

2018 Common Rule Implementation Checklist

High Priority Action Items

The following table outlines certain actions institutions should consider taking ahead of the 2018 Common Rule’s effective and general compliance date of **January 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. If you have questions about the checklist or require assistance with your organization’s compliance planning, 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	Timing	Comments
IRB SOPs	<input type="checkbox"/> Revise definition of “research” to include new carve-outs.	Before January 19, 2018 Aim for September 2017 to allow for adequate training time.	<i>Human Subject:</i> 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.
	<input type="checkbox"/> Revise definition of “human subject.” See associated comments.		
	<input type="checkbox"/> Revise existing exemptions.		
	<input type="checkbox"/> Include new exemptions.		
	<input type="checkbox"/> Document process and conditions for limited IRB review for exemptions (d)(2), (d)(3), (d)(7), and (d)(8). See associated comments.		
	<input type="checkbox"/> Revise continuing review policy to account for new carve-outs and to require documentation of rationale if IRB will conduct continuing review when not otherwise required.		

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	<input type="checkbox"/> 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. <input type="checkbox"/> Revise waiver process to reflect limitation when broad consent is sought and refused. Determine how refusals of broad consent will be tracked. <input type="checkbox"/> Revise screening and recruitment policy to reflect elimination of requirement for consent (or waiver) for these activities.		<p><i>Limited IRB Review:</i> IRB members, particularly anyone to whom expedited review may be delegated, will need 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).</p>
Informed Consent	<input type="checkbox"/> Revise specific consent template to reflect new elements and organization of consent. <input type="checkbox"/> Create new broad consent template (and potentially combined broad/specific consent template where secondary research is contemplated). See associated comments. <input type="checkbox"/> 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.	<p>Before January 19, 2018</p> <p>Aim for September 2017 to allow for adequate training time.</p>	<p><i>Broad Consent:</i> 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).</p> <p><i>Secondary Research:</i> 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</p>

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	<input type="checkbox"/> 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. <input type="checkbox"/> 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. <input type="checkbox"/> Create policy on posting of consent forms for clinical trials to public federal website. <input type="checkbox"/> 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.		<p>concurrent consent to an underlying specific research study. Institutions will need to determine how to coordinate these requirements to the extent the HIPAA authorization remains embedded in the informed consent form.</p> <p><i>LAR:</i> 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.</p>
IRB Application Process	<input type="checkbox"/> Revise IRB application forms to reflect new definitional carve-outs, exemption categories, and research eligible for expedited review. <input type="checkbox"/> Consider revising the IRB consent waiver application form to seek an investigator certification that broad consent was not previously sought and refused. <input type="checkbox"/> Consider creating separate IRB application form for limited IRB	<p>Before January 19, 2018</p> <p>Aim for September 2017 to allow for adequate training time.</p>	

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	review, targeting the information necessary to meet the required conditions.		
Single IRB	<input type="checkbox"/> 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. <input type="checkbox"/> Develop or revise policy on cooperative research to reflect single IRB mandate and NIH Single IRB Policy. <input type="checkbox"/> Develop or revise IRB reliance agreement template(s). <input type="checkbox"/> 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. <input type="checkbox"/> Designate a local point person for coordination and tracking of reliance relationships and communication with external IRB(s). <input type="checkbox"/> Identify IT systems to help manage/track reliance relationships.	<p>Before January 20, 2020 (the Final Rule’s separate compliance date for the single IRB mandate)</p> <p>Aim to begin ASAP, as many of the same implementation steps are relevant for compliance with the NIH Single IRB Policy as well, which has a compliance date of September 25, 2017. Prioritize significant, long-term, programmatic arrangements. Address one-off arrangements next.</p>	

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	<input type="checkbox"/> 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).		
	<input type="checkbox"/> Develop information sheet to gather key information about external IRB(s) or institution(s) seeking to rely on the local IRB.		
	<input type="checkbox"/> Train investigators on expectations for working with external IRB(s).		
FWA	<input type="checkbox"/> 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).	ASAP	<p>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.</p>
Secondary Research	<input type="checkbox"/> Identify existing databases and repositories in which information and materials are stored for possible secondary research purposes.	ASAP	<p><i>Transition Provisions:</i> 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</p>
	<input type="checkbox"/> Determine whether existing repositories will remain governed by the pre-2018 Common Rule, or whether a voluntary shift to compliance with the 2018 Common		

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	Rule will occur. See associated comments.		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.
On-Going Research	<input type="checkbox"/> Determine which on-going research studies subject to the Common Rule will straddle the general compliance/effective date. <input type="checkbox"/> 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).	Before January 19, 2018 Aim for October / November 2017 to allow for adequate time for IRB review of any studies that will migrate to 2018 Rule compliance.	
Training	<input type="checkbox"/> 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.	Before January 19, 2018 Aim for October / November 2017 to build in adequate training time and time for Principal Investigators to assess on-going research.	

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	<input type="checkbox"/> 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 preparation steps ahead of the general effective / compliance date.		