

## EXEMPT RESEARCH UNDER THE REVISED COMMON RULE

Research activities that involve one or more of the categories listed in this section may be exempt from the full requirements of IRB review. HOWEVER, investigators are NOT authorized to make this determination. McLaren IRB staff must make the determination of exemption based on regulatory and institutional criteria. All procedures in a protocol must meet exemption criteria for the study to be deemed exempt.

NOTE: The exemption categories below do not apply to research involving prisoners (except if research is aimed at involving a broader subject population that only incidentally includes prisoners), subjects vulnerable to coercion, persons considered to be legally incompetent, and certain types of research with children as noted below. Additionally, categories 1 thru 5 do not apply to research regulated by the Food and Drug Administration (FDA).

Even when research is exempt from further requirements of federal regulations, basic ethical standards still apply.

- Research data must be handled and stored securely, in compliance with HIPAA regulations and institutional policy.
- Access to research data must be limited to study team members and other authorized personnel.
- All members of the research team must be current on human subjects training

Each exempt category below is described from **45 CFR 46.104(d)**.

### Category 1

#### EDUCATIONAL PRACTICES

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. This includes most

- i. Research on regular and special education instructional strategies, and
- ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

### Category 2

#### EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- i. 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; or

- ii. 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
- iii. 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 subject, and an IRB conducts a limited IRB review to make the determination required by the 45 CFR 46.111(a)(7).

NOTE: Individuals under the age of 18 may participate in (i) or (ii) if the research involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

### **Category 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:

- (A) 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, OR
- (B) Any disclosure of the human subjects' responses outside of 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
- (C) 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 determination required by 45 CFR 46.111(a)(7).

NOTE: Benign behavioral interventions are brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has not reason to think the subjects will find the intervention offensive or embarrassing. Deception is only permitted if subject prospectively agrees.

### **Category 4**

#### **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; OR
- 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; OR
- 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 (HIPAA), for the purposes of "health care operations" or "research" as described under 45 CFR 164.512(b); OR
- iv. The research is conducted by, or on behalf of, a Federal dept or agency using government-generated or government-collected information obtained for non research activities, fit 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 USC 3501 note, if all 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 USC 552a, and if applicable, the information used in research was collected subject to the Paperwork Reduction Act of 1995, 44 USC 3501 et seq [\_.104(d)(4)].

**NOTE: This involves secondary research (i.e., reusing identifiable information/biospecimens that are collected for another reason [e.g., clinical or research]) and includes both retrospective and prospective data/specimens. To qualify under (iii), PHI cannot be shared outside of a covered entity.**

#### Category 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, including procedures for obtaining benefits or services under those 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.** Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Note: Each Federal department or agency conducting or supporting 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. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

#### Category 6

##### **TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES, if:**

- i. wholesome foods without additives are consumed, or
- ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.