

Companion Q&As about the Revised Common Rule

Last updated: July 24, 2018

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Transition Provision

[Are studies initiated before January 21, 2019 subject to the revised Common Rule as of that date?](#)

It depends. If an institution takes no action, studies initiated before January 21, 2019 will continue to be subject to the pre-2018 Common Rule. However, if an institution takes action to transition a study or studies to the revised rule during the delay period (July 19, 2018 through January 20, 2019), those studies will then be required to comply with the revised Common Rule as of January 21, 2019.

[Refer to 45 CFR 46.101(l) of the [revised Common Rule](#).]

What type of documentation is necessary if an institution makes the determination to transition a study that was initiated before January 21, 2019 to comply with the revised Common Rule?

The institution or IRB must document and date the institution's determination to transition a study to the revised Common Rule. Beyond that requirement, the transition provision does not prescribe how institutions must document these decisions as long as the decision is dated. For example, this institutional determination could be documented in IRB meeting minutes or in an IRB reviewer checklist (if an institution uses a checklist system and maintains checklists). The determination also could be documented in an institution's existing electronic system, if it has one, or in a spreadsheet created and maintained by the institution or IRB to keep track of which studies have been transitioned to the 2018 Common Rule.

[Refer to 45 CFR 46.101(l) of the [revised Common Rule](#).]

Do institutions have to transition studies to comply with the revised Common Rule one at a time?

No. Institutions may make the voluntary determination for studies that were initiated before January 21, 2019 to comply with the revised Common Rule on a per-study basis or for a group of studies. For example, the transition provision permits an institution to determine and document that all studies at that institution initiated before January 21, 2019, will transition to comply with the revised Common Rule. Similarly, an institution is permitted by the transition provision to determine, for example, that only oral history studies will transition to comply with the revised Common Rule.

[Refer to 45 CFR 46.101(l) of the [revised Common Rule](#).]

Can my institution implement the entirety of the revised Common Rule before January 21, 2019?

No. During the delay period (July 19, 2018 through January 20, 2019) institutions are not permitted to comply with the entirety of the revised Common Rule. Studies that an institution voluntarily transitions to take advantage of the three burden-reducing provisions during the delay period must, except to the extent substituted by the burden-reducing provisions, comply with the pre-2018 Common Rule during that time. Beginning on January 21, 2019, these studies must then comply with the entirety of the revised Common Rule.

Remember that through institutional or IRB policy or discretion, aspects of the revised Common Rule that do not conflict with the pre-2018 Common Rule can be implemented at any time during the delay period. An example of a revised provision that does not conflict with the pre-2018 Common Rule is one that addresses new elements of informed consent (revised Common Rule at §46.116(b)(9), (c)(7)-(9)). It

is permissible to incorporate these new elements of consent because the pre-2018 Common Rule does not prohibit including these elements in informed consent.

[Refer to 45 CFR 46.101(l) of the [revised Common Rule](#).]

What are the three burden-reducing provisions of the revised Common Rule and how can institutions take advantage of them before January 21, 2019?

Regulated entities cannot implement all provisions of the revised Common Rule prior to the general compliance date of January 21, 2019. However, from July 19, 2018 through January 20, 2019 (i.e., the delay period), institutions can voluntarily elect early implementation of three burden-reducing provisions of the revised Common Rule. The three burden-reducing provisions of the revised Common Rule are: (1) The revised definition of “research,” which deems certain activities not to be research covered by the Common Rule; (2) the elimination of the requirement for annual continuing review with respect to certain categories of research; and (3) the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research.

If an institution wants to take advantage of these three burden-reducing provisions before January 21, 2019, the revised Common Rule requires that several steps must be taken:

- (1) The institution, through an appropriately designated official with authority to act for the institution, must determine that the research study (or a set of research studies) under consideration will transition to be conducted in accordance with the revised Common Rule as of January 21, 2019.
- (2) Either the institution or the IRB must document the transition decision (including the date of the decision), and the documentation must be retained in accordance with 45 CFR 46.115.
- (3) After the institution’s transition decision is documented and dated, the three burden-reducing provisions are available to be implemented for the transitioned research study (or set of research studies).

Studies that transition to take advantage of the burden-reducing provisions must comply with the pre-2018 Common Rule in conjunction with the three burden-reducing provisions of the 2018 Common Rule during the delay period. On and after January 21, 2019, these studies must then comply with the entirety of the revised Common Rule as applicable. Once an institution has made the voluntary election to use the three burden-reducing provisions in a specific study or group of studies, the institution cannot revert the study to comply with the pre-2018 Common Rule.

The three burden-reducing provisions only apply as a flexibility during the delay period. Studies that transition prior to January 21, 2019 (thereby taking advantage of the three burden-reducing provisions during the delay period) must, beginning on January 21, 2019, comply with the revised Common Rule.

[Refer to 45 CFR 46.101(l) of the [revised Common Rule](#).]

What are the primary considerations for an institution that plans to transition to the revised Common Rule during the delay period?

During the delay period from July 19, 2018 through January 20, 2019, the primary questions that an institution should answer before making the voluntary election to transition a study (or group of studies) to comply with the revised Common Rule are: (1) does the institution want to utilize the three burden-reducing provisions of the revised Common Rule during the delay period, and (2) are the institution's IRB operations ready for the transitioned study (or transitioned studies) to comply with the entirety of the 2018 Requirements on and after January 21, 2019. Remember: if an institution elects for a study or group of studies to use the three burden-reducing provisions during the delay period, those studies must comply with the entirety of the 2018 Requirements on and after January 21, 2019.

[Refer to 45 CFR 46.101(l) of the [revised Common Rule](#).]

Definition

Has the revised Common Rule changed the definition of research?

The revised Common Rule adds a provision that identifies four types of activities as not being “research” as defined in the Rule. In other words, the revised Common Rule does not apply to the following types of activities because they do not meet the regulatory definition of research:

- Certain scholarly and journalistic activities,
- Certain public health surveillance activities,
- Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and
- Certain authorized operational activities for national security purposes

[Please refer to 45 CFR 46.102(l) of the [revised Common Rule](#) for the full description of the excluded categories of activities. Also refer to the January 19, 2017 preamble to the revised Common Rule at 82 FR 7172 for further information regarding which types of activities fall within these four categories, and to the OHRP draft guidance available on the OHRP website.]

IRB Review

How has the requirement for continuing review changed under the revised Common Rule?

Under the revised Common Rule, continuing review is not required for:

- Research that is eligible for expedited review,
- Exempt research conditioned on limited IRB review,
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,

- Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

Importantly, the IRB can override this default and still choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision.

[Refer to 45 CFR 46.109(f), 46.110, and 46.115(a)(8) of the [revised Common Rule](#).]