

Transition Requirements

09.03.2018

- New studies approved on or after January 19, 2018, must use the new consent format (originally posted 12.20.2017).
- Existing approved consents are not required to convert to the new template. However, the IRB may require the addition of new elements during the review process.
 - See **INFORMED CONSENT** for a summary of consent form changes.
- Use new templates for new submissions as soon as the templates are released.
- Always download all forms and templates fresh from the IRB website. Stop recycling earlier versions.
- The UMMS IRB will determine on a case-by-case basis whether research approved before January 21, 2019, stays under the existing regulations or transitions to the new rules.
- The effective date of the New Rule is January 21, 2019. We refer to “Pre-2018” and “2018 Regulations” because the original effective date was January 19, 2018.
- The current goal is to transition eligible research only when it does not require Modification to the approved informed consents or study plans. In most cases, this is research that obtained informed consent, is not FDA regulated or federally funded, and has only data analysis or long-term follow-up left to complete.
- Turn the page for a summary table of when the IRB may transition existing approved research to the New Rule.

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The effective date is January 21, 2019.

	Review Category	Potential Transition Point	The IRB may transition research to the new regulations if the research:	What is the advantage of transitioning?
Approved before the effective date of the New Rule	Exempt	Modification – Any change involving HIPAA, risks, exemption category, or scope of research requires prior IRB review and approval	Fits entirely within new exemptions	There is none
	Expedited	Continuing Review (with or without Modification)	Has no additional research-related interventions or interactions	Permits three-year approval period
	Committee		Does not involve a waiver of informed consent Is not FDA-regulated Is not federally funded or supported	