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

 (ACHS Use only)

**Category 4: Research with 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. 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?

\_\_\_\_ Yes

\_\_\_\_No

 If 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? No Yes If No, explain:
2. Will an Honest Broker be used to de-identify these specimens and/or data? No Yes
If No, describe how the research team will receive specimens and/or data without identifiers:
3. If paraffin tissue blocks from UPMC will be studied, provide the name of the pathologist who has reviewed this project and approved the allocation of tissue: Name: E-mail:

B. 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:

C. 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:

D. Will this study use specimens (and if applicable, data) obtained *directly from a commercial vendor*?

\_\_\_\_ Yes

\_\_\_\_No

 If Yes, identify the vendor by name:

E. 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

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

\_\_\_\_ Yes

\_\_\_\_No

If No, explain:

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

\_\_\_\_\_No:

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

\_\_\_\_\_ Yes

G.Purpose and background of the research

This is a chance for you to give the reviewers a background in the area of interest, educate them so they can understand your project and provide a full review in as short of time as possible.

* 1. Background (what literature exists on 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 IRB 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

1. Research Design and Methods
	1. How will the study be conducted?
2. Types of specimens (e.g., tissue, blood, bodily fluids) to be studied:
	1. What specimens will be accessed?
	2. Describe the original collection of the specimens and/or data (how, where, and by whom):
	3. If specimens are still being collected, who will be responsible for obtaining the specimens?
		1. Is that person a member of this research team? No  Yes
	4. If applicable, provide a list of data variables that will be collected (e.g., diagnosis, age, laboratory results, etc.):
	5. How will confidentiality be maintained?
	6. Are personal identifiers associated with the original specimen?  No  Yes
	If Yes, address the following questions:
		1. Who will access the specimens and/or data?
		2. What is their right to do so? (e.g., specify their right to access to the materials; clarify that they will only have access to de-identified materials, etc.).
		3. Describe the process of obtaining specimens and/or data?
		4. Describe how the specimens and/or data will be de-identified prior to being provided to investigators (if applicable).

			1. If specimens and/or data will be obtained from the University and/or UPMC, specify the identity of the **IRB-approved Honest Broker System/Process** that will be used in obtaining the specimens and/or data. If multiple systems are used, include all below:
				1. Honest Broker System or Process:
				2. UPMC/IRB Honest Broker Approval Number:
				3. Name of individual who has agreed to provide Honest Broker service to this project:
				4. If applicable, the specified Honest Broker must complete and sign the Assurance Form (next page). One copy should be retained by Honest Broker, and one copy should be uploaded into OSIRIS

**OR**

* + - 1. If a **non-approved Honest Broker** is used, provide a justification:
				1. Name the person or group, independent of this research team, who has agreed to serve as the honest broker and has completed the honest broker assurance form:
1. **Additional Information, Clarification, or Comments for the IRB Reviewer**: