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	

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)

	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.