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

(ACHS Use only)

**Category 3a: Retrospective Medical Record Review 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. Describe the extent to which this medical record review is consistent with the researcher’s patient care responsibilities:
2. Name the individual(s) who will conduct the medical record review (as PI or under the supervision of the PI):

C. Will any member of this research team record patient names, ID numbers or other linkage codes with the data abstracted from the medical records (even temporarily)?

\_\_\_\_ Yes

\_\_\_\_No

If Yes, STOP. Your project does not meet criteria for this exempt category; contact ACHS at achs@muskingum.edu.

D. Are all records currently 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.

E. **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 publically 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, 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. **Medical Records to be studied**
   1. Specify the inclusion/exclusion criteria for the selection of medical records requested for this study:
   2. Specify the approximate number of individual patient medical records that will be requested for the purpose of this study:
   3. Describe or list the specific data elements that will be extracted from these medical records for the purpose of this study:
   4. Describe the location / source of the medical records to be accessed:
2. **Data Analysis**
   1. How will the medical record information be analyzed to determine that the objectives aims of this study have been met?
3. **Additional Information, Clarification, or Comments for the IRB Reviewer**:

**NOTE**:

1. **Under NO circumstances can identifiers (i.e., names, social security numbers, phone numbers, medical record numbers, street addresses, etc.) be recorded with the data, nor can linkage codes be used (even temporarily). The dataset must be completely anonymous.**

For that reason, once the information has been extracted from the medical record, it will not be possible for the investigator to go back to that same medical record and add other patient-specific information to this research dataset.

Note, however, that investigators can keep a separate listing of the medical records that they have accessed as part of this study, but this listing should be restricted to the medical record number, and should not include any other medical record information or linkage codes!

**2. Also, this exemption is not appropriate when medical record data are coming from more than one source (e.g., multiple medical record offices/databases) when that linking process requires investigators to record linkage codes, at least temporarily.**

In either situation, the investigator should complete an expedited application with a request for a waiver of consent and a waiver of HIPAA Authorization.