**GUIDANCE:** Use this Exemption Protocol Template as a guide for protocols anticipated to meet the Criteria for Exemption. 45 CFR 46.101(b) defines those human research activities that are exempt from IRB review.

* If the IRB determines your study does not meet the criteria, additional protocol elements will be required.
* Depending on the nature of what you are doing, some sections may not be applicable to your research. **If so, please mark “N/A.”**

**Please Note:**

* May **NOT** be subject to FDA regulations (e.g., drug devices, or biologics)
* Do **NOT** apply to research involving prisoners as designed for recruitment. *\*Incidental subjects are allowed*
* May **NOT** involve decisionally-impaired unless justified
* A child cannot be included in research under exemption 2 below except for research involving observations of public behavior when the investigator(s) will not participate in the activities being observed.

**Please indicate your category of Exemption below** (select only one category):

☐ [(1)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Research conducted in established or commonly accepted educational settings

☐ [(2)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Research only including interactions involving: educational tests, survey procedures, interview procedures

☐ [(3)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Research involving benign behavioral interventions in conjunctions with the collection of information

☐ [(4)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Secondary research for which consent is not required

☐ [(5)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Research and demonstration projects conducted by a Federal Department or Agency heads

☐ [(6)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Taste and food quality evaluation and consumer acceptance studies

☐ [(7)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Storage or maintenance for secondary research for which broad consent is required

☐ [(8)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) Storage research for which broad consent is required

**Protocol Title:**

**Version Date:**

**Principal Investigator (PI):** Name of PI, degree

 Name of Institution

 Street Address

 City, State, Zip code

 Telephone Number

 Email address

**Sub-Investigator(s):** Name of PI, degree

 Name of Institution

 Street Address

 City, State, Zip code

 Telephone Number

 Email address

**Objectives and Study Design/Procedures**

1. Describe the purpose, specific aims, or objectives
2. Provide a description of the subject population and study-related research process/procedures

*\*Be sure to attach any surveys, focus group scripts or other related materials in the other attachments.*

**Research Participants**

*Indicate of you will specifically recruit any of the following special populations:*

 ☐ Adults unable to consent

 ☐ Minors (up to age 18) (If selected, this study may not qualify for exemption.)

 ☐ Pregnant Women

 ☐ Neonates

 ☐ Employees of SLHS

☐ Prisoners (If selected, this study does not qualify for exemption) *\*Incidental subjects are allowed*

 ☐ Illiterate Individuals *\*unless justified*

 ☐ Non-English Speaking

**Interaction with Research Participants**

Will there be interactions with research participants?

☐ Yes ☐ No

*If yes, explain who will obtain consent and the process for obtaining informed consent. \*Be sure to attach a consent script or information sheet.*

**Inclusion/Exclusion Criteria:**

\*The criteria that define who will be included or excluded in your final study sample

**Confidentiality of Data**

Individually identifiable means that the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Protected Health Information (PHI) is (1) any individually [identifiable](https://case.edu/research/sites/case.edu.research/files/2018-04/PHI-under-HIPAA.pdf) health information transmitted or maintained in a medical record paper or electronic, or (2) designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.

1. ☐ This study involves accessing or collecting PHI (requires HIPAA authorization or request to waive the requirement to obtain HIPAA authorization)

☐ This study does not involve collecting Individually Identifiable Data

☐ This study involves collecting Individually Identifiable Data, but not PHI

1. If you are collecting identifiable data, please provide the following information:

To maintain the confidentiality of the data:
☐ I will use a unique study identifier to code individuals’ data and will store the master list separate from the study data.

 ☐ Other (please explain)

**Storage location of the electronic data (choose all that apply):**

☐ SLHS Redcap
☐ Other Secure Research Environment (SRE)
☐ SHLS Secure Network Drive
☐ Other, explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Storage location of the paper research data and documents, if applicable:**

☐ Paper research data and documents will be stored in a double-locked secure environment in the following location:

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**Risks**

\*A breach of confidentiality is the main risk associated with this research

**Benefits**

\*The participants are not likely to receive any benefit from the proposed research; however, society and investigators may benefit from the knowledge gained

**Statistical Considerations:**

Proposed sample size (the minimum number of participants/records necessary to carry out the objectives of your study). Specify how data will be analyzed and by whom.

**APPENDIX**

Must be completed and included with the protocol for “Data Review” projects

**Appendix A:** Data Collection Document

\*List all elements to be collected during the review. It should not contain any direct or indirect identifiers except for a unique participant code

**Appendix B:** Coded Identifier List-

\*This list will serve as the link between the unique participant code and any identifiers needed to conduct this review study (e.g., name, medical record number, date of birth, address, telephone number, social security number]