The Revised Common Rule Compliance Dates and Transition Provision (45 CFR 46.101(l))

January 2019

***NOTE**: This draft guidance is consistent with the 2018 Requirements (i.e., the revised Common Rule).*

This draft guidance, when finalized, will represent the Office for Human Research Protections' (OHRP's) current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word "must" in OHRP guidance means that something is required under the Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

Office for Human Research Protections

Department of Health and Human Services

Contents

I. Introduction

A. Terms

Pre-2018 Requirements: The term "pre-2018 Requirements" refers to subpart A of 45 CFR part 46 as published in the 2016 edition of the Code of Federal Regulations. The pre-2018 Requirements were originally promulgated in 1991, and subsequently amended in 2005. The pre-2018 Requirements may also be referred to as the "pre-2018 Common Rule."

2018 Requirements: The term "2018 Requirements" refers to the Common Rule as published in the July 19, 2018 edition of the e-Code of Federal Regulations. The 2018 Requirements were originally published on January 19, 2017 and further amended on January 22, 2018 and June 19, 2018. The 2018 Requirements may also be referred to as the "revised Common Rule."

Please refer to section III.B of this document for more information about the special rules that apply from July 19, 2018 through January 20, 2019 for studies subject to the 2018 Requirements.

Transition provision: The term "transition provision" refers to 45 CFR 46.101(*l*) of the 2018 Requirements. This provision outlines which studies must comply with the pre-2018 Requirements and which studies must comply with the 2018 Requirements. It also describes how an institution can voluntarily transition a study subject to the pre-2018 Requirements (i.e., a study initiated before January 21, 2019) to be subject to the 2018 Requirements. Finally, it describes the regulatory requirements that apply during the delay period to a study that has been transitioned to utilize the three burden-reducing provisions.

During the delay period, the regulations allow transitioned studies to comply *only* with three specific provisions of the 2018 Requirements (see "three burden-reducing provisions of the 2018 Requirements" below). Other than these three specific provisions, transitioned studies must continue to comply with the pre-2018 Requirements during the delay period.

Delay period: This term refers to the time period of July 19, 2018 through January 20, 2019.

Delay period requirements: During the delay period, any study that has been transitioned must comply with the three burden-reducing provisions of the 2018 Requirements. Other than these three burden-reducing provisions, these studies must comply with the pre-2018 Requirements. On and after January 21, 2019 studies that have been transitioned to comply with the 2018 Requirements must comply with the entirety of the 2018 Requirements (except for §46.114(b) for which compliance is required on and after January 20, 2020).

Initiated: Consistent with 45 CFR 46.101(*l*) of the 2018 Requirements, references in this document to "initiated" refer to the date on which: (1) research was initially approved by an institutional review board (IRB); (2) IRB review was waived pursuant to §46.101(i); or (3) a determination was made that the research was exempt.

The regulatory requirements apply differently depending on whether the study was initiated before January 21, 2019 or on or after January 21, 2019.

Ongoing research or ongoing study: These terms refer to research that was initially approved before January 21, 2019 and that continues on or after January 21, 2019.

Three burden-reducing provisions of the 2018 Requirements: As described in the transition provision at 45 CFR 46.101(*l*)(4)(i)(A), if an institution elects during the delay period to transition a study to comply with the 2018 Requirements, beginning on the date that the transition determination is documented, through January 20, 2019, such studies must comply with the three burden-reducing provisions instead of, or in addition to, the comparable pre-2018 Requirements (specified in §46.101(*l*)(4)(i)(A)(*1*)-(*3*)). These three burden reducing-provisions are:

- The definition of research in the 2018 Requirements (§46.102(*l*)) will apply instead of the definition of research in the pre-2018 Requirements (§46.102(d))
- The revised certification requirement that eliminates IRB review of the application or proposal (§46.103(d) of the 2018 Requirements) will apply instead of the relevant certification requirements found in §46.103(f) of the pre-2018 Requirements.
- Certain exceptions to mandated continuing review in the 2018 Requirements (§46.109(f)(1)(i) and (iii)) will apply instead of the pre-2018 Common Rule's certification requirements that relate to continuing review (found in §46.103(b) of the pre-2018 Requirements) and in addition to the continuing review requirements found in the pre-2018 Requirements (§46.109(e)).

Other than the three burden-reducing provisions of the 2018 Requirements, studies that transition to comply with the 2018 Requirements must comply with the pre-2018 Requirements during the delay period.

Transition date: The date that an IRB or institution dates and documents that an institution determined that a study initiated before January 21, 2019 will comply with the 2018 Requirements instead of the pre-2018 Requirements (and, for studies with a transition date during the delay period, that the study will follow the delay period requirements during such period). This determination may be made on a per-study basis or with respect to a broader group of studies conducted at an institution.

If the institutional determination occurs prior to the documentation of that determination, the date of the documentation is the transition date.

Transitioning a study: In this document, transitioning a study refers to the process of an institution making the voluntary determination to switch a study initiated before January 21, 2019 to comply with the 2018 Requirements. In addition to the institutional determination, this process includes an institution or IRB documenting and dating the transition determination. Note that studies subject to the pre-2018 Requirements (i.e., studies initiated before January 21, 2019) may be transitioned at any time on and after July 19, 2018. During the delay period, transitioned studies may only implement the three burden-reducing provisions of the 2018 Requirements (described in more detail below).

B. Scope and Regulatory Background

This guidance document pertains to research conducted or supported by HHS and subject to 45 CFR part 46.

This guidance document discusses the regulatory implications of institutional decisions to voluntarily transition research studies initiated before January 21, 2019 to the 2018 Requirements (as described in the transition provision). This document is also responsive to recommendations and requests for clarification made by the Secretary's Advisory Committee on Human Research Protections (SACHRP) in its August 2, 2017 letter to the Secretary of Health and Human Services.[1]

In addition to discussing when and how an institution may transition a study initiated before January 21, 2019 to the 2018 Requirements, this document describes the regulatory impact that transitioning a study will have on the administration of that study. Depending on when a transition determination is made, it may be necessary, for example, for investigators to revise informed consent forms. Finally, this document discusses logistical issues, in the form of Q&As, that pertain to the transition of a study from the pre-2018 Requirements to the 2018 Requirements.

HHS recommends that institutions carefully consider the implications of transitioning a study (or set of studies) before any transition determination is made. Such an analysis could include consideration of whether there will be administrative benefit or administrative burden created by transitioning a study, and whether there might be additional protections or benefits to subjects participating in a research activity.

C. Audience

The target audience for this document includes IRBs, investigators, research administrators and other relevant institutional officials, and funding agencies that may be responsible for review or oversight of human subjects research conducted or supported by HHS, and the general public.

II. General Transition Principles

A. 2018 Requirements Apply Prospectively to Transitioned Studies

When an institution transitions studies initiated before January 21, 2019, the 2018 Requirements apply with respect to IRB actions and research-related activities that occur on or after the transition date. An IRB need not review IRB actions or research-related activities that occurred prior to the transition date in order to ascertain whether those actions or activities meet the 2018 Requirements. In other words, the 2018 Requirements apply only to future actions or activities (i.e., prospectively) beginning on or after the transition date.

[1] See Attachment A of SACHRP Recommendations Approved May 26, 2017. Available at: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-august-2-2017/index.html.

For example: Assume that a study was initiated in May 2017. Subjects have been enrolled in the study using a consent form and process that complies with the pre-2018 Requirements. The institution determines and the IRB documents in December 2019 that the study will transition to the 2018 Requirements. In this example, there is no need to seek reconsent after the transition date from already-enrolled subjects using a consent process consistent with the 2018 Requirements, just because the study transitioned to the 2018 Requirements. However, any subject enrolled in the study on or after the transition date must be enrolled using a consent form that complies with the 2018 Requirements.

B. Flexibility through Institutional Policy is Permitted without Triggering the 2018 Requirements

For studies subject to the pre-2018 Requirements, institutions may implement provisions of the 2018 Requirements that do not conflict with the pre-2018 Requirements at any time through institutional or IRB policy. Voluntarily applying provisions of the 2018 Requirements to research subject to the pre-2018 Requirements does not constitute transitioning a study. An example is a decision to implement the new elements of informed consent (2018 Requirements at §46.116(b)(9), (c)(7)-(9)). Without transitioning a study, it is permissible to incorporate these new elements of consent because the pre-2018 Requirements do not prohibit including such information in an informed consent document.

An example of a revised provision that conflicts with the pre-2018 Requirements and thus could not be implemented in studies subject to the pre-2018 Requirements is the new exemption for secondary research when broad consent has been sought and obtained (§46.104(d)(8)). Because the pre-2018 Requirements do not include this exemption, implementing this exemption for a study that is not transitioning, or before a study's transition date (and before January 21, 2019), would be considered noncompliance.

Similarly, institutions and IRBs may retain or implement institutional policies related to the pre-2018 Requirements for studies that are subject to the 2018 Requirements, as long as the policies do not conflict with the 2018 Requirements. Examples of institutional or IRB policies that could be voluntarily implemented or retained for studies subject to the 2018 Requirements include:

- Implementing a periodic administrative check-in with investigators conducting exempt and nonexempt research to verify that no changes have been made to the research activity during a specified time period;
- Implementing administrative review of protocols involved in cooperative research when a different IRB of record is used;
- Requesting a copy of the grant application from investigators (when available) and reviewing that application as part of the protocol review process.

III. Implementation of the Transition Provision

A. General Implementation Timeline for the 2018 Requirements

The transition provision of the 2018 Requirements states that studies initiated before January 21, 2019 must comply with the pre-2018 Requirements. There is one exception to this: if an institution transitions a study, special rules apply (as described below).
Studies initiated on and after January 21, 2019 must comply with the 2018 Requirements.

Rules for Transitioning Studies:

Institutions may begin to transition studies initiated before January 21, 2019 at any time on or after July 19, 2018.

During the delay period, transitioned studies must comply with the delay period requirements.

Transitioned studies must comply with the entirety of the 2018 Requirements on and after January 21, 2019 (except for the cooperative research provision at §46.114(b), for which compliance is required on and after January 20, 2020). Note that §46.114(b) is described in more detail in section III.C.

Institutions may transition studies on a per-protocol basis or with respect to a broader category of research conducted at an institution.

Institutions are not required to transition research; rather, this is a flexibility that the revised Common Rule permits. Only studies initiated before January 21, 2019 may be transitioned; studies initiated on and after January 21, 2019 are required to comply with the 2018 Requirements.

A decision to transition a study may not be reversed. For example, an institution may not transition an ongoing study and then later determine that the study will instead comply with the pre-2018 Requirements. Similarly, an institution may not transition a study during the delay period (in order to take advantage of the three burden-reducing provisions of the 2018 Requirements) and then, on or after January 21, 2019, determine that the study will comply with the pre-2018 Requirements.

To summarize:

- By default (and if no transition occurs), all studies initiated prior to January 21, 2019 are subject to the pre-2018 Requirements.
- Any research activity initiated on or after January 21, 2019 must comply with the entirety of the 2018 Requirements (except for §46.114(b), for which compliance is required on and after January 20, 2020).
- Institutions may begin to transition research to the 2018 Requirements at any time on and after July 19, 2018.
- If an institution transitions a study during the delay period, the study:
    - Must comply with the delay period requirements from the study's transition date through January 20, 2019; and
    - Must comply with the entirety of the 2018 Requirements on and after January 21, 2019.

- Once a study initiated prior to January 21, 2019 is transitioned to the 2018 Requirements, the decision cannot be reversed, and the study cannot be transitioned back to the pre-2018 Requirements.

To assist the regulated community in understanding how the transition provision works, OHRP has prepared several timelines graphically depicting the information described above. These are available on the OHRP website on the "Revised Common Rule Resources" page, in the "Education & Outreach" section.

Example 1: Study A is initiated in August 2018

- As described in the transition provision, the default is that Study A must comply with the pre-2018 Requirements.
- The institution does not elect to transition Study A to the 2018 Requirements.
- **Result:** Study A must comply with the pre-2018 Requirements for the duration of that research activity because the institution has not elected to transition it.

Example 2: Study B is initiated in August 2018

- As described in the transition provision, the default is that Study B must comply with the pre-2018 Requirements.
- In March 2020, Study B's institution transitions the study to the 2018 Requirements.
- **Result:** Beginning on Study B's transition date, the study must be conducted in compliance with the 2018 Requirements. The institution may not revert Study B back to the pre-2018 Requirements.

Example 3: Study C is initiated in August 2018

- Study C is initially approved under the pre-2018 Requirements.
- After initial approval and during the delay period, the institution transitions Study C to the 2018 Requirements.
- **Result:** Study C must comply with the delay period requirements from the date the transition determination is dated and documented through January 20, 2019.
- On January 21, 2019 Study C is ongoing.
- **Result:** Beginning on January 21, 2019, Study C must comply with the entirety of the 2018 Requirements (except for §46.114(b), with which it must comply on and after January 20, 2020).

Example 4: Proposed Study D is initially submitted to the IRB in August 2018

- In accordance with the transition provision, proposed Study D is initially submitted to the IRB in August 2018, during the delay period. The next day, the institution transitions Study D to the 2018 Requirements, the IRB dates and documents the transition decision, and Study D is determined by the IRB administrator to qualify for one of the exclusions to the definition of "research" under the 2018 Requirements.

- **Result:** As of the transition date, Study D need not comply with the pre-2018 Requirements or the 2018 Requirements.
- On January 21, 2019 Study D is ongoing.
- **Result:** Study D continues to not need to comply with the 2018 Requirements.

B. The Three Burden-Reducing Provisions of the 2018 Requirements (Only Applicable to a Transitioned Study during the Delay Period)

As previously described, institutions may transition research initiated before January 21, 2019 to the 2018 Requirements at any time on and after July 19, 2018. During the delay period (July 19, 2018 through January 20, 2019), studies that have been transitioned must comply with the delay period requirements. By way of reminder, during the delay period, transitioned studies must comply with the three burden-reducing provisions of the 2018 Requirements; other than these three burden-reducing provisions, transitioned studies must continue to comply with the pre-2018 Requirements during the delay period.

The three burden-reducing provisions of the 2018 Requirements are described below. Notes on how these requirements should be interpreted during the delay period are also described.

Provision 1: The 2018 Requirements' definition of "research" at §46.102(l)

- This provision applies instead of §46.102(d) of the pre-2018 Requirements. The definition of research in the 2018 Requirements includes a list of four activities that have been explicitly excluded from the definition of research.
- During the delay period, the reference to a "public health authority" at §46.102(*l*)(2) will be given the meaning provided in the definition of "public health authority" in the 2018 Requirements (§46.102(k)).
- *Note:* if the project is altered so that it no longer is excluded from the definition of "research," the investigator should submit the project to the appropriate office within an institution for further consideration.

Provision 2: The elimination of the requirement that the IRB review the application or proposal (revised certification requirement that eliminates IRB review of application or proposal at §46.103(d) of the 2018 Requirements)

- This provision applies instead of the relevant portion of §46.103(f) of the pre-2018 Requirements.
- The reference in §46.103(d) of the 2018 Requirements to research "exempted under §46.104" will be interpreted during the delay period to refer to research exempted under §46.101(b) of the pre-2018 Requirements.

Provision 3: The elimination of the requirement for annual continuing review of certain categories of research at §46.109(f)(1)(i) and (iii) of the 2018 Requirements, unless otherwise required by the IRB

- This provision applies instead of §46.103(b) of the pre-2018 Requirements (as related to the requirement for continuing review) and in addition to §46.109 of the pre-2018 Requirements.
- During the delay period, the reference to "[r]esearch eligible for expedited review in accordance with §46.110" in §46.109(f)(1)(i) will be interpreted to refer to §46.110 of the pre-2018 Requirements.
- During the delay period, the IRB is not required to document an IRB's rationale for conducting continuing review when such review is not otherwise required by the regulations. If an IRB conducts continuing review of a transitioned study on or after January 21, 2019 when the 2018 Requirements do not otherwise require the review, the IRB must document the rationale for such review, even when an institution transitioned a study during the delay period (see §46.115(a)(3)).

If an institution transitions a study or a group of studies to take advantage of these three burden-reducing provisions during the delay period, the revised Common Rule requires that several steps must be taken:

1. The institution must determine that the research study (or a set of studies) under consideration will transition to be conducted in accordance with the revised Common Rule. During the delay period, these studies must comply with the delay period requirements; on and after January 21, 2019, these studies must comply with the entirety of the 2018 Requirements (except for §46.114(b), for which compliance is required on and after January 20, 2020).
2. Either the institution or the IRB must document the transition decision (including the date of the decision) in accordance with §46.101(*l*)(4), and retain such documentation for at least 3 years in accordance with §46.115(b).
3. After the institution's transition decision is documented and dated, the transitioned studies will be subject to the three burden-reducing provisions.

When an institution transitions a study, all three of the burden-reducing provisions outlined in the transition provision are substituted for their corresponding provision in the pre-2018 Requirements. However, if one or more of the three burden-reducing provisions of the 2018 Requirements has no impact on the research activity, then an institution or an IRB does not have to take any additional action to comply with the provision(s).

While the three burden-reducing provisions are a regulatory package, an institution that takes advantage of this flexibility for a study or set of studies may, as a matter of institutional policy, adopt a more stringent standard (such as that of the pre-2018 Requirements) for any or all of the circumstances addressed by these three provisions. For example, if an institution chooses to adopt a policy that studies that qualify for expedited review under a certain category should continue to be subject to annual continuing review, the 2018 Requirements do not prevent the institution from adopting and implementing that policy.

On and after January 21, 2019, transitioned studies must comply with the entirety of the 2018 Requirements (except for §46.114(b), for which compliance is required on and after January 20, 2020).

OHRP has developed a number of educational resources describing how the transition provision functions during the delay period. These educational resources can be viewed by going to the "Revised Common Rule Resources" page under the "Education & Outreach" section of the OHRP website.

C. Implementation of the Cooperative Research Provision of the 2018 Requirements (45 CFR 46.114(b))

The compliance date of the cooperative research provision (§46.114(b) of the 2018 Requirements) is January 20, 2020. For studies subject to the 2018 Requirements,

- Reliance on a single IRB of record in cooperative research is optional before January 20, 2020, even for research subject to the 2018 Requirements.
- Reliance on a single IRB of record in cooperative research is required beginning January 20, 2020, unless the study meets the criteria for an exception described in §46.114(b)(2) of the 2018 Requirements.

The compliance date for the cooperative research provision (January 20, 2020) is not affected by the delay of the compliance date of other provisions of the 2018 Requirements.[2]

The requirement for the use of a single IRB in cooperative research only applies to US institutions and the portion of the collaborative research conducted within the US.

For research activities subject to the 2018 Requirements: While §46.114(b) of the 2018 Requirements has a delayed compliance date, other 2018 Requirements that are integrated with the cooperative research provision are not delayed. If an institution is conducting cooperative research subject to the 2018 Requirements and voluntarily relies on a single IRB from January 21, 2019 through January 19, 2020, that institution must document its reliance on that IRB for oversight of research. It must also document the responsibilities that each entity will undertake to ensure compliance with the requirements of the Common Rule (see §§46.103(e), 46.115(a)(9) of the 2018 Requirements).

Ongoing studies subject to the pre-2018 Requirements (i.e., where the study has not been transitioned to comply with the 2018 Requirements) are not required to use a single IRB in cooperative research on and after January 20, 2020.

IV. Questions and Answers (Q&A)

The Q&As below address specific questions IRBs, institutions, and investigators might have about the specific implications of transitioning ongoing research to the 2018 Requirements. Note that these questions address situations that might arise on and after July 19, 2018. Additional Q&As about the revised Common Rule's transition provision can be found on the OHRP website.

[2] See 83 FR 2885.

When an institution transitions a study during the delay period, that study must comply with the entirety of the 2018 Requirements on and after January 21, 2019 (except for §46.114(b), for which compliance is required on and after January 20, 2020).

A. Transition Determinations

1. Who determines that a study (or set of studies) will transition?

Section 46.101(*l*) specifies that the institution has the authority to elect whether studies initiated before January 21, 2019 will transition to comply with the 2018 Requirements. The institution has the flexibility to determine who makes these transition determinations on the institution's behalf.

2. Who can document the transition determination?

Section 46.101(*l*) specifies that the institution or the IRB can document transition determinations. The institution and the IRB have the flexibility to determine who will document these determinations on the institution's or IRB's behalf. Remember: If the institutional determination occurs prior to the documentation of that determination, the date of the documentation is the transition date.

B. IRB Review

1. Under which version of the Common Rule should a protocol amendment be evaluated?

As a general rule, protocol amendments must be reviewed and evaluated under the version of the Common Rule to which a study is subject, regardless of when the amendment is made. For example, if a study initiated before January 21, 2019 is not transitioned to the 2018 Requirements, any amendment to that study must be evaluated under the pre-2018 Requirements regardless of when the amendment is made. Thus, an amendment made in 2025 would still be evaluated under the pre-2018 Requirements.

As another example, on April 5, 2022, an institution transitions an ongoing research activity. Before April 5, 2022, any protocol amendment for this activity would be reviewed under the pre-2018 Requirements. On and after April 5, 2022 (i.e., the study's transition date), amendments would be evaluated under the 2018 Requirements.

2. An institution is considering transitioning an ongoing study to the 2018 Requirements. Under the 2018 Requirements, continuing review would not be required for this study (unless the IRB determines otherwise). How can continuing review be conducted in these circumstances?

Under §46.109(f)(1) of the 2018 Requirements, continuing review is not required in three circumstances *unless* an IRB determines otherwise (i.e., determines that continuing review will remain a requirement for such studies).

In some situations, institutions or IRBs may want to conduct continuing review even when not otherwise required by the 2018 Requirements. If an institution or IRB determines that it wants to conduct continuing review of research that is not otherwise required to undergo such review by the 2018 Requirements, there are two pathways available.

Pathway 1: Review required by institutional policy

Consistent with the principle that the Common Rule establishes a regulatory floor, an institution can implement any kind of additional review that it wants as a matter of institutional policy for research conducted at that institution. Such reviews could mirror the continuing review process described in the 2018 Requirements or could be different.

Notwithstanding institutional policy, if an IRB determines that continuing review is otherwise required, as set forth in §46.109(f)(1) of the 2018 Requirements, then continuing review must be conducted in accordance with the 2018 Requirements, including documentation of the IRB's rationale for requiring continuing review. Such continuing reviews will be subject to OHRP compliance oversight.

Pathway 2: Regulatory continuing review

If an IRB determines that continuing review is warranted for a study (even if continuing review would not otherwise be required under §46.109(f)(1) of the 2018 Requirements), continuing review will be required for the study. Such continuing reviews will be subject to OHRP compliance oversight.

The determination and documentation requirements set forth in §§46.109(f) and 46.115(a)(3) of the 2018 Requirements must also be satisfied.[3] These requirements can be satisfied as long as an IRB determines that continuing review is warranted, either on a study-specific basis or with respect to broader categories of research, and the rationale for this determination is documented. Given that the regulatory language refers to an IRB's determination, an institutional policy would not satisfy this requirement without the involvement of an IRB. However, an IRB could make a determination at a convened meeting that certain research at the institution or all research at the institution warrants continuing review and that determination could be documented in an institutional or IRB policy. The rationale for why continuing review is required should be specific to the review of a particular study or group of studies. For example, a rationale that a study is using new or novel analytical techniques is an appropriate reason for why continuing review for a particular study or group of studies would be appropriate.

3. If an IRB determined that a study was nonexempt human subjects research under the pre-2018 Requirements, may an institution transition the study to the 2018 Requirements in order to take advantage of an exclusion from the definition of research or an expanded exemption?

[3] It should be noted, however, that during the delay period, IRBs are not required to document the rationale of why the IRB determined continuing review is required when the regulations do no otherwise require such review.

Yes. The 2018 Requirements expand the categories of research eligible for exemption, and specify several categories of activities that are deemed "not human subjects research" (by excluding these categories from the definition of research). Institutions are permitted to transition research in order to take advantage of the explicit exclusion of certain categories of studies from the definition of research (beginning July 19, 2018), and the expanded exemption categories (beginning January 21, 2019).

4. Do the 2018 Requirements specify how an institution or IRB must ensure that a transitioned study complies with the 2018 Requirements on and after its transition date?

No. While an IRB does not need to revisit actions taken before a study's transition date, it must ensure that the study is complying with the appropriate requirements on and after the study's transition date. As a matter of administrative convenience, an IRB or institution could consider reviewing studies for compliance with the 2018 Requirements before a study is officially transitioned, provided that the IRB's actions taken before the study's transition date are consistent with the pre-2018 Requirements. Such actions taken before a study's transition date to ensure that a study will be conducted consistent with the 2018 Requirements need not be re-reviewed on and after a study's transition date.

C. Informed Consent

1. If a new consent is sought from already enrolled subjects in ongoing research that transitions to the 2018 Requirements, what standards must that consent meet?

All regulatory IRB actions that occur prior to an ongoing study's transition date (or prior to January 21, 2019 for studies that transition during the delay period) must comply with the pre-2018 Requirements (studies that transition during the delay period also must comply with the 3 burden-reducing provisions of the 2018 Requirements, if relevant); all actions taken on or after the date an ongoing study transitions to the 2018 Requirements (or on and after January 21, 2019 for studies that transition during the delay period) must comply with all of the 2018 Requirements. Informed consent used in subject enrollment after the transition date (or on and after January 21, 2019 for studies that transition during the delay period) must comply with the 2018 Requirements. At the time of transition (or January 21, 2019, for studies transitioned during the delay period), there is no need to automatically seek a new consent from subjects who have already provided informed consent.

However, if after a study's transition date (or on and after January 21, 2019 for studies that transition during the delay period), the IRB approves a new or amended informed consent (either based on an IRB determination that this is required by the regulations or is an advisable action), such a new or amended consent form must comply with the 2018 Requirements (e.g., must incorporate any §46.116 provision of the 2018 Requirements that was not included in the original consent).[4]

[4] The 2018 Requirements for informed consent differ from the pre-2018 Requirements in several key ways. Differences include several clarifications about the role of the legally authorized representative in informed consent, new requirements for how information in the informed consent should be presented to prospective subjects (45 CFR

Example: Study D is a non-exempt human subject research activity initiated by an IRB in May 2015. Study D begins enrolling subjects in May 2016. The informed consent complies with the pre-2018 Requirements, and does not include a key information section, nor the other new elements of consent required under the 2018 Requirements. On August 6, 2018, while recruitment and enrollment in Study D is continuing, the institution transitions the study.

From August 6, 2018 through January 20, 2019, Study D's consent form is not required to include a key information section or the other new elements of consent set forth under the 2018 Requirements, because, during the delay period, compliance is not yet required for the 2018 Requirements' additional informed consent provisions. However, any subject enrolled in Study D on or after January 21, 2019 must be enrolled using an informed consent process and document that complies with the 2018 Requirements. There generally will be no need to obtain re-consent from subjects who were enrolled prior to that date merely because the compliance date has passed.

In July 2020, an IRB determines that, as an advisable action, a new consent will be sought from all subjects enrolled in Study D. Because this IRB action will occur after the date on which the study must comply with the entirety of the 2018 Requirements, this revised informed consent must comply with the 2018 Requirements (including any §46.116 provision that was not reflected in the original consent).

2. An institution is considering transitioning a study in which subject enrollment will continue after the transition date. If an IRB determines prior to that study's transition date that an informed consent form complies with the 2018 Requirements, does the consent form need to be re-reviewed by the IRB after the study transitions?

As long as the IRB records include documentation that an IRB has determined (in accordance with §46.111(a)(4) and (5)) that the study's informed consent satisfies the 2018 Requirements, the IRB or institution need not take additional steps to verify that an informed consent form complies with the 2018 Requirements on or after the study's transition date (or January 21, 2019 for studies that transition during the delay period).

An IRB is not required to assess informed consent for compliance with the 2018 Requirements prior to January 21, 2019; as a matter of administrative convenience, an investigator may choose to request an IRB to conduct such review so that a study's transition to compliance with all of the 2018 Requirements on January 21, 2019 may be streamlined.

As an example of a process that would be permissible, assume that a study is subject to the pre-2018 Requirements and uses an IRB-approved consent form consistent with the pre-2018 Requirements that does not include any new elements of consent introduced in the 2018 Requirements. In the month before the institution transitions the study, staff work with the study's investigator to amend the consent form to include the elements of informed consent that

46.116(a)(4)-(5)), and several new required elements of consent (45 CFR 46.116(b)(9), (c)(7)-(9)). An IRB generally can waive the requirement to obtain informed consent under 45 CFR 46.116(a), (b), and (c) or alter the requirements of 45 CFR 46.116(b) and (c) by making the determinations required by 45 CFR 46.116(e)(3) or (f)(3)).

are new to the revised Common Rule. The IRB reviews and approves the modifications to the consent form, and documents in the IRB minutes (if reviewed by the convened IRB) that the modified consent form complies with both the pre-2018 and the 2018 Requirements. On the study's transition date, there is no need for the IRB to re-review the consent form to ensure that it complies with the 2018 Requirements.

3. A study initiated before January 21, 2019 was approved using the waiver of informed consent criteria found in the pre-2018 Requirements. If an institution transitions that study, is the new waiver of informed consent criterion in the 2018 Requirements applicable to that study?

It depends. The 2018 Requirements include a new criterion for waiver of informed consent: if the research involves using identifiable private information or identifiable biospecimens, the IRB must determine that the research could not practicably be carried out without using such information or biospecimens in an identifiable form (§46.116(f)(3)(iii)). While a study must comply with the 2018 Requirements on and after its transition date an IRB does not need to review actions that occurred prior to a study's transition date (or January 21, 2019 for studies that transitioned during the delay period) for compliance with the revised Common Rule.

Thus, the 2018 Requirements' new waiver criterion is only relevant if subjects are still being enrolled in the study on and after the study's transition date (or on and after January 21, 2019 for studies that transition during the delay period). If all subjects have been enrolled in a study before the study's transition date (or before January 21, 2019 for studies that transition during the delay period), then the new waiver criterion at §46.116(f)(3)(iii) is not relevant because this element of waiver did not apply at the time that subjects were enrolled. If subject enrollment is ongoing on or after the study's transition date (or on or after January 21, 2019 for studies that transition during the delay period), an IRB must ensure that such enrollment complies with all of the waiver criteria outlined in the 2018 Requirements (including §46.116(f)(3)(iii)).

This will mean that, before these new subjects are enrolled, the IRB must review and approve the study in light of the 2018 Requirements' waiver of informed consent criteria, in order to make the determination that the research could not be practicably carried out without using the identifiable information or identifiable biospecimens. In order to streamline the study's transition to compliance with the 2018 Requirements, the IRB could have made such a determination during a review conducted prior to the study's transition date (or before January 21, 2019, for studies that transition during the delay period).

4. An institution transitions an ongoing study to comply with the 2018 Requirements and the study's investigator modifies the consent form to be consistent with the 2018 Requirements. May an IRB review the study's revised consent form using the expedited review procedure to verify that the consent form is in compliance with the 2018 Requirements?

IRBs may consider whether modifying the consent form to satisfy the 2018 Requirements represents a minor change to the research. If such a determination is made, the IRB may use the

expedited review procedure to evaluate the consent form changes, as permitted under §46.110(b)(1)(ii).