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2018 Common Rule Implementation Checklist

Action Items

The following table outlines certain actions institutions should take or consider taking in light of the 2018 Common Rule's now-delayed effective and general compliance date of **July 19, 2018**. This table does not reflect every policy and process change that may be necessary under the 2018 Common Rule; it addresses only the most significant areas of change. *Also note*: while some changes are mandatory as of the compliance date, others (such as the option of obtaining broad consent to secondary research use, and the availability of certain related new exemptions) can be characterized as optional regulatory flexibility that institutions may, but are not required, to implement. Ahead of July 19, 2018, institutions are required to comply with the existing regulations and may only implement aspects of the 2018 Common Rule that are not in conflict (i.e. those that impose requirements beyond the existing regulations). Institutions may not avail themselves of the regulatory flexibility offered by the 2018 Common Rule until it becomes effective. If you have questions about the checklist or require assistance with your organization's compliance planning or implementation, please contact the member of Verrill Dana's Academic and Clinical Research Group with whom you normally work, or email us at ACRG@VerrillDana.com.

Topic	Action Item	Comments
IRB SOPs	☐ Revise definition of "research" to include new carve-outs.	*Human Subject*: Regarding the definition of "human subject," the new definition of "identifiable biospecimen" will need to be included. Furthermore, institutions will want to find a way to include a placeholder in their SOPs to account for the further federal guidance on the definitions of identifiable private information and identifiable biospecimen due within 1 year of the effective date, as well as the list of technologies (also forthcoming within 1 year) deemed to generate individual private information or an identifiable biospecimen. *Limited IRB Review*: IRB members, particularly anyone to whom expedited review may be delegated, will need
	☐ Revise definition of "human subject." *See associated comments.*	
	☐ Revise existing exemptions.	
	☐ Include new exemptions.	
	☐ Document process and conditions for limited IRB review for exemptions (d)(2)(iii), (d)(3)(i)(C), (d)(7), and (d)(8). *See associated comments.*	
	☐ Revise continuing review policy to account for new carve-outs (e.g., no continuing review required for research that is eligible for expedited review) and	

	to require documentation of rationale if IRB will conduct continuing review when not otherwise required.	careful training on how to perform limited IRB reviews (as well as all changes in approval and process requirements). Although the IRB may perform limited IRB review on an expedited basis, discuss internally whether institutional policy would require limited IRB review by the full board under any circumstances (and if so, identify what those circumstances are). *Expedited Review*: It is anticipated that the list of available categories of expedited review will need to be revised by OHRP to reflect the revisions to the Common Rule, particularly with respect to existing Categories 8 and 9, which reflect research that will no longer be required to receive continuing review.
	□ Revise expedited review procedures to include research for which limited IRB review is conducted and to require documentation of rationale if reviewer determines research on the expedited review list is more than minimal risk. *See associated comments.*	
	□ Revise waiver process to reflect limitation when broad consent is sought and refused. Determine how refusals of broad consent will be tracked.	
	□ Revise screening and recruitment policy to reflect elimination of requirement for consent (or waiver) for these activities.	
Terms of Grant	□ Revise any relevant policies, procedures and practice to eliminate the requirement that IRB review and approve the grant application.	
Informed Consent	□ Revise specific consent template to reflect new elements and organization of consent.	*Broad Consent*: Institutions will need to develop a process for tracking any refusals of broad consent (see above related to changes to IRB SOPs regarding waiver of consent process, and proposed change to IRB Application Process below related to IRB waivers). *Secondary Research*: Note that the 2018 Common Rule is less specific than HIPAA with respect to how a broad consent to future research can or should be distinguished from a concurrent consent to an underlying specific research study. Institutions will need to determine how to coordinate these requirements to the extent the HIPAA
	□ Create new broad consent template (and potentially combined broad/specific consent template where secondary research is contemplated). *See associated comments.*	
	□ Discuss internally how the changes to informed consent interact with the institution's requirements related to HIPAA authorization in the context of secondary research. *See associated comments.*	
	□ Update investigator guidelines for informed consent (if applicable) to reflect changes and explain	

	context for use of specific vs. broad consent and how they relate to one another.	authorization remains embedded in the informed consent form. *LAR*: In states where the law does not address the authority of individuals to provide consent for a prospective subject to participate in research or in the procedures involved in the research, the 2018 Common Rule (through a revised definition of "legally authorized representative") will recognize the authority of such individuals as are specified in institutional policy.
	□ Revise policy on documentation of consent and waiver of documentation to reflect new requirements for when short form may be used and new basis for waiver of documentation.	
	□ Create policy on posting of consent forms for clinical trials to public federal website.	
	□ Create or revise policy on legally authorized representatives to include individuals acceptable for providing consent to a subject's participation in the procedures involved in the research. *See associated comments.*	
IRB Application Process	□ Revise IRB application forms to reflect new definitional carve-outs, exemption categories, and research eligible for expedited review.	
	□ Consider revising IRB consent waiver application form to seek an investigator certification that broad consent was not previously sought and refused.	
	□ Consider creating separate IRB application form for limited IRB review, targeting the information necessary to meet the required conditions.	
Single IRB	□ Ensure all current reliance arrangements with external IRBs are documented and that the respective responsibilities of the institution and the external IRB(s) are set forth in the agreement or otherwise in an institutional policy.	

	□ Develop or revise policy on cooperative research to reflect single IRB mandate and NIH Single IRB Policy.	
	□ Develop or revise IRB reliance agreement template(s).	
	□ Assess institutional reliance relationships and determine whether the number can be streamlined by participating in large network arrangements and/or "master" agreements covering multiple protocols.	
	□ Designate a local point person for coordination and tracking of reliance relationships and communication with external IRB(s).	
	□ Identify IT systems to help manage/track reliance relationships.	
	□ Develop local context information sheet and plan for coordination with external IRB(s) re: institutional issues (e.g., ancillary reviews, coordination of consent forms with sponsored research contract provisions).	
	□ Develop information sheet to gather key information about external IRB(s) or institution(s) seeking to rely on the local IRB.	
	□ Train investigators on expectations for working with external IRB(s).	
FWA	□ For institutions that have "checked the box" on their FederalWide Assurance, determine any implications of removal of option to check the box (e.g., under state laws referencing compliance with federal human subject standards).	The commentary to the 2018 Common Rule notes that voluntarily extending the Common Rule to an institution's research regardless of funding source for the research will no longer be an option. Because this is not a regulatory change, the effective date for when this option will cease to exist is currently unclear.

Secondary Research	□ Identify existing databases and repositories in which information and materials are stored for possible secondary research purposes.	*Transition Provisions*: The 2018 Common Rule is not entirely clear about how an institution might transition an existing database or repository. As a practical matter, the pre-2018 Common Rule requirements for storing and using identifiable private information or identifiable biospecimens continue to be available under the 2018 Common Rule (there is no requirement to use the new available exemptions for storage and secondary use). However, it is unclear how, logistically, institutions might bifurcate existing databases and repositories to apply voluntarily the 2018 Common Rule to storage and use going forward. See below regarding On-Going Research.
	□ Determine whether existing repositories will remain governed by the pre-2018 Common Rule, or whether a voluntary shift to compliance with the 2018 Common Rule will occur. *See associated comments.*	
On-Going Research	□ Determine which on-going research studies subject to the Common Rule will straddle the general compliance/effective date.	
	□ For each identified study, determine whether to continue to comply with the pre-2018 Common Rule, or elect to comply with the 2018 Common Rule (assuming an IRB documents the institution's determination).	
Training	□ Develop and implement mandatory training sessions for IRB members, institutional officials, and the research community (investigators, research coordinators, and other research staff) to apprise them of the significant changes in the 2018 Common Rule.	
	□ Consider making a web portal of resources and investigator guidance documents available to researchers, including an investigator-focused compliance checklist, to enlist investigators in relevant implementation steps.	