

New Human Subjects Regulations

Who, What, When, Where, Why, and How

09.03.2018

WHO

All users are affected by changes the UMMS IRB is making to forms and processes to ensure compliance with the new human subjects regulations.

WHAT

The changes that will be most noticeable to users include:

- A new consent template – **originally posted 12.20.2017**
- Additional exemption categories that do not require Continuing Review (but do require Modification & Study Closure)
- Three-year approval periods for some new expedited research
- Annual reminders from eIRB of investigator obligations

Research that is FDA-regulated or funded/supported by Department of Justice will use the new consent template, but is not eligible for new exemption categories or extended approval periods.

WHEN

The effective date of the New Rule is January 21, 2019.

- We refer to “Pre-2018” and “2018 Regulations” because the original effective date of the New Rule or Revised Common Rule was January 19, 2018.
- New studies approved on or after January 19, 2018, must use the new consent template (originally posted December 20, 2017).
- Studies approved before January 19, 2018, are not required to transition to the new consent template.
- The IRB is already asking for some consent form changes during the review process.

WHERE

Users will encounter changes in:

- Forms and templates – Check <https://www.umassmed.edu/ccts/irb/> regularly for updates
- Approval letters - Look for expiration dates and set a reminder for yourself; once the New Rule is in effect, the approval letter will indicate if the research is under the Old Rule or the New Rule
- eIRB Notifications - All research will trigger an annual reminder of investigator obligations until the PI closes the research

WHY

Why does expedited research at UMMS have a three-year approval period? Don't the new regulations do away with continuing review for minimal risk research?

- The new regulations continue to hold UMMS responsible for all research that the institution conducts.
- A three-year approval period reduces burden on investigators, while allowing UMMS to maintain oversight of non-exempt research and the capability to generate reporting metrics required by accrediting bodies and funding agencies.
- In the future, UMMS may consider extending the approval period or removing expiration dates entirely for minimal risk research.

HOW

Research that is FDA-regulated or funded/supported by Department of Justice will use the new consent template, but remains subject to the existing regulations.

All other research approved on or after the effective date is subject to the New Rule.

For all other research approved before the effective date, the UMMS IRB will determine on a case-by-case basis whether the research stays under the existing regulations or transitions to the New Rule.

- Research that involves intervention or interactions with human subjects will continue under the existing regulations. It will have a one-year approval period.
- 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, the IRB may transition research that obtained informed consent, is not FDA-regulated or federally funded, and only has data analysis or long-term follow-up left to complete.