-PIs through the "My Contacts" tab. There is a button that will allow you to upload their CITI or NIH training certificates.

Signatures

- The PI will be asked to electronically sign the protocol.
- If a student is the PI, the faculty research supervisor will also need to electronically sign the protocol.
- For faculty research, the department chair or dean will need to electronically sign the protocol.