Changes to the Common Rule

This site outlines the upcoming changes to human subject's research regulations. Additional information will be posted as new policies and processes are implemented. Please contact Dusty Layton for questions you may have at dlayton@southalabama.edu

The changes, as outlined in the Common Rule (45 CF 46) take effect January 19, 2008.

Category	Topic	Details	Impact
IRB operations	Single IRBs for multisite research ("cooperative research") (46.114)	Single IRBs generally required; however, some flexibility is provided in determining and documenting when a single IRB is not appropriate	Single IRBs for multi-site research compliance date is January 20, 2020. U.S. Institutions engaged in cooperative (multi-site) research must rely upon approval by a single IRB. The lead IRB is determined via proposal by the lead institution subject to acceptance of Federal Dept. or agency supporting the research. USAIRB, as appropriate, will sign agreements with other institutions to accept or cede IRB approval. This will impact PI's to ensure conversations and agreements to identify the lead IRB is completed ahead of time between USA and the other sites.
	External IRBs (46.103)	Reliance arrangement with non-institutional IRB must be documented	Non-institutional IRB must certify proposed research study covered by the assurance has been reviewed and approved by the IRB prior to initiation of the research. As noted above, RCS is already completing authorization agreements. It may impact the PI specific to time required for approval of the project, dependent on other sites completion of agreements.
	Checking the box (46.101)	Option for FWA holders to check the box has been eliminated	The option to "check" or "uncheck" the box on Federal Wide Assurances (FWA) been eliminated. The changes to the Common Rule preamble notes that Institutions will have flexibility in determining whether or not to apply the Common Rule to all IRB projects regardless of funding. Since we have

			previously “unchecked,” the box we believe this will have little impact on current processes (i.e. reporting noncompliance, unanticipated problems, adverse events to OHRP only for projects that are federally funded).
	Continuing review (46.109 & 46.115)	Continuing review of research is no longer required under various circumstances	Unless the IRB determines otherwise, continuing review will no longer be required for: projects under expedited categories, projects requiring limited IRB review, or projects that have progressed to data analysis (including analysis of identifiable private information or identifiable biospecimens). This will decrease PI and IRB staff time.
Informed consent	New language/clarity (46.116)	Consent forms must be clearer and more focused; many changes added to emphasize that information provided must facilitate a potential subjects’ understanding of why one would participate or not	**Subsection.116(a)(4)** is new and states that subjects must be provided with the information that a “reasonable person” would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information. **Subsection.116(a)(5)(i)** is new and states that the informed consent process must begin with a concise and focused presentation of the “key information” that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection also requires that this part of the informed consent be “organized and presented in a way that facilitates comprehension.” Presumably further guidance will explain what that means and how to achieve the goal along with what qualifies as a concise and focused presentation. **Subsection .116(a)(5)(ii)** is also new. It takes the form of an admonition present informed consent information in sufficient detail and organize and present the information in a way that does not “merely provide lists of isolated facts, but rather facilitates the prospective subject’s ……. understanding of the reasons why one might or might not want to participate.” **Subsection .116(b)**, the basic elements of consent, has no change to the eight (8) previous elements. Added is a requirement to include one of two statements about the collection of private information or identifiable biospecimens for future research (either that identifiers might be removed

			and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or, that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed). **Subsection .116(c)**, the additional elements of consent, has no change to the six (6) previous elements, but three new requirements have been added. Subsection .116(c)(7) requires a statement that 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. **Subsection .116(c)(8)** requires a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects. Subsection .116(c)(9) requires a statement about whether the research project might include whole genome sequencing. This will impact both the PI and IRB with regard to time in order to understand and implement the changes to informed consent requirements. In addition, the IRB will be drafting or revising template language to assist in this area along with awaiting further guidance on how best to implement these requirements from now until the effective date of January 19, 2018.
	Basic and additional elements of informed consent (46.116)	New basic element on collection of identifiable private information or identifiable biospecimens; three new additional elements on commercial profit, return of clinically relevant research results and whole genome sequencing	Section .116 is one of more extensively modified sections, primarily due to added regulations for the use of biospecimens in research. The unnumbered list of conditions appearing in the old "preamble" before .116(a) has been separated and the conditions numbered as .116(a) (1-3) and (6). Subsection .116(b) now contains the basic elements of consent and .116(c) the additional elements. A new subsection .116(a) has been added that is essentially a table of contents, which states that broad consent may be obtained in lieu of informed consent only with respect to the storage, maintenance, and secondary research uses of private information and identifiable biospecimens. Organizational SOPs, consent templates and checklists will have to be updated and investigators and IRB members trained for the new biospecimen

			and general consent requirements. This will be a major change and will impact and IRB time. Further information will be provided to the USA research community through training presentations and website updates.
	Broad consent (46.111 & 46.116) (Currently, USA IRB is not planning to implement use of Broad Consent, this is optional and not required)	Broad consent is an option for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens	**Subsection .116(d)** is new and addresses elements of "broad consent" for the storage, maintenance, and "secondary research use" of private information or identifiable biospecimens. Broad consent for secondary research use is permitted as an "alternative" to the standard informed consent requirements. **Subsection .116(d)(1)** still requires risks, benefits, confidentiality, voluntary statement, commercial profit, and whole genome sequencing elements be included. Subsection .116(d)(2) requires a general description of the types research that may be conducted. **Subsection .116(d)(3)** requires a description of the information or biospecimens that might be used in future research; whether sharing might occur; and, the types of institutions or researchers that might conduct research. **Subsection .116(d)(4)** requires a description of the length of time that the information or biospecimens may be stored, maintained and used. **Subsection .116(d)(5)** requires a statement either that subjects will or will not be informed of the details of any specific research studies that might be subsequently conducted. **Subsection .116(d)(6)** requires a statement that research results either will or will not be disclosed to subjects. **Subsection .116(d)(7**) requires contact information to be provided in the broad consent. The usefulness and ethics of broad consent remains to be further elucidated in guidance. At this time, the USA IRB will not implement use of broad consent.
	Recruitment/screening waivers (46.116)	Allows waiver of informed consent for subject recruitment or screening,	**Subsection .116(f)** addresses "general" waivers or alterations of informed consent. Subsection .116(f)(1) cautions that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research

		under certain conditions	use of information or biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use. **Subsection .116(f)(2)** addresses alterations (partial waivers) of informed consent. Two new conditions/restrictions are included. An IRB may not omit or alter any of the .116(a) general requirements for informed consent requirements. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required, i.e., alteration is not permitted. The four existing waiver conditions are included unchanged in subsection .116(f)(3), but added for research that involves accessing or using private information or identifiable biospecimens, is a requirement that the research could not practicably be carried out without accessing or using such information or biospecimens in an identifiable format. **Subsection .116(g)** is new. It addresses waivers of informed consent to obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects. One of two conditions must be met: the information will be obtained through oral or written communication with the prospective subject or by accessing records or stored biospecimens. This will again impact PI and IRB Office time to understand and implement the changes. Further information will be provided to the USA research community through training presentations and website updates.
	Clinical trials consent forms (46.116)	Some clinical trials must post consent form online	Subsection .116(h) is new and adds a requirement for posting clinical trial consent forms on a publicly available federal website that will be established (i.e., not yet a reality- likely clinicaltrials.gov) as a repository for consent forms. According to subsection .116(h)(3), one consent form for each study must be posted on the federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. The responsibility for posting is the awardee or the federal department or agency component conducting the study. We are estimating a small number of current or future projects will have to meet this requirement. However, please review the revised definition of a

			clinical trial below.
	Electronic consent (46.117)	Electronic consent is ok; must provide written copy	**Subsection .117(a)** now specifically allows electronic signatures for consent documentation and specifies that a written copy must be given to the person signing the consent form. **Subsection .117(b)(1)** specifically allows consent forms to be read to the subject. **Subsection .117(b)(2)** requires that, when using the short form to document consent, the informed consent must begin with a concise and focused presentation of the key information to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection requires that this part of the informed consent must be organized and presented in a way that facilitates comprehension. **Subsection .117(c)** still addresses waivers for the requirement to obtain a signed consent form and maintains the two pre-existing exceptions. Importantly a third category is added that allows waiver if the subjects are members of a distinct cultural group or community in which signing forms is not the norm. This will take time for the IRB and PI's to understand and implement. Organizational SOPs, templates and checklists will have to be updated and investigators and IRB members trained for the new waiver and consent requirements. Further information will be provided to the USA research community through training presentations and website updates.
	Legally authorized representatives (46.102)	If no law, institution can designate a representative	Legally authorized representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

			The USA IRB will work with General Counsel, as necessary, to define under what parameters USA would designate someone as an acceptable LAR.
Scope	Definition: Research (46.102)	Defines what's NOT research: certain journalistic, public health surveillance, and criminal justice or intelligence activities	The following activities are deemed not to be research: **(1)** Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. **(2)** Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). **(3)** Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. **(4)** Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
	Definition: Human subjects (46.102)	Includes "information or biospecimens" obtained from through intervention and interaction OR "identifiable private information or identifiable biospecimens"	Human subject means a living individual about whom an investigator (whether professional or student) conducting research: **(i)**Obtains information or biospeciments through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR

			(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
	Definition: Clinical trial (46.102)	Clinical trials are now specifically defined	Clinical trial means 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.
	Definition: Identifiable biospecimen/identifiable private information (46.102)	Will be re-examined within one year and every four years after	An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
	Definition: Vulnerable populations (46.111)	Pregnant women and "handicapped" removed; replaces "mentally disabled" with "individuals with impaired decision-making capacity"	Vulnerable populations are individuals that are vulnerable to coercion or undue influence, such as children, prisoners or individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
	Tribal law (46.101, 46.114, 446.116)	Tribal law applies where applicable; added throughout	More clearly defines where Tribal law applies.
New guidelines for exemptions	Additional exemptions for low-risk studies (46.104- see also 46.103, 46.109, 46.110, 46.111)	Exemptions added for secondary research on identifiable private information and identifiable biospecimens under various circumstances and regulatory requirements, such as limited IRB review and broad consent,	Additional exemptions and new categories along with limited IRB review have been added. This will take time for the IRB and PI's to understand and implement. Organizational SOPs, checklists, and IRB members will require time for updating and training. Further information will be provided to the USA research community through email notifications, newsletters and website updates.

		may apply	
Compliance dates	1 year (1/19/18), 3 years for multisite (1/20/20) (46.101)	Previous Rule applies to research approved prior to 1/19/18; new rule to approvals 1/19/18 or later	