**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”.*

**ADDITIONAL CRITERIA**

* May **NOT** be subject to FDA regulations (i.e., drugs, devices, or biologics).
* **DOES NOT** apply to research involving prisoners as designed for recruitment*, please note that incidental subjects are allowed.*
* May **NOT** involve decisionally impaired subjects, unless justified.
* A child cannot be included in research under Exempt category 2, except for research involving observations of public behavior when the investigator(s) will not participate in the activities being observed.

**TYPE OF STUDY**

Select the Exempt Category that applies to your study:

[ ]  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.

[ ]  Category [**(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.

[ ]  Category [**(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.

[ ]  Category [**(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.

[ ]  Category [**(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.

[ ]  Category [**(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.

[ ]  Category [**(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.

[ ]  Category [**(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.

Exempt Protocol form to fill out and submit to the IRB starts on the next page of this document. Please reach out to the HRPP Office with any questions regarding completing and submitting the protocol.

**Exempt Review Protocol**

**Project Title:**

**Version Date:**

**Principal Investigator:**

**OBJECTIVES/STUDY DESIGN**

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.)*

**RESEARCH PARTICIPANTS**

1. Indicate if you will specifically recruit any of the following vulnerable populations:

[ ]  Adults unable to provide consent.

[ ]  Minors (up to age 18) (*Note: If selected; this study may not qualify for exemption.)*

* *Children may only be enrolled in research that qualifies for exempt category 2 [surveys, interviews, public observations] if the investigators do not participate in the activities being observed;*
* *Children may not be enrolled in research qualifying for exempt category 3 [benign behavioral interventions].*

[ ]  Pregnant Women

[ ]  Neonates

[ ]  Employees of SLHS

[ ]  Prisoners *(Note: If selected; this study may not qualify for exemption. Incidental subjects are allowed.)*

[ ]  Illiterate Individuals

[ ]  Non-English Speaking Individuals

1. Will there be interactions with research participants?

[ ]  Yes

[ ]  No

If yes, explain the process for obtaining agreement to participate in the study.

*(Be sure to attach a script or information sheet containing the information to be shared with participants.)*

**INCLUSION/EXCLUSION CRITERIA**

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

**RISKS**

Example: *A breach of confidentiality is the main risk associated with this research.*

**BENEFITS**

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

**DATA COLLECTION**

1. Description of Data:

Provide a general description of the **types or categories of data** that will be collected during this study (e.g., lab test results, procedure outcomes, length of stay, questionnaires, surveys).

1. Source of Data:

Describe the **source** of the data and how that data will be accessed and obtained (e.g., electronic medical record, previous research study, clinical database, surveys/questionnaires).

1. Protected Health Information (PHI):

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.

Below are the 18 HIPAA Identifiers that when paired with health information constitute PHI. Please select which of these elements (if any) are being accessed and/or recorded as part of this study.

|  |  |  |
| --- | --- | --- |
| **HIPAA Identifiers** | **Accessed Only** | **Recorded** |
| 1. Name/Initials
 | ​​[ ]  | ​​[ ] ​  |
| 1. All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)
 | ​​[ ]  | ​​[ ]  |
| 1. Elements of date, including year, for persons 90 years or older
 | ​​[ ]  | ​​[ ]  |
| 1. Medical record number
 | ​​[ ]  | ​​[ ]  |
| 1. Account number
 | ​​[ ]  | ​​[ ]  |
| 1. Health plan identification number
 | ​​[ ]  | ​​[ ]  |
| 1. Social Security Number
 | ​​[ ]  | ​​[ ]  |
| 1. Device identifiers and serial number
 | ​​[ ]  | ​​[ ]  |
| 1. Certificate/License number
 | ​​[ ]  | ​​[ ]  |
| 1. Telephone number
 | ​​[ ]  | ​​[ ]  |
| 1. Fax number
 | ​​[ ]  | ​​[ ]  |
| 1. Email addresses
 | ​​[ ]  | ​​[ ]  |
| 1. Web addresses (URLs); Internet IP addresses
 | ​​[ ]  | ​​[ ]  |
| 1. Street address, city, county, precinct, zip code or equivalent geographical codes
 | ​​[ ]  | ​​[ ]  |
| 1. Full face photographic images and any comparable images (this includes use of video recordings via Teams)
 | ​​[ ]  | ​​[ ]  |
| 1. Biometric identifiers, including finger and voice print (this includes recorded Teams audio)
 | ​​[ ]  | ​​[ ]  |
| 1. Vehicle identifiers and serial numbers, including license plate number
 | ​​[ ]  | ​​[ ]  |
| 1. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. student or employee ID number)
 | ​​[ ]  | ​​[ ]  |

1. Sensitive Data:

If collecting or accessing sensitive data which pose legal, economic, or reputational harm if breached, please specify here (or indicate “Not applicable”).

**DATA STORAGE**

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

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

1. 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATA CONFIDENTIALITY**

* 1. Explain your plan to maintain the confidentiality of the data being collected:

[ ]  I will use a unique study identifier to code individuals’ data and will store the master list separate from the study data.

[ ]  Other, explain below.

**HIPAA AUTHORIZATION**

This section is only required if you have indicated above that you are accessing and/or recording PHI.

If you are NOT accessing and/or recording PHI you do not have to complete the rest of this form.

1. If accessing and/or recording PHI, select your plans for addressing HIPAA authorization:

[ ]  **Obtaining the participants’ signature on a HIPAA authorization form.**

*(Must include a copy of the HIPAA authorization to be used with your submission in iMedRIS. This can be a stand-alone authorization form, or it can be combined with a study information sheet.)*

[ ]  **Requesting partial waiver of HIPAA authorization for screening purposes –** Will be waiving HIPAA authorization initially to identify potential participants. Then, once participants are identified and approached to participate in the study, we will obtain signed HIPAA authorization from participants who choose to join the study.

*(Must include a copy of the HIPAA authorization to be used with your submission in iMedRIS. This can be a stand-alone authorization form, or it can be combined with a study information sheet.)*

[ ]  **Requesting full waiver of HIPAA authorization** - Will not be obtaining HIPAA authorization from participants at any point during the study.

[ ]  **Requesting alteration of HIPAA authorization** – We will be obtaining HIPAA authorization from participants, but altering/removing one or more of the requirements elements of authorization. Please indicate below which requirement(s) you propose to alter.

*(Must include a copy of the HIPAA authorization to be used with your submission in iMedRIS. This can be a stand-alone authorization form, or it can be combined with a study information sheet.)*

[ ]  **Signature**: We will not be obtaining a signature from participants or their Legally Authorized Representative (LAR).

[ ]  **Identification:** We will not be including the name or identification of the person(s) who can use or disclose the protected health information (PHI).

[ ]  **Purpose:** We will not be including a description of each reason for the requested use or disclosure.

[ ]  **Expiration:** We will not be including an expiration date for the authorization.

[ ]  **Plain language:** Our entire subject population is highly educated and therefore the authorization does not need to be written in plain language.

[ ]  **Revocation:** We will not be providing participants with the ability to revoke their authorization in writing.

1. If you chose an option above that includes a partial waiver, full waiver, or alteration of HIPAA authorization, the following criteria must be met:

Describe your plan to protect the identifiers from improper use and disclosure.

Describe your plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

[ ]  **Check this box**: To confirm that the Protected Health Information (PHI) will not be reused or disclosed to any other person or entity; except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.