***THIS FORM SHOULD BE DOWNLOADED AND THEN OPENED IN ADOBE ACROBAT BEFORE BEING FILLED OUT. FILLING IT OUT IN A BROWSER WINDOW OR IN ANOTHER PROGRAM MAY RESULT IN DATA LOSS.**

Section 1: Investigator(s) Information

Name(s) of Principal Investigator(s) at Gettysburg College:	
Department or Program:	
College Status/Position:	
Name of Faculty Sponsor (if student):	
Name(s) and institution(s) of co-researcher(s) at other institution(s) or collaborator(s) at local organization(s), if this is community-based participatory research:	
CITI Training Date (w/in past five years):	enter mm/dd/yyyy
Proposal Submission Date:	
Approximate Start Date for Research:	
Approximate End Date for Research:	

Have you received, or do you hope to receive, funding to conduct this research? select:

for external funding, name the (potential) granting institution:

Section 2: Request for Exemption

☐ I have read the IRB categories in full on the IRB webpages before making this request for Exemption. I understand that Exempt categories were revised in January 2019 to accord with new federal guidelines.

My proposal qualifies for Exemption under the category indicated below (check the one that applies). If there is a box under the category you select, please provide the information requested.

◯ **Category 1**: Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices (link to see the full text of this category)

Clarify how you will ensure that this research does not adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

☐ If you are conducting research in a Gettysburg College classroom, check here to confirm that you have asked the chair of the department that sponsors the class to email the IRB a note stating that the department approves research with students in a class that they sponsor.

◯ **Category 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of three criteria is met (link to see the full text of this category)

Note: this form will fulfill the requirements for limited IRB review

The criteria that are met include: ☐ i ☐ ii ☐ iii

◯ **Category 3**: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of three criteria is met (link to see the full text of this category and the definition of "benign behavioral intervention")

Note: this form will fulfill the requirements for limited IRB review

The criteria that are met include: ☐ A ☐ B ☐ C

If the research involves deception or incomplete information about the project, explain how you will inform the subject that (s)he will be deceived about or unaware of certain aspects of the research, but you will provide full information afterwards (if this is not done, apply with Expedited form).

◯ **Category 4**: Secondary research for which consent is not required if at least one of four criteria is met (link to see the full text of this category).

The criteria that are met include: ☐ i ☐ ii ☐ iii ☐ iv

○ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs (link to see the full text of this category).

☐ I have included a letter from the Agency stating that I am carrying out the research on behalf of the Agency.

○ **Category 6**: Taste and food quality evaluation and consumer acceptance studies (link to see the full text of this category).

○ **Category 7**: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required (link to see the full text of this category)

Note: this form will fulfill the requirements for limited IRB review
Note also: Researchers can simultaneously obtain informed consent for participation in a current project and broad consent for participation in a secondary, future project. However, they must submit two separate IRB proposals and they must use different consent forms with each research subject, so that research subjects do not confuse the two distinct types of consent.

○ **Category 8**: Secondary research on identifiable private information or identifiable biospecimens for which broad consent is required and four criteria are met (link to see the full text of this category)

Note: this form will fulfill the requirements for limited IRB review

Additional Information for Determination of Exempt Status (please check boxes):

A. I understand that this research poses "No more than minimal risk," which means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"

☐

B. I understand that research on the following populations is only Exempt for the Exempt categories that are listed (otherwise the research requires full review):

☐
- Pregnant women: all of the Exempt categories can be applied
- Children (individuals under the age of 18): Exempt categories 1 & 4-8 can be applied; category 2 (i) and (ii) only applies to children when the research involves educational tests or the observation of public behavior if the investigator(s) do not participate in the activities being observed. Category 2 (iii) ("identifiable data") and 3 ("benign interventions") cannot be applied to children.

C. I understand that research on the following populations and topics is not Exempt (all such research would require full review):

☐ **Populations**
- Prisoners
- Cognitively impaired persons
- Seriously ill persons
- Refugees, if targeted or questioned about their experiences as refugees
- Victims of abuse, if targeted and if questioned about their experiences as victims of abuse
- Stigmatized populations, if targeted or if questioned about bias, discrimination, or harassment
- Undocumented immigrants, if targeted or questioned about their status or experience as undocumented immigrants

Topics

● The research involves requests for information that might be considered offensive, threatening, or degrading by the respondents.

● The research focuses on stigmatizing or illegal aspects of the subjects' behavior if this topic is central to the research objective and if research is more extensive than a brief survey question

D. I understand that Exemptions cannot be secured for research that requires:

☐ ● Deception, unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research

● Experimental manipulations, unless they are "benign" (see above; click here for definition)

● Collection of biological specimens

● Research that necessitates referral to counseling or other medical professionals to manage risk

Section 3: Project Information

A. Project Title:

B. Research question: BRIEFLY describe the objective of your research in language that a non-expert can understand:

C. Research locale: Where will the research take place (what country(ies), state(s), and town(s))?

Will your research take place in a particular institution or organization (Gettysburg College, or a school, prison, business, government agency or NGO)? select:

If yes, specify what institution or organization:

☐ If yes, and if the research is *not* at Gettysburg College, check here to confirm that you have attached a letter or email from an authority in the institution granting you permission to conduct research on their premises or at institutionally-sponsored events.

D. Research Subjects (RSs): Describe the population that will participate in your study. How many individuals will participate? Break down participants into categories, if appropriate.

E. Methodology: Describe all of the methods that you will use to collect data from your research subjects (RSs) in order to answer your research question. Include a discussion of all activities that RSs will engage in and all ways in which they will be observed (describing the events and the settings of observation). Estimate how much time each task will take, and describe any equipment or procedures used.

☐ Check here to confirm that you have attached copies of all stimulus materials, questionnaires, protocols, and interview guides to be used (if you plan to conduct informal, unstructured interviews, provide a guide that includes the topics that you will address).

F. Inducements: Will participants receive inducements before or rewards after the study? select:

If yes, explain what these inducements will be

If yes, under what conditions will RSs receive partial or no payment?

Section 4: Privacy Considerations

This section will assess privacy in soliciting participation, privacy in data collection and storage, and privacy in reporting of research results.

A. Privacy in soliciting participation: Will you use individually identifiable information (for example, a list of names or a set of email addresses) to contact and recruit participants? select:

If yes, describe the identifiers and explain what will happen to the identifiers after the recruitment process is complete.

B. Privacy in data collection and storage: Do you plan to collect and store individually identifiable information (names or indirect identifiers like emails, IP addresses, or ID numbers) that will be associated with participants' data? select:

Note: If you create a key linking direct identifiers with unique identification numbers, the data are considered identifiable.

If yes, answer all of the questions below:

i. Describe the direct identifiers that will be associated with participants' data. Explain why it is necessary to collect these identifiers.

ii. Who else, if anyone, will know the names of those who participate in your study (field assistants, data analysts, student researchers)? Explain why and give assurance that this person is aware of U.S. research norms regarding confidentiality.

iii. Data protection plan: Explain the security controls that you will employ to ensure that nobody, aside from individuals mentioned above, will have access to the identities of your RSs.

C. Privacy in reporting: Will you use RSs' names in your presentations, publications, reports, webpages or creative works? select:

If yes, explain your decision to do so, and specify how you will secure permission from RSs.

Section 5: Informed Consent & Broad Consent

A. Informed Consent

**Only researchers applying under Exempt categories 1-6 must fill out this section*

*Note that in making your selection, you commit to abiding by the terms in the "Clarification and Proviso," below.

How will you obtain informed consent?* select:

***Clarification and Proviso**: There are three methods to obtain informed consent, each with stipulations:*

1) through a signed **consent form** or *an* **electronic signature** *given by a RS after a consent form is received (this is the most common option used by researchers; records must be kept)*

2) through **implied consent** *(When a survey is used in low-risk research, the researcher may include at the beginning of the survey a full explanation of the nature of the research. If the subject proceeds to answer the survey questions, consent is implied. The implied consent text must ask RSs to print or download a copy of the consent text that they can keep for their records.)*

3) through **verbal consent** (When conducting low-risk research in which RSs are members of a **distinct cultural group** or community in which signing forms is not the norm, or when the only record linking the subject and the research would be the consent form and **potential harm** would result from a breach of confidentiality. In either case, there must be a mechanism for documenting that informed consent was obtained, and an info-sheet on the research must be provided.)

Researchers whose work is Exempt do not need to submit consent forms for review, but are nevertheless expected to obtain informed consent, and to do so properly (when children are the RS, consent must be obtained from parents and assent from children). Researchers may construct their own consent forms or scripts or use the

Sample Consent Form provided on the IRB webpages. If you want to construct your own form, click here to see a list of the key components of informed consent.

Are there any power dynamics (eg, instructor-student, supervisor-employee) that could potentially hinder RSs' ability to freely accept or decline to participate in the study? select:

If yes, explain the efforts you will make to assure RSs that their participation is entirely voluntary.

B. Broad Consent—click here to learn what this is

**Only researchers applying under Exempt categories 7 & 8 must fill out this section*

For those applying under Exempt category #7, check both:

- ☐ I have included a copy of the broad consent form that I will use in this research
- ☐ I understand that I must keep a record of which research subjects have given broad consent and which have declined, and I understand that once I have completed the collection of information or biospecimens, I will provide this record to the IRB (to consult when future researchers apply to use these data or biospecimens).

For those applying under Exempt category #8, check one:

- ◯ I have included a copy of the original broad consent form used when the information or biospecimens were collected, along with the IRB letter of approval for this research. I have also included the original researcher's records indicating which individuals gave and declined broad consent for their information or biospecimens to be used in secondary research.

  -or-
- ◯ Documentation of broad consent is appropriately waived, and a copy of the IRB waiver is included here.

Section 6: Final Submission

A. If you are a student, has your faculty sponsor reviewed and approved this application? select:

Students must ask their faculty sponsor to email the IRB (irb@gettysburg.edu) on their behalf with the following statement: **"I assume responsibility for ensuring that [student's(s') name(s)] is/are aware of their responsibilities as researcher(s). I have mentored him/her/them in filling out this proposal and have reviewed the final draft, which I approve. I will oversee this research in its entirety**."

B. Will you contact the IRB if a substantive change occurs in the research methods and ethical measures proposed here? select:

C. Have you included all supporting documents (recruitment materials, informed consent materials, questionnaires/surveys/research instruments, debriefing scripts, letters of permission to conduct research in institutional settings, photo or video release forms, and broad consent forms or waivers)? select:

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Once you have answered all of the above questions and verified that you have completed this form fully and accurately, email this application and all necessary attachments, converted to PDF, to the IRB (irb@gettysburg.edu). Note that the IRB will not review any proposal unless *all required fields are checked off or filled in and all supporting material is attached.*