PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

Here is PRIM&R's quick reference guide to the most significant changes in the final Common Rule published January 19, 2017. Although we have not included every change, nor every detail of the changes listed, we believe this list provides a clear overview of the revisions to the Rule that will affect researchers, institutions, and IRBs.

Category	Topic	Details	Location
IRB operations	Single IRBs for multisite research ("cooperative research")	Single IRBs generally required; however, some flexibility is provided in determining and documenting when a single IRB is not appropriate	46.114
	External IRBs	Reliance arrangement with non-institutional IRB must be documented; more stringent requirements proposed in the NPRM are not included	46.103
	Checking the box	Option for FWA holders to check the box has been eliminated	46.101
	Continuing review	Continuing review of research is no longer required under various circumstances	46.109, 46.115
Informed consent	New language/clarity	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	46.116
	Basic and additional elements of informed consent	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	46.116
	Broad consent	Broad consent is an option for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens	46.111, 46.116
	Recruitment/screening waivers	Allows waiver of informed consent for subject recruitment or screening, under certain conditions	46.116
	Clinical trials consent forms	Some clinical trials must post consent form online	46.116
	Electronic consent	Electronic consent is ok; must provide written copy	46.117
	Legally authorized representatives	If no law, institution can designate a representative	46.102

Category	Topic	Details	Location
Scope	Definition: Research	Defines what's NOT research: certain journalistic, public health surveillance, and criminal justice or intelligence activities	46.102
	Definition: Human subjects	Includes "information or biospecimens" obtained from through intervention and interaction OR "identifiable private information or identifiable biospecimens"	46.102
	Definition: Clinical trial	Clinical trials are now specifically defined	46.102
	Definition: Identifiable biospecimen/identifiable private information	Will be re-examined within one year and every four years after	46.102
	Definition: Vulnerable populations	Pregnant women and "handicapped" removed; replaces "mentally disabled" with "individuals with impaired decision-making capacity"	46.111
	Tribal law	Tribal law applies where applicable; added throughout	46.101, 46.114, 46.116
New guidelines for exemptions	Additional exemptions for low-risk studies	New exemptions added, including exemptions for secondary research on identifiable private information and identifiable biospecimens under various circumstances; various regulatory requirements, such as limited IRB review and broad consent, may apply	46.104 (see also 46.103, 46.109, 46.110, 46.111)
Compliance dates	1 year (1/19/18), 3 years for multisite (1/20/20)	Previous Rule applies to research approved prior to 1/19/17; new rule to approvals 1/19/17 or later	46.101

Almost as important as the changes that are in the revised rule are the previously proposed changes that are NOT in the final regulations. Things that appeared in the NPRM but are NOT included in the final Rule include: the inclusion of research with nonidentified biospecimens within the definition of human subjects research; the concept of "exclusions"; reference to or reliance on any of the proposed tools, standards, or templates that had not been developed at the time of the NPRM (exemption determination tool, standardized privacy and data security safeguards, broad consent template, etc.); the clinical trials extension; the requirement to include non-required element of consent in an "appendix" to the form; and modifications to the definition of minimal risk.