UofL	HUMAN SUBJECTS PROTECTION PROGRAM	**New Common Rule Revisions University of Louisville IRB Policy Addendum**	Human Subjects Protection Program Office MedCenter One 501 E. Broadway, Suite 200 Louisville KY 40202-1798 P: 502-852-5188 Service Acct: hsppofc@louisville.edu

This policy addendum addresses the Revised Common Rule and how it will be implemented at the University of Louisville.

The IRB Consent Template and instructions have been revised to reflect the required changes discussed in this document. Updated templates can be found on the HSPPO website under "templates".

Implementation Date: January 21, 2019
The following table describes the regulations that apply to the various categories of research before and after the January 21, 2019 implementation date.

	Research approved before Jan 21, 2019	**Research approved on or after Jan 21, 2019**
FDA regulated research	FDA Regulations	FDA Regulations Use new UofL ICF template
Research regulated by federal department or agency (other than DOJ)	Original Common Rule	Revised Common Rule Use new UofL ICF template
Unregulated research	Original Common Rule	Revised Common Rule Use new UofL ICF template Consent form exceptions that are recommended, not required: -Consent summary information -Consent new elements -Posting consent on public website
Research regulated by DOJ	Original Common Rule	Original Common Rule Use new UofL ICF template

Topic	Rule Change and Implementation
Implementation Date	The revised common rule applies to federally funded or supported projects approved on or after the implementation date of January 21, 2019. University of Louisville will apply it as indicated in the table above.
Projects approved prior to the implementation date	All projects reviewed and approved prior to the implementation date remain under the old rule. These projects retain their existing level of review and all other IRB requirements, including continuing review requirements.

REVISED AND NEW DEFINITIONS

Topic	Rule Change and Implementation	Source
Research	The new rule explicitly removes four categories of activities from the rule jurisdiction: • Scholarly or journalistic activities, including oral history, journalism, biography, literary criticism, legal research, and historical scholarship • Public health surveillance • National security missions • Criminal justice activities	**46.102**
Human Subjects	The new rule defines a human subject as: A living individual about whom an investigator: • Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or • Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.	**46.102**
Clinical Trial	The old rule provided no definition of a clinical trial. The new rule defines a clinical trial as: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.	**46.102**

Topic	Rule Change and Implementation	Source
Vulnerable Populations	The new rule removes pregnant women and "handicapped." The new rule replaces "mentally disabled" with "individuals with impaired decision-making capacity."	**46.111**
Identifiable Bio-specimen/ Identifiable Private Information	Identifiable biospecimen is a biospecimen for which the identity of the subject is or may be readily be ascertained by the investigator or associated with the biospecimen. Identifiable private information is a private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.	**46.102**
Benign Behavioral Intervention	The old rule provided no definition of benign behavioral interventions. The new rule defines a benign behavioral intervention as: 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 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.	**46.102**

EXEMPT CATEGORIES

Topic	Rule Change and Implementation	Source
Exempt Project Determination	The exemption must be made by the IRB or a designated member of the IRB. This is current UofL IRB practice, so no change in process for this new requirement. Revised University of Louisville policy: Researchers must submit personnel changes for exempt studies. Additionally, amendments must be submitted if they could change the exempt status. Human subjects and HIPAA research training will be required for all personnel on an exempt research project exempted	

Topic	Rule Change and Implementation	Source
	on or after 1/21/2019.	
Exempt Categories	The exempt categories have been revised as noted below. The (*) items represent the change for revised categories. **REVISED** Exempt category 1– research in educational settings *Revised to include that the research does not adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction.	**46.104**
Exempt Categories (continued)	**REVISED** Exempt category 2 – research involving educational tests, survey procedures, interview procedures, or observations of public behavior *Revised to include review for privacy and security of data and that harm may result from potential damage to the subjects' educational advancement. **NEW** Exempt category 3 – research involving benign interventions *This research cannot involve deception unless the deception is authorized by the participant **REVISED** Exempt category 4 – secondary research for which consent is not required of identifiable private information or identifiable biospecimens *Revised to remove word 'existing' and to allow for a HIPAA exemption *Information must be publicly available, or not identifiable by the investigator directly or through links, the investigator will not contact subjects, and will not re-identify subjects; **REVISED** Exempt category 5 – research and demonstration projects conducted or supported by a federal department or agency *Revised to allow for easier applicability	

Topic	Rule Change and Implementation	Source
	Unchanged Exempt category 6 – taste and food evaluations **NEW** Exempt category 7 – storage and maintenance for secondary research for which broad consent is required involving identifiable private information or identifiable biospecimens **NEW** Exempt category 8 – secondary research or which broad consent is required involving use of identifiable private information or identifiable biospecimens for secondary research use	
Exempt Research and Vulnerable Populations	**Pregnant Women** – All exemptions may apply if the condition of the exemption is met. **Prisoners** – None of the exemptions apply, except for research aimed at involving a broader subject population and only incidentally includes prisoners. **Children** – Exemptions (d)(1) and (d)(4-8) may involve children. Exempt (d)(2) (research on educational tests, surveys, interviews or observations) may include children, but: *Exempt (2)(i) and (ii) only apply to educational tests or observation of public behavior when the investigator(s) do not participate in the activities being observed; and *Exempt (2)(iii) is not applicable to research with children. This exemption is where the investigator can readily ascertain the identity of the child.	**46.104**
Use of Protected Health Information in Exempt Research	In the previous regulations, there was no exempt category that allowed for the collection of identifiable Protected Health Information (PHI). These were generally determined to fall under an Expedited category. In the revised Exempt categories, there is now a HIPAA exemption for identifiable secondary research of PHI that was collected for some other purpose or intent than the proposed study. Informed consent is not required for research limited to identifiable secondary research utilizing Protected Health	

Topic	Rule Change and Implementation	Source
	Information (PHI), including identifiable bio-specimens (exempt category 4). A HIPAA authorization is required for future and secondary use, or a waiver of authorization is granted by the IRB/Privacy Board. Human subjects and HIPAA research training will be required for all personnel on an exempt research project exempted on or after 1/21/2019.	

EXPEDITED CATEGORIES

Topic	Rule Change and Implementation	Source
Expedited Review Categories	There is no change to the expedited categories under the new rule. The Federal Government will assess the categories every four years. The rule clarifies that projects involving only activities on the list of expedited categories should be treated under expedited review unless the IRB determines and documents that the study involves more than minimal risk.	**46.110**
Continuing Review Requirement for Expedited Studies	Projects approved after the implementation date may no longer be subject to a continuing review, unless the IRB finds and documents the need to require a continuing review to enhance the protections of research subjects. Continuing review is still required of FDA-regulated studies. The IRB requires continuing review for minimal risk research when: • The research is regulated by the FDA or Dept. of Justice/National Institute of Justice or other agency that has not adopted the revised common rule; • The Principal Investigator (PI) has a corrective action plan issued within the past two years; • The project involves deception; • A conflict of interest management plan exists related to the research; OR • Determined by the IRB Chair/Vice Chair for oversight	**46.109**

Topic	Rule Change and Implementation	Source
	of subject enrollment or other concern that requires increased oversight. For expedited studies approved on or after January 21, 2019 where the reviewer determines continuing review is not required, the IRB analyst will set an expiration date of three years minus a day from the approval date. If the study is still open at that time, the investigator will be required to submit a continuation request to extend the study. **Requirements for submitting personnel changes, study amendments, deviations, etc…have not changed.**	
Single IRB (sIRB) review for multi- site studies	The University of Louisville has allowed for single IRB review of research. The new rule requires that all multi-site (meaning more than one site) conduct sIRB review. The sIRB is determined by the prime awardee and the federal agency supporting the study. The implementation date of sIRB review is three years from the implementation date of the rule (January 19, 2020). Note that the NIH single IRB policy is effective January 25, 2018.	

INFORMED CONSENT: INCLUDING BROAD CONSENT, WAIVER OF CONSENT AND WAIVER OF DOCUMENTATION

Topic	Rule Change and Implementation	Source
Summary of Informed Consent Requirements	The informed consent requirements have been modified. A brief explanation of the changes are noted, with more detailed explanation in the following sections: • Significant changes to the content, organization, and presentation of information and process to facilitate a subject's decision about whether to participate; • Changes to the basic and additional elements of consent; • Creation of the concept of broad consent; • Changes in the criteria for the waiver or alteration of consent;	**46.116**

Topic	Rule Change and Implementation	Source
Summary of Informed Consent Requirements (Continued)	• New provisions that allow IRBs to approve research for which investigators obtain information or biospecimens without consent for the purposes of screening, recruiting, or determining the eligibility of prospective subjects provided certain conditions are met; and • Requirement to post* to a federal website a copy of the IRB approved version of the consent form. *Only one posting is required per multi-site study, which can be done by the sponsor. This only applies to clinical trials that are conducted or supported by a federal department or agency. Clinicaltrials.gov and regulations.gov have been listed as sites for posting. The Revised Common Rule states that informed consent must begin with a "concise and focused presentation of the **key information**" that would assist subjects in deciding why they may or may not want to participate in the research. It needs to be organized and presented in a way that facilitates comprehension. The revised consent template and instructions can be found on the HSPPO Website at: http://louisville.edu/research/humansubjects/templates/links-to-forms	
Informed Consent Elements	**NEW** required element of informed consent for studies involving collection of identifiable private information or identifiable biospecimens. One of the following statements must be in the informed consent: • A statement that the identifiers might be removed from the information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research without additional informed consent; **OR** • A statement that the subject's information or specimens, even if identifiers are removed, will not be used or distributed for future research.	**46.116**

Topic	Rule Change and Implementation	Source
	NEW additional elements of informed consent will be required of applicable research studies. These additional elements are: • A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; • A statement regarding whether clinically relevant research results; including individual research results, will be disclosed to subjects, and if so, under what conditions; and • For research involving biospecimens, whether the research includes whole genome sequencing.	
Electronic Consent	The new rule specifies that electronic consent can be utilized. The consent must be approved by the IRB and signed by the subject or the subject's legally authorized representative. A written copy must be given to the person signing the informed consent. Electronic signatures must meet all applicable requirements (e.g. local, state, federal regulations)	46.117
Waiver or Alteration of Informed Consent	The IRB is prohibited from waiving or altering consent when broad consent is used. If a participant withdraws their broad consent, the IRB is prohibited from waiving consent for use of any information collected. Investigators will be required to provide justification for a **NEW** required element for obtaining a waiver of consent: • If the research involves using identifiable private information or biospecimens, the research could not practicably be carried out without using such information in an identifiable format.	
Broad Consent At this time, the University of Louisville IRB is not approving	Detailed guidance has not been issued on broad consent. Once additional guidance is available the UofL IRB will review requests for broad consent and provide additional information to researchers. Broad consent is an option to obtain consent for studies involving storage, maintenance, and secondary use of identifiable data or specimens. Broad consent is not in	

Topic	Rule Change and Implementation	Source
broad consent forms. **Broad Consent (continued)**	addition to traditional informed consent, but separate from traditional informed consent. The elements of broad consent are: o Risks, benefits, confidentiality, voluntariness, and whom to contact; o Whether identifiable information or specimens will be sold for commercial profit and whether the subject will or will not share in this commercial profit; o Whether research may involve whole genome sequencing; o General description about the types of research that will be done with the identifiable information or specimens; o Description of the identifiable information or specimens that might be used in the research, whether sharing of such information will occur, and the types of institutions or researchers that might conduct research with the identifiable information or specimens; o Time information will be stored and maintained, and stored and used for research; o Unless told otherwise, a statement that individuals will NOT be informed of the details of any results of studies; and o Unless told otherwise, a statement that clinically relevant results will NOT be shared. **When a participant withdraws their broad consent, the IRB cannot issue a waiver or alteration of consent to allow continued use of the identifiable information or specimens.** The new rule allows waiver of a signature requirement (e.g. waiver of documentation) when a broad consent is used, so long as all the elements above are met. However, it is	

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	expected that use of a waiver of a signature for broad consent will be used rarely (e.g. for distinct cultural groups where signing documents is not the norm, or when the initial activity involved only oral communication through activities like a phone survey).	