Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 400: RESEARCH EXEMPT FROM IRB REVIEW

POLICY

Research activities in which the only involvement of human subjects will be in one or more specific categories, which are listed below, may be exempt from IRB review. Exempt from IRB review also means exempt from consent. Determination of exemption must be based on regulatory and institutional criteria, and must be documented.

PROCEDURES

1. Exempt Research

1.1 **Exemption 1**: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

1.2 **Exemption 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey, or observation of public behavior (including visual or auditory recordings) if at least one of the following criteria are met:

1.2.1 The information obtained 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;

1.2.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

1.2.3 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects **can readily be ascertained**, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the necessary determination.

1.3 **Exemption 3**: Research involving ***benign behavioral interventions*** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

1.3.1 The information 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;

1.3.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

1.3.3 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects **can readily be ascertained**, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the necessary determination.

1.4 **Exemption 4**: Secondary research for which consent is not required: Secondary research uses identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1.4.1 The identifiable private information or identifiable biospecimens are publicly available;

1.4.2 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;

1.4.3 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"; or

1.4.4 The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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 Code.

1.5 **Exemption 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

1.5.1 Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision.

1.6 **Exemption 6**: Taste and food quality evaluation and consumer acceptable studies.

1.7 **Exemption 7**: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the necessary determination.

1.8 **Exemption 8**: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

1.8.1 Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the regulations; and

1.8.2 Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the regulations; and

1.8.3 An IRB conducts a limited IRB review and makes the necessary determination, and also makes the determination that the research to be conducted is within the scope of the broad consent referenced above; and

1.8.4 The investigator does not include returning individual research results to subjects as part of the study plan.

2. Definition(s)

2.1 Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples: Subjects play an online game, solve puzzles under various noise conditions, or decide how to allocate a nominal amount of received cash between themselves and someone else.

2.2 Secondary research is research use of information or biospecimens for other than the original purpose(s) for which the information or biospecimens were initially collected through interaction or intervention with living individuals, including:

2.2.1 A separate research study, or

2.2.2 A non-research activity (e.g., clinical care)

3. Exclusions

3.1 The DMH IRB will not be participating in the limited IRB review process.

3.2 The DMH IRB will not adopt broad consent, thus rendering Exemption 7 and Exemption 8 non-permissible for use.

SCOPE

This SOP applies to all IRB members, all investigators and other members of the research community.