 Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (ACHS Use only)

**Category 4: Secondary Research with Identifiable Private Information or Biological Specimens Application for Exemption Form**

Primary Investigator(s), Department, Email:

1.

2.

3.

Researcher's Status (Check One):

 Undergraduate Student

 Graduate Student

 Faculty

 Other (Explain):

Research assistants (anyone other than PI or Faculty Advisor who will have contact with participants; the reason is that the researcher is therefore responsible to assure that all assistants are briefed on the ethical treatment of participants and the maintenance of confidentiality)

1.

2.

Faculty Advisor (if PI is a student) Department, Email:

1.

2.

Title of Project:

Desired Start Date: \_\_\_\_\_\_\_\_ Upon Approval

 \_\_\_\_\_\_\_\_\_\_ Other: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

 Please state why, e.g. grant deadline or class deadline so committee can prioritize if needed.

Expected End Date: \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Length of Project:

\*Note: Approval is only good for one (1) calendar year from date of approval. After that year, the researcher must inform the committee if the research is ongoing in writing.

Will this research be submitted to an external agency for funding?

If yes, please name agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. *Secondary research uses of* ***identifiable private information*** *or* ***identifiable biospecimens****, if at least one of the following criteria is met (*Exempt Criteria 45 CFR 46.104(d)(4))*.* Select which criteria will be met in your research.

*\_\_\_\_\_ (i) The identifiable private information or identifiable biospecimens are publicly available;*

*\_\_\_\_\_ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;*

*\_\_\_\_\_ (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);*

*or*

*\_\_\_\_\_ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.*

1. Will this study use residual specimens (and if applicable, data) that were obtained originally for *clinical treatment* or *pathology* purposes – independent of this research project?

\_\_\_\_ No. Go to C.

\_\_\_\_ Yes. Answer the following questions.

1. Will the specimens and/or data (e.g., medical record information) be provided to this research team without personal identifiers or linkage codes?

 \_\_\_\_\_ Yes

 \_\_\_\_\_ No If No explain:

1. Will an identifier be used to de-identify these specimens and/or data?

 \_\_\_\_\_ No. If No, describe how the research team will receive specimens and/or data without identifiers.

 \_\_\_\_\_ Yes. Identify the manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects.

1. Will the investigator contact the subjects or re-identify the subjects?

 No\_\_\_\_\_\_\_­­­­ Yes \_\_\_\_\_\_\_\_

 If Yes, STOP – this is not an exempt study. Contact ACHS at achs@muskingum.edu.

1. Will this study use specimens (and if applicable, data) obtained from a *tissue bank or repository?*

\_\_\_\_ Yes

\_\_\_\_No

If Yes, answer the following questions:

1. Identify bank/repository by name and provide IRB number or attach bank/repository consent form or description.
2. Will specimens (and if applicable, data) be provided to the research team without identifiers?
\_\_\_\_ Yes

\_\_\_\_No

If No, explain:

1. Will this study use specimens (and if applicable, data) obtained from a *prior research study?*

\_\_\_\_ Yes

\_\_\_\_No

If Yes, answer the following questions:

1. Did the consent form signed by the subjects restrict the use of their samples in any way?

 \_\_\_\_ Yes

 \_\_\_\_No

 If Yes, describe restrictions:

1. Is copy of initial consent form attached?

\_\_\_\_ Yes

\_\_\_\_No

1. Information from the prior research study:
	1. Study Title:
	2. PI name:
	3. ACHS number:
2. Will this study use specimens (and if applicable, data) obtained *directly from a commercial vendor*?

\_\_\_\_ Yes

\_\_\_\_No

 If Yes, identify the vendor by name:

1. Address each of the following questions:
	* + 1. Will the investigator(s) access (look at) *identifiable* private information?

\_\_\_\_ Yes

\_\_\_\_No

 If Yes, explain:

1. Will the investigator collect or receive specimens and/or data with *identifiable* private information?

\_\_\_\_ Yes

\_\_\_\_No

If Yes, explain:

1. Will the investigator record subject *identifiers* and link them to the specimens and/or data?

\_\_\_\_ Yes

\_\_\_\_No

If Yes, STOP – this is not an exempt study.

1. Do the specimens and/or data have a numerical code such that a link exists that could allow the specimens and/or data to be re-identified?

\_\_\_\_ Yes

\_\_\_\_No

If Yes, is there a written agreement that prohibits the PI and the research staff from accessing the link?

\_\_\_\_ Yes

\_\_\_\_No

If No, explain:

1. Are all specimens and/or data in existence as of the date the protocol is submitted to ACHS?

\_\_\_\_\_ Yes

 \_\_\_\_\_No:

If No, STOP. Your project does not meet criteria for this exempt category; contact ACHS at achs@muskingum.edu.

1. **Study Information.** Please briefly describe the study using the questions below.
	* + 1. List the sourceof records or datato be studied:
			2. Does the researcher have permission to use this data if it is not publicly available?

\_\_\_\_ Yes, please provide copy of permission to ACHS

\_\_\_\_No

\_\_\_\_ N/A

1. Purpose and background of the research

This is a chance for you to give the reviewers a background in the area of interest. Provide enough information in order for the reviewers to understand the purpose of the research.

* 1. Background (What literature exists in this area of interest? What does the existing literature say about the topic & how does this project add to our knowledge of the phenomena of interest? Please include basic citations (author and year only) of existing literature. (**NOTE:** This should not be a literature review; instead provide a background for the reviewers who may not be from your discipline to understand the project at hand.)
	2. Define Terms: Because reviewers are not necessarily from the same discipline as the researcher, we need researchers to define terms and concepts for us. For example, what is known by psychology might not be known by communication, e.g. helicopter parents, snowball sampling
	3. Research question and/or hypotheses: Please tell us your research question and any hypotheses you might have.
		+ - 1. Additional Information, Clarification, or Comments for the ACHS Reviewer:

**INVESTIGATOR’S ASSURANCE STATEMENT**

I have read Muskingum University's policy concerning research involving human subjects and by signing below:

1. I agree to accept responsibility for the ethical conduct of research conducted in this project;
2. I agree to obtain approval from the Animal Care & Human Subject’s committee prior to modifying any of the procedures that might affect an exempt determination;
3. I attest that the information submitted in this application is true to the best of my knowledge.

Principal Investigator(s):

Date

Date

Date

Faculty Review of Student Projects: I have reviewed and approved the procedures to be used in the project described in this application. I agree to meet with the investigator on a regular basis to monitor study progress and assure that the well being of subjects is adequately safeguarded.

Faculty Advisor(s):

Date

Date

Basic Exempt Criteria *45 CFR 46.101(b)(1)* [eCFR :: 45 CFR 46.104 -- Exempt research.](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)

“Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under [45 CFR parts 160](https://www.ecfr.gov/current/title-45/part-160) and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at [45 CFR 164.501](https://www.ecfr.gov/current/title-45/section-164.501) or for “public health activities and purposes” as described under [45 CFR 164.512(b)](https://www.ecfr.gov/current/title-45/section-164.512#p-164.512(b)); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, [44 U.S.C. 3501 note](https://www.govinfo.gov/link/uscode/44/3501), if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, [5 U.S.C. 552a](https://www.govinfo.gov/link/uscode/5/552a), and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, [44 U.S.C. 3501](https://www.govinfo.gov/link/uscode/44/3501) *et seq.”*