REVISED COMMON RULE

ICF:

Informed consent must be brief and specific and highlight the key information that is necessary for the prospective subjects or legally authorized representative to understand the reasons why one might or might not want to participate in research. The content on the informed consent must be organized and presented in a way that facilitates comprehension.

The goal is to:

1) Simplify the information on the complex research projects (lower reading level)
2) Enhance decision making
3) Highlight the important information that will be valuable in the decision making process
4) Focus on what a reasonable person would want to know
5) Address misconception (nature of research, misestimating of potential risks and unrealistic expectations)
6) Give meaning to the facts

Major themes to highlight:

1) Purpose for research
2) Nature of the intervention
3) Brief summary of procedures
4) Common risks as we as any potential serious risk
5) Challenges/things to consider

Federal regulations encourage a creative approach in the development of this section of the consent form. Investigators are encourage to use graphics, charts and diagrams to promote comprehension of the study.

Continuing Review Changes

The Revised Common Rule removes the requirement for continuing review for minimal risk research and for greater than minimal risk research that is in long-term follow-up or data analysis only, unless the research is FDA-regulated.

Single IRB Review

A component of the Revised Common Rule required Single IRB review for studies conducted or supported by other federal agencies. This change aligns with NIH's policy January 2, 2019 changes requiring all multi-center NIH-funded studies to use single IRB review for domestic sites, which went into effect on January 25, 2018. More information can be accessed from NIH's policies and procedures on single IRB review for multi-site research.

Key Changes – Exempt Category

EXEMPT CATEGORY 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. 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.

Changes to this exempt category include the stipulation that there must not be any impact on the subjects' opportunity to learn or any negative impact if the research involves an evaluation of the instructors. If the research involves diverting significant time and attention away from the delivery of regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if instructors are being evaluated. Research involving randomization to an unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

EXEMPT CATEGORY 2: 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) (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.

This exemption category involves several changes from pre-2018 rules. The wording of this exemption was changed to clarify that the category applies to research that only involves interactions. Additionally, the use of potentially sensitive information might be allowable if appropriate protections are in place and the IRB conducts a new process called 'limited IRB review.'

This category involves interactions (verbal and written responses) and data collection only. The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

EXEMPT 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:

(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; Effective January 21, 2019 Page 3 of 6

(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.

For the purpose of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless 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 misled regarding the nature or purposes of the research. This exempt category is completely new in the 2018 revisions to the federal regulations. There are limits on the interventions that are considered 'benign' and requirements on IRB review of this type of research.

EXEMPT 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;

(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 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); 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 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 applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

The 2018 changes significantly broaden the type of secondary research that can be done under this exemption category:

• The requirement that all study data be existing at the time of IRB submission has been eliminated. Data under this exemption may be both retrospective and prospective.
• As noted in the regulatory definition above, informed consent is not required for this category of research.
• The requirement that the study involves data only has been eliminated. This exemption category may also involve the use of specimens *if the specimens are publicly available or provided to the researcher in a coded/de-identified manner.*
• If the investigator uses identifiable specimens for the research, it will not qualify for this exemption category; however, it may be approvable under an Expedited review process.
• Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straight-forward approach.
• If investigators need to retain data that contains any HIPAA elements or need to retain a linking list, then appropriate HIPAA protections could make the project approvable. Depending on the circumstances of the data, the HIPAA protections might include a, a Data Use Agreement or a waiver of HIPAA authorization with accounting of disclosures.
• Certain sources of publicly available data require the recipient to sign an agreement outlining restrictions on access, use, security and transfer. Most often, those agreements will need review by the university's general counsel.
• Collaborations with non-KUMC researchers who are not members of a HIPAA covered entity or covered component will add data protection requirements and move the project outside of this exemption category.

It is important to note the Exemption Category 4 only applies to the *re-use* of data and specimens that were or will be collected for non-research purposes or from 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 investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

EXEMPT 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. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.

This category has been updated to allow projects that are simply funded by a Federal agency. The scope has been expanded to include purposes not only to study and evaluate but also to improve these

programs. Note that projects eligible for this exemption will be posted on a Federal website. Investigators who have a project in this category are asked to consult with IRB staff prior to submission.

EXEMPT CATEGORY 6: Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or 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.

This exemption category was not changed in the revised Common Rule. Note that it is the only exemption that is allowable for FDA-regulated research.

EXEMPT CATEGORY 7*:* 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 and makes the determinations required by §__.111(a)(8).

EXEMPT CATEGORY 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:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.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 §__.117;
(iii) An IRB conducts a limited IRB review and makes the determination required by §__.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 479
(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 any legal requirements to return individual research results.