**Categories of Research Activities Exempt from Review By Muskingum University’s ACHS**

These exemptions **DO NOT APPLY** when **deception** of human subjects may be an element of the research; when the activity might expose the human subjects to **discomfort** or **harassment** beyond levels encountered in daily life; or individuals **involuntarily confined** or **detained** in penal institutions are subjects of the activity.

**Category 1: Educational Strategies, Curricula or Classroom Management Methods**

Basic Exempt Criteria *45 CFR 46.101(b)(1)*

**Need:**

* Research takes place in established or commonly accepted educational setting
* Involves study of normal educational practices (e.g., regular and special education instructional strategies; studies effectiveness or comparison among instructional techniques, curricula, or classroom management methods)

**Additional General Requirements or Considerations**

* When children are studied in school or other institutional settings, approval from relevant school official (including the school system IRB or research review committee, if available) must be attached to this application at the time it is submitted to the ACHS
* If children are studied, investigators must provide a rationale for why a particular age range was selected, indicate their expertise in working with children, describe the adequacy of their facilities for pediatric research, and indicate whether they will have sufficient numbers of children to adequately address the research question

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**Category 2: Tests, Surveys, Interviews, Observations**

Basic Exempt Criteria *45 CFR 46.101(b)(2)*

Research includes evaluation of individuals using educational or cognitive tests, surveys, questionnaires, structured or open-ended interviews, or systematic observations of public behavior.

**NOTE:** Studies cannot be exempt if the participant's name (or other identifiers like birth date and initials, social security number, phone number, etc.) is linked to "private" or "sensitive" information (i.e., any information that could possibly affect the individual's reputation, employability, or financial standing). For example, if questions about medical history, substance use, mood state, sexual behaviors, and possible criminal activity are asked, identifiers cannot be linked to responses.

**Needs:**

* If subjects are children, only educational tests and/or passive observation of behavior is permitted; investigators cannot interact with child subjects.
* If subjects are adults, tests, surveys, interviews or behavioral observations can be included.
* Data should ordinarily be recorded without identifiers.
* If appropriately justified, identifiers may be recorded, but only if no sensitive information is collected.
* Subjects (or their parents, if subjects are minors) should be provided with overview of project ("script") that contains basic elements of informed consent, but no formal written consent is obtained.

**Additional Requirements or Considerations**

* If subjects are followed over time and assessed repeatedly, written informed consent should be obtained (and the study submitted for expedited review) unless it is truly impracticable (e.g., the only contact with subjects is over the phone).
* Focus groups can be considered to be open-ended interviews, and may be approved for adults, provided the basic exempt criteria are met.
* If children are studied, investigators must provide a rationale for why a particular age range was selected, indicate their expertise in working with children, describe the adequacy of their facilities for pediatric research, and indicate whether they will have sufficient numbers of children to adequately address the research question.
* Copies of all measures must be attached for ACHS review.
* When studies are conducted in foreign countries, written authorization to conduct the research at that location must be attached to this application. If identifiers are collected as part of that research activity, the investigator has the responsibility to ensure that responses to questionnaires or interviews about political, economic, cultural, or religious topic will not affect the participant's reputation, employability, or financial standing. This may require additional documentation from someone with first-hand familiarity with the country's laws and mores.

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**Category 3: Existing Data, Documents, or Records** (not applicable for medical record reviews)

Basic Exempt Criteria *45 CFR 46.101(b)(4)*

Research is most commonly conducted on data public records or government data sources, but other research or clinical records may also be accessed under this exemption. Although investigators can review those records (if they have a legitimate right to access those records), they cannot record any private identifiable information from these records.

**Needs:**

* All information is publically available, **OR**
* All information is recorded anonymously, **OR**
* Data are recorded in such a way that researchers cannot identify subjects. Two acceptable strategies for this de-identification exist:
* Identifiable data are de-identified by an appropriate software program  
  OR
* The de-identification of data is carried out by a person who is independent of the research who has been identified by name in the protocol.

**Additional Requirements or Considerations**

* Source of the data must be documented in protocol

**Category 3A: Retrospective Medical Record Review**

Basic Exempt Criteria *45 CFR 46.101(b)(4)*

Research studies involving the retrospective review, collection and analysis of medical record information are descriptive studies that ordinarily seek to evaluate relationships between one or more biomedical, treatment, and/or demographic variables and one or more outcome measures in patients. Data may include a wide range of information from the medical record (e.g., results of lab tests, nursing and physician notes, summary reports - including intake and discharge summaries and consultant reports, raw data from electrophysiological or imaging tests, etc.).

Because this research involves medical records, compliance with the HIPAA Privacy Rule (46 CFR Part 160; Part 164 (subparts a,e) ) is required.

Muskingum University recognizes three somewhat different pathways for conducting these studies, depending on (a) whether the investigator recording information has patient care responsibilities, and (b) whether identifiable information will be recorded. Note that in the latter case, investigators who wish to record identifiable information must request a waiver of informed consent/HIPAA authorization. **This is NOT an exempt application**.

1. Recording of Medical Information, Without Identifiers, By or Under the Oversight Of a *Principal Investigator Who Would Normally Have Access to this Information by Virtue of His/Her Patient Care Responsibilities*:

**Needs:**

* An investigator may personally review medical records and abstract relevant data from the medical records if ALL of the following conditions are met:
* All medical records to be accessed for study are currently in existence at the time of the IRB submission.
* The desired medical record data is recorded by the investigator in such a way that the patients cannot be identified (i.e., by the investigator or others) either directly, or indirectly via linkage codes assigned to the data. This means that the investigator cannot link names, social security numbers, or any other patient identifiers to the data set. As a consequence, the resulting research data set is necessarily 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 the medical record and add other patient-specific information to this research dataset.
* The principal investigator (PI) of the research study has legitimate access to the desired medical information insofar as he or she is a UPMC staff member and/or has been granted UPMC privileges and provides related care (i.e., related to the information desired) to the patients, or is in the position to provide related care (including treatment, and/or diagnostic services) to the patients.
  + For example, any health professional providing patient care to a particular set of patients (e.g., all patients treated in the Emergency Department; all patients with aphasia; all patients undergoing CT scans), would ordinarily have access to the related medical record information of those patients as part of his or her current or future job responsibilities, and hence would be in a position to serve as the P.I. of a research study involving a retrospective review of those medical records (regardless of whether he or she actually provided direct care to those particular patients).

Note that the University IRB will not approve a retrospective medical record research study if the medical record information desired is not in some way related to the patient care responsibilities of the listed PI.

**Category 4: Research with Biological Specimens**

Basic Exempt Criteria *45 CFR 46.101(b)(4)*

Research includes studies of biological specimens that have been banked for research purposes. Although health information about the individuals who provided these specimens can be linked to them, researchers cannot have direct access to their names, or other information that would allow them to be identified. It may be appropriate to use an Honest Broker.

**Needs:**

* Specimens may include tissue, blood, or bodily fluid
* Specimens were obtained independent of this research study
* Specimens are archived in a recognized tissue bank
* All specimens and corresponding data are recorded anonymously, **OR**
* Data are recorded in such a way that researchers cannot identify subjects.
* Two acceptable strategies for this de-identification exist:
* Identifiable data are de-identified by an appropriate software program OR
* The de-identification of data is carried out by a person who is independent of the research (i.e., an independent "honest broker") and who has been identified by name in the protocol, and has completed the "honest broker" certification form. Information linking the assigned code numbers to the subjects’ identity (if applicable) is maintained solely by the independent "honest broker"
* All specimens are currently in existence

**Additional Requirements or Considerations**

* Tissue bank or repository must be identified by name, and the IRB number or a copy of the consent form completed by subjects must be included
* If specimens were collected as part of another research project, a copy of the initial consent form must be attached to ensure that subjects participating in the initial project did not restrict the use of their sample to that initial project or to certain types of analyses
* If specimens are still being collected, the investigators of the proposed study cannot personally participate in the collection of those specimens. Under these circumstances, the study must be approved by the IRB as "not human subjects research" (45CFR46.102(f)). This issue needs to be addressed explicitly in the protocol