COMMON RULE CHANGES TO THE EXEMPT RESEARCH CATEGORIES

Saint Louis University Institutional Review Board

The new Common Rule effective date is January 21, 2019. Many of the changes impact the background operations of the IRB and do not directly impact researchers. However, changes to the Exempt categories will directly impact researchers. The chart below outlines the important information. Note that the Department of Health and Human Services has not issued any guidance for institutions on how to implement or interpret the new rule. The IRB will inform researchers if policies and procedures change as a result of evolving interpretations and guidance.

Note: Existing studies (approved before Jan 21 or pending approval) will remain with their approved categories.

Exempt Category 1- Normal Education Practices	***Revised** (see bold text)*
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** research on regular and special education instructional strategies, **and** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	
Summary of changes:	Added caveat that there must not be any impact of subject's opportunity to learn or any negative impact if the research involves an evaluation of the instructors.
Vulnerable Population Exceptions:	• Research targeting **prisoners** is not allowed. However, research aimed at a broader population that only incidentally includes prisoners is allowed.
Considerations for existing studies:	• eIRB may require completion of new questions upon Amendment or at time of comment/contingency. Existing answers will not need to be revised, even though the text of the question changed slightly.
Exempt Category 2- Interaction/Behavioral Research	***Revised** (see bold text)*
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; (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 subjects, and an IRB conducts a *limited IRB review.***	
Summary of changes:	• Wording was added to clarify that the category applies to research that only involves interactions. Interventions or manipulations (of the subject or subject's environment) are still not allowed. • Clarification that visual or auditory recording is allowed. • The use of potentially sensitive information might be allowable if appropriate protections are in place and the project is reviewed under 2(iii).
Vulnerable Population Exceptions:	• Research targeting **prisoners** is not allowed. However, research aimed at a broader population that only incidentally includes prisoners is allowed. • **Children** may not be included as subjects except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. Children may not be included in projects under 2(iii).

Considerations for existing studies:	• eIRB may require completion of new questions upon Amendment or at time of comment/contingency. Existing answers will not need to be revised.
Exempt Category 3- Benign Behavioral Interventions	***New!***
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; (B) 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 (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.*	
Benign Behavioral Intervention:	Interventions 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.
Deception/Incomplete Disclosure:	If the research involves deceiving subjects regarding the nature or purposes of the research, exemption is only allowed if the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or mislead regarding the nature or purposes of the research.
Guidance/More Information:	The IRB will release a guidance specifically addressing allowable research under this new category complete with examples of qualifying and non-qualifying projects.
Vulnerable Population Exceptions:	• Research targeting **prisoners** is not allowed. However, research aimed at a broader population that only incidentally includes prisoners is allowed. • **Children** not allowed.
Exempt Category 4- Secondary Data Analysis	***Revised** (see bold text)*
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; (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; **(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined [by HIPAA] or for "public health activities and purposes" as described under [HIPAA]; or** **(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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 the E-Government Act, if all of 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 and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act.**	
Summary of changes:	• Some of the flexibility introduced in the revisions applies only to institutions with capacity to obtain front door consent or broad consent. Because SLU is not yet equipped for those types of consent, researchers will not be able to

	take advantage of all of the flexibility of this category.
Clarification Note:	This category only applies to the *re-use* of data and specimens that were or will be collected for nonresearch purposes or from previously approved research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between the investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then the study would need to be approved under the Expedited categories or Fullboard review.
Vulnerable Population Exceptions:	• Data/specimens from **prisoners** could be allowed as long as the research isn't designed to recruit prisoners and prisoners are only incidentally subjects of the research.
Considerations for existing studies:	• eIRB may require completion of new questions upon Amendment or at time of comment/contingency. Existing answers MAY need to be revised.
Exempt Category 5- Federal Program/Demonstration Projects	***Revised (see bold text)***
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 agreements, 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.**	
Summary of changes:	• The scope of this category has been broadened. Previously the demonstration projects were conducted by the Federal agency. Now projects simply funded by a Federal agency would be allowed. • The scope has been expanded to include purposes not only to study and evaluate but also to improve these programs. • Eligible projects will be posted on a Federal website.
Vulnerable Population Exceptions:	• Research targeting **prisoners** is not allowed. However, research aimed at a broader population that only incidentally includes prisoners is allowed.
Considerations for existing studies:	• eIRB may require completion of new questions upon Amendment or at time of comment/contingency. Existing answers MAY need to be revised.
Exempt Category 6- Taste and Food Quality	***No Changes***
Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome food 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.	
Clarification Note:	This category is the only one which is allowable for FDA-regulated research.
Vulnerable Population Exceptions:	• Research targeting **prisoners** is not allowed. However, research aimed at a broader population that only incidentally includes prisoners is allowed.
Considerations for existing studies:	• Existing answers will not need to be revised.
Exempt Category 7- Secondary Research Storage/Maintenance	***New- SLU not using***
Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of	

identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review.	
Implementation Note:	This exemption category is new with the 2018 Common Rule. It will be implemented at SLU when capacity to meet the regulatory requirements has been confirmed.
Exempt Category 8- Secondary Research Using Broad Consent ***New- SLU not using***	
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: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.	
Implementation Note:	This exemption category is new with the 2018 Common Rule. It will be implemented at SLU when capacity to meet the regulatory requirements has been confirmed.