**Application for Exemption**

Protocol title:   
Principal Investigator (PI):

E-mail: example@brown.edu Phone: (xxx) xxx-xxxx

PI’s affiliation with Brown University:  Brown Faculty  Brown Staff  Brown Graduate/Medical Student  Other:

If this research is funded by an external agency (e.g., NSF, NIH), which agency?      Title of the proposal to that agency for funding:       (include grant proposal as an attachment to this form)

**Investigator Conflict of Interest Statement:**

The[*Brown University Conflict of Interest Policy for Officers of Instruction and Research*](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-policy) *(“COI Policy”)* defines the term “Investigator” as “the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, graduate student, trainee, collaborator, or consultant), who is responsible for the design, conduct, or reporting of sponsored research.” Using this definition of “Investigator,” please ensure that all Investigators on this protocol answer questions (a) and (b) below [attach additional sheets for any Investigators who are not the PI; they only need to answer (a) and (b)]:

*(a)* Is your annual Assurance of Compliance form (and, if necessary, reporting form) accurate and up-to-date as of the time of this submission, as required by the [COI Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-policy)? (You may access the system [here](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/conflict-interest/electronic-coi-assurance-and-reporting) to confirm.) YES NO

*(b)* Do you have a [significant financial interest](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-frequently-asked-questions#interest) (SFI) that is related to this research protocol? “Related” could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI and/or that the SFI could be affected by the proposed research or its results. YES NO

**Principal Investigator certifies to the following: *(1)*** The rights and welfare of the participants are adequately protected. ***(2)*** The risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained. ***(3)*** This protocol is accurate and complete; if the project scope or design is later changed, the PI will submit an amendment for review. ***(4)*** **All research personnel**, including the PI and advisors on graduate student research, has been, or will be, adequately educated in human research protections prior to beginning work on the project.

**Principal Investigator signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

=============================================================================

*Graduate/Medical students conducting human research must have a faculty advisor review the protocol and sign this section before submitting an application to the IRB.*

Brown Faculty Advisor Name:

*I have reviewed this application and will oversee this research in its entirety.*

***Advisor's signature:*** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ***Date:***  *\_\_\_\_\_\_\_\_\_\_\_\_\_*

## Part I: Review Exemption Checklist

*Check all that apply. If you can check* ***all*** *items, proceed to Part II. If not, your research does not qualify for exemption.*

The research does not involve prisoners, fetuses, the seriously ill, or mentally or cognitively compromised adults.

The research does not involve participants under the age of 18 OR only involves observation of participants under the age of 18 in which there is *no interaction between the researcher and participants [45CFR 46.401(b) or educational research* [45CRF 46.101(b)(1)]

The procedures of this research are generally free of foreseeable riskto participants. *[i.e. research involves only procedures, and data is collected and maintained in a manner such that the study is unlikely to cause physical, psychological, social, financial or legal harm to participants]*

The research does not involve the use of FDA-regulated drugs, biologics or devices.

## Part II: Exemption Category Checklist

*Check any that apply. If you can check* ***at least one*** *item* ***AND*** *all activities you intend to conduct fall into one of the below categories, your research may qualify for exemption.* ***You must answer the questions in Part III to complete this application****. If not, use IRB Form #1 to submit a protocol for expedited or full committee review.*

[45CRF 46.101(b)(**1**)] The research will be conducted in *established or commonly accepted educational settings* (e.g., school or university classrooms, educational centers, etc.) involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research goals are pedagogical, focused on improving student understanding, educational performance, ability to function productively in the classroom, and so forth.

[45CRF 46.101(b)(**2**)] The research will involve the use of educational tests (cognitive, diagnostic, aptitude or achievement tests); survey procedures; interview procedures; or observation of *public* *behavior.* In order for a study to fall into this exemption category, *at least one* of the following must be true:

*Information will be recorded* ***anonymously*** (i.e., so that participants cannot be identified, directly or through identifiers linked to individuals)

The information collected could not reasonably place participants at risk of civil or criminal liability nor be damaging to participants’ financial standing, employability or reputation if disclosed.

[45CRF 46.101(b)(**3**)] The research will involve the use of cognitive, diagnostic, aptitude or achievement tests; survey procedures; interview procedures; or observation of public behavior *that is not exempt under (b)(2) above* **AND** *all participants are elected or appointed public officials or candidates for public office; or federal statutes require that without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.*

[45CRF 46.101(b)(**4**)] The research will involve the collection or study of *existing data, documents, records, pathological specimens, or diagnostic specimens*. These sources are either publicly available or recorded by the investigator anonymously (i.e. subjects cannot be identified). All data, documents, or records must already exist prior to IRB review; the proposed research must be strictly retrospective.

[45 CRF 46.101(b)(**5**)] The research (including demonstration projects) will be conducted by or subject to the approval of federal department or agency heads, and is designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs (e.g., social security, welfare, etc.); (ii) Procedures for obtaining benefits or services under those programs or procedures; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) Possible changes in methods or levels of payment for benefits or services under those programs.

[45 CRF 46.101(b)(**6**)] The research involves *taste or food quality evaluations* or *consumer acceptance studies* and the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture.

[Brown University exempt category 7] [Minimal risk](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) (46.102[i]) exempt research activities that will not induce distress beyond that of daily life may include (but are not limited to) non-physically invasive interventions or performance of tasks such as reading/writing/drawing tasks, physical activities such as walking, sitting, or manipulating an object, computer tasks and/or Internet searches, talking and/or listening to words, then making selections, or “think-aloud” exercises, viewing media, role-playing, completing a specific physical or mental action (“imagining”), passive monitoring of space (environment) with sensors, playing a game, height/weight measurements. *This exemption category does NOT apply to federally-funded research.*

## Part III: Study Specific Information - Required

*Please type or copy-and-paste answers to the following questions in the text boxes provided. The boxes will expand as needed to accommodate your text, but keep in mind that clear, concise answers will facilitate expeditious review.*

***Note: The IRB cannot accept proposals in which the answers to these questions are marked in a separate project summary or grant proposal document. Copy-and-paste or type the relevant information into the fields below.***

1. **What is the purpose of the proposed study?**

1. **Describe the pool of participants that will be involved in the proposed research, including participants’ expected age range.**

1. **Describe how subjects will be recruited and selected.** *Include copies of all recruitment scripts, flyers, e-mail notices, etc. you will be using with your proposal (in Word - .doc or .docx -format).* If the research will be carried out in an institutional setting (i.e., at a school, social service agency, hospital, etc.), *include an email or letter from an appropriate administrator at that institution, indicating that he/she gives permission for the research to be done in that setting and what that institution is expected to do or provide.*

1. **Briefly describe all research procedures that will apply to participants.** Approximately how much time is each participant expected to devote to the research? Will all of the data be collected at one time or is data collection spread out over time?

1. **If you are collecting data directly from participants, list or describe any research instruments that will be used ‑‑** that is, anything that a participant must complete (surveys, tests or measures, demographic forms, etc.) and attach copies of each to your submission.

1. **Describe how you will preserve participant anonymity and/or confidentiality of data.**

1. **If subjects will receive payment or compensation (i.e., gift card, entry into lottery, etc.) for their time and effort,** describe in detail the amount or value of this compensation, when and how it will be delivered, and how the researcher will prorate compensation for subjects who withdraw early. If you plan on using a raffle or lottery, indicate the chances of winning.

1. **Describe any relationships between the researcher(s) and subjects, such as: teacher-student, friend-friend, employer-employee, etc.** If such a relationship exists, what procedures will you use to ensure that participants are free to decline participation without penalty and that no undue influence to participate exists?

1. **Briefly describe the consent procedure to be used, if applicable**. At a minimum, a consent procedure should includethat the activity involves research, participation is voluntary, a description of the procedures, and investigator contact information.