*Please complete this form if you believe your project to fall under an Exempt Category of 45 CFR Part 46.104. Please review the* ***Exempt Category criteria below*** *and the* ***Exempt Category Guidance*** *documents carefully, including the definitions and limitations. Check the appropriate* ***Exempt Category(s)*** *that your research falls under. Applications that do not meet the criteria for exempt review will be withdrawn and you will be asked to complete the INITIAL IRB APPLICATION and submit as a NEW STUDY.*

1. **EXEMPT CATEGORY – *PLEASE CHOOSE ONLY ONE***

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| **Category** | **Citation** | **Description** | **Conditions/Allowances/Limitations** |  |
| **1** | 104(d)(1) | Research in established or commonly accepted educational settings, involving normal educational practices. | * Not likely to adversely impact students’ opportunity to learn or assessment of educators providing instruction |  |
| **2** | 104(d)(2) | Research only includes interactions involving educational tests, surveys, interviews, or public observation (including visual or auditory recording) if at least one of the following criteria is met: | * Data Collection Only; * May include visual or auditory recording; * May NOT include intervention, only interactions |  |
| Recorded information cannot readily identify the subject (directly or indirectly/linked) | * Surveys & Interviews: No Children; * Educational tests or observations of public behavior: Can only include children when investigators do not participate in activities being observed |  |
| Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation) | * Surveys & Interviews: No Children; * Educational tests or observations of public behavior: Can only include children when investigators do not participate in activities being observed |  |
| Information is recorded with identifiers or code linked to identifiers | * No Children |  |
| **3** | 104(d)(3)(i) | Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and at least one of the following met: | * No Children; * May not include medical interventions; Subject prospectively agrees;   (ii) BBI must be:   * Brief in duration * Painless/harmless * Not physically invasive * Not likely to have a significant adverse lasting impact on subjects * Unlikely that subjects will find interventions offensive or embarrassing   (iii) No deception unless participant prospectively agrees. |  |
| 1. Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR** |  |
| 1. Any disclosure of responses outside of the research would not reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR** |  |
| 1. Information is recorded with identifiers & IRB conducts limited review |  |

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| **Category** | **Citation** | **Description** | **Conditions/Allowances/Limitations** |  |
| **4** | 104(d)(4) | Secondary Research for Which Consent is Not Required: Use of Identifiable Information or Identifiable Biospecimen that have been or will be collected for some other ‘primary’ or ‘initial’ activity, if ONE of the following criteria met: | * No primary collection from subjects for research; * Allows Both Retrospective and Prospective Secondary Use |  |
| 1. Biospecimens or information is Publically Available: **OR** | * Must be publically available |  |
| 1. Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects; OR | * PI does not contact |  |
| 1. Collection and Analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”; **OR** | * HIPAA still applies; * HIPAA protections include authorization or waiver of authorization; |  |
| 1. Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities | * If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list) |  |
| **5** | 104(d)(5) | Research and demonstration projects supported by a Federal Agency/Dept.  AND Designed to study … improve… public benefit or service programs. | * Must be posted on a Federal Website |  |
| **6** | 104(d)(6) | Taste and Food Quality |  |  |

1. **PROJECT TITLE**

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1. **PERSONNEL**

***INSTRUCTIONS****:* *Include Principal Investigator’s, co-investigator’s, and student investigator’s title and College/Dept. If research will be used for thesis or dissertation, include thesis/dissertation approval form and thesis/dissertation proposal.*

* 1. **PRINCIPAL INVESTIGATOR (NAME, COLLEGE/DEPT., PHONE)**

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* 1. **CO-INVESTIGATOR(S) (NAME, COLLEGE/DEPT., PHONE)**

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* 1. **STUDENT INVESTIGATOR(S) (NAME, COLLEGE/DEPT., EMAIL)**

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| ***\*\*\**** *If research will be used for thesis or dissertation, include* ***thesis/dissertation approval form*** *and* ***thesis/dissertation proposal****.* |

* 1. **KEY PERSONNEL (NAME, COLLEGE/DEPT., EMAIL)**

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1. **LOCATION OF RESEARCH**

***INSTRUCTIONS:*** *List specific site(s) at which the research will be conducted. If non-URI entities will be used,* ***provide written authorization*** *from the appropriate site authority for the study to be done at that site must be provided.* *Permission must be granted from Principal, Superintendent or other individual with responsibility over the site.*

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1. **RESEARCH DESIGN AND METHODS**
   1. **PURPOSE AND PROCEDURES**

***INSTRUCTIONS:*** *Briefly describe study purpose and procedures associated with the proposed study including whether the study activities differ from standard practice, and if so, how. Also, should data collection instruments be used,* ***please provide a copy of each instrument*** *as well as ensure this section of the application clearly describes procedures associated with the instrument including who will administer and how, such as in person, by phone, mail, e-mail, web site; how often; the amount of time required to complete the instrument; etc.*

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* 1. **PARTICIPANT POPULATION**
     1. Total number of participants (or number of participant records) for whom you are seeking URI IRB approval:
     2. Will all participants be above the age of 18?  YES  NO
     3. Will any participants be decisionally impaired? YES  NO
     4. Will any participants be non-English speakers? YES  NO
     5. Are prisoners the intended study population? YES  NO
  2. **RECORDING**
     1. Will subjects be audiotaped or videotaped? YES  NO
     2. If yes, describe procedures associated with such taping as well as how tapes will be used, who will have access, and final disposition of the tapes.

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1. **RECRUITMENT**

***INSTRUCTIONS:*** *Briefly describe the recruitment procedures associated with the proposed study.* ***Please provide a copy of any materials*** *(e.g., emails, flyers, verbal scripts) that will be used to recruit subjects.*

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1. **INFORMED CONSENT**
   1. **PROCEDURES FOR CONSENT**

***INSTRUCTIONS:*** *For survey and interview research, URI generally requires consent be obtained from subjects with or without collecting identifiers. Describe the consent process (e.g., explain when and where consent will be obtained). If a waiver of consent or waiver of documented consent is being requested, please ensure this section provides appropriate justification for such a waiver. For more information on waiver of consent or waiver of documented consent please see* <https://web.uri.edu/research-admin/office-of-research-integrity/human-subjects-protections/irb-application-review-process/>*.* **All IRB forms, policies, procedures, resources and tools can be found on the**[**Research Resources**](https://web.uri.edu/research-admin/forms/)**page and**[**IRBNet**](http://www.irbnet.org/)**.**

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* 1. **CONSENT DOCUMENTS**

***INSTRUCTIONS:******Provide a copy of the document(s)*** *that will be used to obtain consent such as a consent form, information sheet, survey cover letter, verbal consent script or letter to subjects. Please ensure the document(s) to be used for consent include the elements of an informed consent document. If possible, please use IRB approved templates located at* <https://web.uri.edu/research-admin/office-of-research-integrity/human-subjects-protections/irb-application-review-process/>*.* **All IRB forms, policies, procedures, resources and tools can be found on the**[**Research Resources**](https://web.uri.edu/research-admin/forms/)**page and**[**IRBNet**](http://www.irbnet.org/)**.**

The consent documents to be used include:

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| --- | --- | --- |
| Informed Consent | Child Assent | Parental Permission |
| Verbal Consent Script | Verbal Assent Script | Verbal Permission |
| Other |  |  |

1. **SECURITY AND CONFIDENTIALITY PROCEDURES**

***INSTRUCTIONS:*** *Briefly describe how confidentiality of the subject’s identity will be maintained. Please ensure this item includes whether/how subjects will be identified, procedures for protecting subject identity including security procedures, the final disposition of identifiers, who will have access to subject identifiers, etc. Refer to* [Exempt 2 Guidance](https://web.uri.edu/research-admin/files/IRB-Guidance-Exempt-Category-2.pdf) or [Exempt 3 Guidance](https://web.uri.edu/research-admin/files/IRB-Guidance-Exempt-Category-3.pdf) for *IRB required data management and security procedures if requesting Exempt Category 2 or 3 with sensitive and identifiable information.*

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1. **FUNDING SUPPORT AND CONFLICT OF INTEREST**

***INSTRUCTIONS:*** *Specifically describe the funding support associated with this study and whether a conflict of interest exists with the PI or any key personnel. If such a conflict exists, this must be clearly described and submit a completed copy of the Significant Financial Interest disclosure form located here:* <https://web.uri.edu/research-admin/office-of-research-integrity/conflicts-of-interest-overview/>*.* ***All IRB forms, policies, procedures, resources and tools can be found on the***[***Research Resources***](https://web.uri.edu/research-admin/forms/)***page and***[***IRBNet***](http://www.irbnet.org/)***.***

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1. **CERTIFICATION AND SIGNATURE**

I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators, including, but not limited to, the responsibilities described in the URI IRB policy.

I verify that the information provided in this IRB Application for Human Subjects Research is accurate and complete.

I verify that this research is consistent with the Exempt Category checked above as described in 45 CFR 46.104.

I verify that the Principal Investigator, Co-Investigator(s) and Student, if using research for Master’s Thesis or Doctoral Dissertation, have signed the package in IRBNet.