Bryant University

Bryant University IRB Application Form (Full Board Review)

SECTION A: CONTACT INFORMATION

Principal Investigator's Name:	
Research Title:	
Bryant Mailing Address:	
Email:	
Telephone:	
Additional Contact Person:	
Email:	
Telephone:	

SECTION B: FUNDING

Provide information regarding ALL funding sources in this section. This includes ANY EXISTING FUNDING, PENDING FUNDING, OR FUNDING THAT HAS BEEN APPLIED FOR TO SUPPORT THIS RESEARCH.

Please check all that apply:	
☐	This research is funded
☐	Funding has been requested
☐	Research is not funded

If the research is funded or funding has been requested, complete the box below.

Sponsor Name		
Title of Grant/Proposal		

*NOTE: Provide a copy of the grant application, funding proposal, scope of work, or sub-award agreement. The University is required to verify that all funding proposals and grants have been reviewed by the IRB before funds are awarded.

SECTION C: STUDY STAFF

List **ALL** current members of the research team in the table below. Add more rows as necessary.

STUDENT RESEARCH:
Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student's human subjects research.

INVESTIGATORS/STUDY STAFF

Name & Department/College	Study Role (e.g. co-investigator, research coordinator, research assistant, project manager, lab manager)

SECTION D: LOCATION OF THE RESEARCH

YES*	NO	
☐	☐	Will this research take place at sites/locations other than Bryant University? Note: If the research will take place at Bryant University, state the location (Building and Room number):

*If **YES,** please complete the boxes below

NOTE: You are responsible for obtaining permission/letters of support for research conducted off-site. This may include locations such as schools, workplaces, community organizations, etc. You must submit the letters/documentation of support with this application.

Institution Name and Address (if known)	Describe Involvement (recruiting, consenting, data analysis, etc.) of the site. If the site or the site staff is not involved (engaged)[1] in research procedures, state NONE.	IRB/Ethics Approval/Site Permission Attached? If no[2], explain the plan to obtain this approval. If the site is not engaged in the research, you do not need to complete the box.

[1]Guidance on Engagement of Institutions in Human Subjects Research: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

[2]If IRB approval will not be obtained at the site, describe the IRB oversight arrangements here:

YES*	NO	
☐	☐	Is the Bryant PI the lead investigator **OR** is Bryant University the lead site for this research? **Note: This box only needs to be completed if the off-site location is engaged in the research.**

*If **YES**, provide the following information in this box:

- The plan for collection and management of data from all the sites
- The plan for reporting and evaluating:
  - Unanticipated problems
  - Serious and/or continuing non-compliance
  - Suspensions and terminations of research
  - Interim results
  - Protocol modifications
- The name of the Principal Investigator from each site
- If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site
- If IRB approval will be obtained at the site, confirmation that the site IRB has a federalwide assurance (FWA)

SECTION E: STUDY SUMMARY

Summarize the study in lay language. This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information. Note: Do not include a list of citations in this section. Please limit this section to no more than 100 words.

SECTION F: RESEARCH METHODS AND ACTIVITIES (Check all that apply)

☐	Collection of audio, video, digital, or image recordings
☐	Biological samples Examples: blood, hair, cheek swab, urine, tears, saliva, etc.
☐	Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. Examples: Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc.
☐	Coordinating Center/Lead Site
☐	Deception
☐	Devices
☐	Drugs
☐	Ethnographic:

	The study of people in their own environment through the use of methods such as participant observation and face-to-face interviewing
☐	Focus Groups
☐	Genetics Testing
☐	MRI
☐	Placebo
☐	Pregnancy Testing
☐	Randomization
☐	Surveys, interviews, questionnaires
☐	Secondary Data Analysis
☐	Other (please describe):

SECTION G: SUBJECT POPULATION

Number of Subjects to be Enrolled:	

Check all categories that apply to your target population:	
☐	Adults
☐	Children (< 18 years of age)
☐	Cognitively-Impaired Adults
☐	Non-English Speaking
☐	Prisoners

☐	Bryant Employees
☐	Bryant Students
☐	Wards of the state
☐	Other (please describe):

If Categories other than 'Adult' are checked, describe the additional safeguards that have been put in place to protect that subject population. For Cognitively-Impaired Subjects, provide the rationale for including this population in this research study.

Eligibility Criteria
Inclusion Criteria:
Exclusion Criteria (exclusion criteria are the specific criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria):

SECTION H: RECRUITMENT

Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified Note: Submit any recruitment materials such as advertisements, brochures, flyers, letters/e-mails, scripts, etc. Please submit these materials as separate documents in either Word or PDF format.

SECTION I: CONSENT AND ASSENT

NOTE: Please provide the consent form in your email submission; refer to the consent form templates on the IRB website when creating.

Indicate the consent and/or assent process and document(s) to be used in this study. Check all that apply

Consent: Adults (≥18 years of age) N/A ☐ **One of the following MUST apply**	
☐	Consent Form/Information Sheet
☐	Verbal Consent (Script) **Note: If written consent will not be obtained, complete the 'Waiver of Written Documentation Consent' box (Box 1) located further down in this section**
☐	Consent will not be obtained **Note: If consent will not be obtained, complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section**

SECTION J STUDY PROCEDURES

In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes versus which procedures are part of standard of care, if applicable. Be sure to include the following information:

- Methods of data collection
- Details regarding research activities/procedures/interventions
- Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)
- Time required from each subject
- Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.*

*Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit Appendix C: Device Form.

Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study. Please submit these materials as separate documents in either Word or PDF format.

Note: If subjects will have standard of care procedures in addition to research procedures, clearly state which procedures are standard of care and which are for research purposes only.

SECTION K: RISKS

Describe any expected risks to subjects. Consider physical, psychological, social, political, legal, economic, or other risks that are related to the study.

Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.

SECTION L: BENEFITS

Describe the potential benefits to subjects related to the study. State if there are no direct benefits. NOTE: Compensation and/or course credit are not considered benefits.

Describe the potential benefits to society and/or others related to the study

SECTION P: CONFIDENTIALITY OF DATA

Describe how data will be stored (e.g. paper, electronic database, etc.)

SECTION Q: CITI Certificate

The Bryant Institutional Review Board (IRB) requires that all faculty researchers and student researchers such as honors students and students in research methods courses (e.g., marketing research, communication research, and psychology research methods) acquire certification for writing grants that comply with federal and state agencies through the CITI program.

To register for CITI, go to: https://about.citiprogram.org/en/homepage. Click "Register" and type/select "Bryant University" from the list of universities/colleges.

Follow the instructions to select the courses you want to take (Social & Behavioral Research: Stage I Basic Course).

Once you complete the course, you will receive certification that lasts 3 to 4 years, depending on the course, and is valid for any other research method courses or honors theses.

Signatures

- By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
- I agree to conduct the describe research in an ethical manner.
- I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
- I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
- I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.

PI printed name _____

PI Signature:_____ Date: _____

Student research: Student research must be signed by the faculty advisor

Faculty Advisor (print name): _____

Student Name (print name): _____

Signature: _____ Date: _____

Submission

This form can be completed, signed, scanned and submitted by email to the IRB at syoon@bryant.edu. Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.

In your email submission, please include: 1) the IRB application form, 2) the interview/survey/experiment stimuli and questionnaire, 3) the consent form (or the Qualtrics survey that contains the consent form) and 4) the pdf version of your CITI certificate.