Institutional Review Board Proposal Questions

The following are the questions PIs will be asked to answer in the IRB online submission process. For more information about IRB policies and procedures and to access the online submission system, please visit https://my.bucknell.edu/irb.html.

PART I

1. The research **[will | will not]** involve prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

2. The research **[will | will not]** involve subjects under the age of 18.

3. The research **[will | will not]** involve collection of information regarding sensitive aspects of the subjects' lives.

> *Note*: The intended meaning of 'sensitive' includes (but is not limited to) information which, if it were to become known outside the research, would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. It also includes questions that might reasonably be expected to make subjects uncomfortable.

4. The information obtained **[will | will not]** be recorded by the investigator in such a manner that the identity of the subjects can readily be ascertained either directly or through identifiers linked to the subjects.

5. The research **[will | will not]** involve either deception or incomplete disclosure of the purpose, methods, or other relevant aspects of the research.

> *If so,* Subjects **[will | will not]** be informed prior to participating that they will be deceived, mislead, or otherwise not fully informed of all relevant aspects of the study.
>
> > *Note:* Please note that deception must be scientifically justified and debriefing procedures must be described in detail. Note also that *incomplete disclosure* to subjects about the relevant aspects of the research is considered to be a mild form of deception (for more information about studies involving deception, please see §6.2 of the IRB Policies & Procedures Manual).

6. Please select one of the following:

> [ ] The procedures of this research present *no more than minimal risk* to the subject (where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are *no greater* than those ordinarily encountered in daily life or during the performance of routine physical/psychological examinations or tests).
>
> [ ] The procedures of this research involve *more than minimal risk* to the subject (where more than minimal risk means that the probability and/or magnitude of harm or discomfort anticipated in the proposed research are *greater* than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
>
> > *Note*: If you identify your study as involving more than minimal risk, you must identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures and describe clearly (1) how such risks are reasonable in relation to anticipated benefits of the research to the subjects, (2) how the study's procedures are designed to protect against or

minimize such risks. Please give careful consideration to potential psychological, legal, or reputational risks to subjects — especially if you answered Question 3 above in the affirmative.

PART I (Continued) *Not all PIs will be asked to respond to these questions.*

7. The research **[will | will not]** be conducted in established or commonly accepted educational settings and will involve normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

8. The research **[will | will not]** involve survey or interview procedures, observation of public behavior (including visual or auditory recording), or educational tests (e.g., cognitive, diagnostic, aptitude, or achievement tests).

9. The research **[will | will not]** involve 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.

> *Note:* In the present context, benign behavioral interventions are understood to be brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and such that subjects are unlikely to find offensive or embarrassing. Examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

10. The research **[will | will not]** involve already existing identifiable private information that has been collected or will be collected solely for non-research purposes. This information may include documents, records, or biological specimens (including pathological or diagnostic specimens).

> *Note:* PIs pursuing research with existing data will be expected to include a detailed description of the nature and source of these data as well as relevant analyses in Part II of this form. Please also check any of the following that apply.

[ ] The identifiable private information or identifiable biospecimens are publicly available.

[ ] The information was recorded in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects and the investigator will not attempt to re-identify subjects.

[ ] The research involves health care operations or public health activities and purposes (as these terms are defined in the HIPAA Regulations; see 45 CFR parts 160 and 164, subparts A and E).

[ ] The research is conducted by (or on behalf of) a Federal department or agency using government-generated or government-collected information obtained for non-research activities (subject to provisions described in 45 CFR 46.104(d)(4)).

11. The research **[will | will not]** be designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs where such research is 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).

> *Note:* Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

12. The research **[will | will not]** involve taste and food quality evaluation and consumer acceptance studies.

> *If so,* **[yes | no]:** Only wholesome foods without additives will be consumed.
>
> **[yes | no]:** Any food ingredients, agricultural chemicals, or possible environmental contaminants that may be consumed will be at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

13. The data collected in this research **[will | will not]** involve secondary analysis for which broad consent is required.

> *Note:* Obtaining subjects' "broad consent" for the collection of identifiable information or biospecimens means obtaining their consent for using such information or specimens for future, unspecified research (see §46.116(d) and the IRB Policies & Procedures Manual §6.)

PART II *All PIs will be asked to respond to these questions. Note that responses are limited to 4,000 characters.*

1. Please describe in some detail the purpose of the proposed study (including, as appropriate, information about the research question and relevant hypothesis or, if the research is exploratory, what the researchers hope to learn).

2. Describe the proposed subject sample. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples. **If your research involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, you must indicate clearly why the use of these subjects is scientifically necessary.**

3. How will subjects be recruited and selected?

4. Describe fully the following: *(NB: Each response to questions (a–f) has its own 4,000 character limit.)*

   a. all research methods and procedures that will be employed in this study.

   b. approximately how much time each subject is expected to devote to the research.

   c. how data will be collected and recorded (With or without identifiers? What instruments, materials, or equipment will be used? Will audio or videotapes be employed in data collection?).

In the final step of this form, please append electronic copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.

d. methods for obtaining and documenting informed consent of subjects (or assent in the case of minors; for minors, please also indicate how the consent of parents or legal guardians will be obtained). **In the final step of this form, append electronic copies of all materials used to obtain informed consent or assent.** See resources on the IRB website and §6 of the IRB Policies & Procedures Manual for requirements and best practices for seeking subjects' informed consent.

e. any use of deception in the proposed study and justification for its use.

f. methods for preserving confidentiality (including plans for storing/disposing of audio- or visual-recordings and other data records at the conclusion of the research); see §7 of the IRB Policies & Procedures Manual for requirements.

5. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.

6. Describe any pre-existing relationships between researcher and subjects — such as teacher–student, superintendent–principal–teacher, employer–employee — that might impact subjects' ability to participate in the research voluntarily. How will any potential for coercion be mitigated by the researchers?

Supporting Documents

In the final step of the proposal, PIs will be asked to upload the following documents (as appropriate).

- Informed Consent Form (unless *not* required)
- Debriefing (required if using deception)
- Research Materials

  Please note that all materials to which subjects will be exposed should be included (this includes surveys, interview or focus group outlines, visual stimuli, and so on). If using online surveys, please include as a PDF or a text document rather than simply providing a URL.
- CITI Completion Reports for all researchers involved with the project (including PIs, co-PIs, research assistants, and so on).