

Companion Q&As about the Revised Common Rule

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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](#).]

Could 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?

Regulated entities could not 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 could voluntarily elect early implementation of three burden-reducing provisions of the revised Common Rule. The three burden-reducing provisions of the revised Common Rule were: (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 wanted 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).

Prior to January 21, 2019, studies that transitioned to take advantage of the burden-reducing provisions must have complied with the pre-2018 Common Rule in conjunction with the three burden-reducing provisions of the 2018 Common Rule. 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 applied as a flexibility during the delay period. Studies that transitioned 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](#).]

***[NEW!]** What is the general compliance date of the revised Common Rule and what does it mean?*

The general compliance date of the 2018 Common Rule remains January 21, 2019. This means that HHS-conducted or supported research initiated on or after January 21, 2019 will need to comply with the revised Common Rule. The term “initiated” refers 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.

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

[NEW!] If an IRB discussed a study before January 21, 2019, but did not approve the study until after January 21, 2019, may that study be conducted under the pre-2018 Common Rule?

No. If an IRB discussed a study before January 21, 2019, but did not approve the study (either as submitted without any conditions, or with conditions, as described in OHRP's "[Approval of Research with Conditions](#)" [guidance document](#)) before January 21, 2019, then the study is subject to the revised Common Rule once approved.

For example, a study is discussed at an IRB meeting on January 5, 2019. The IRB decides to table the study at the January 5, 2019 meeting, and the IRB subsequently approves the study at an IRB meeting on January 24, 2019. Because the IRB did not approve the study before January 21, 2019, this study is subject to the revised Common Rule once approved.

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

[NEW!] If an IRB approves a study with conditions before January 21, 2019, but verification that the conditions are satisfied occurs after January 21, 2019, is that study subject to the pre-2018 Common Rule?

As per OHRP's guidance on "[Approval of Research with Conditions](#)," the date the IRB approves the research with conditions is the date of IRB approval. The effective date of the IRB's approval is the date that it is verified that the investigator has satisfied all conditions related to the approval. This is also the date on which the research may actually begin. The IRB is not required to verify that the conditions are satisfied; this verification may be completed by anyone who has been designated by the IRB to do so.

For the purposes of determining whether a study is subject to the pre-2018 Common Rule or the 2018 Common Rule, the date that the IRB voted to conditionally approve the study is the date that should be used. Thus, if the date of the IRB's conditional approval is before January 21, 2019 (even if the IRB chair or the person designated by the IRB determined that the conditions are satisfied later), the study is subject to the pre-2018 Common Rule. (Please note the special circumstances involved if the study transitions from the pre-2018 Common Rule to the 2018 Common Rule, discussed below).

For example, assume that a study is approved with conditions on January 15, 2019. Verification that all conditions have been satisfied occurs on February 1, 2019. This study would be subject to the pre-2018 Common Rule because the date of conditional approval is before January 21, 2019.

The transition provision permits an institution to determine and document that studies subject to the pre-2018 Common Rule (i.e., studies initially approved before January 21, 2019) will instead comply with the 2018 Common Rule. Such a determination would need to be made by the institution, and documented and dated by either the institution or the IRB.

[Refer to OHRP’s guidance on “[Approval of Research with Conditions](#)” and 45 CFR 46.101(l) of the [revised Common Rule](#).]

Definitions

Has the revised Common Rule changed the definition of research?

The revised Common Rule added 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.]

Has the revised Common Rule changed the definition of human subject?

The regulatory definition of human subject remains substantively unchanged in the revised Common Rule. The definition has not been expanded. However, there have been clarifications to the wording that make explicit OHRP’s current interpretation of the definition included in the pre-2018 Common Rule. The pre-2018 Common Rule referred to “data” obtained by an investigator through intervention or interaction with the individual, but in the revised Common Rule “data” is replaced with “information or biospecimens” for clarity. In addition, language has been added related to “using, studying, or analyzing individuals’ information or biospecimens or generating identifiable private information or identifiable biospecimens” to clarify OHRP’s understanding of the meaning of “obtaining” in the pre-2018 Common Rule’s definition of human subjects. The definition also now specifies what is meant by an identifiable biospecimen, and includes a requirement for Common Rule departments and agencies to reexamine the meaning of “identifiable private information” and “identifiable biospecimen”. In addition, the revised definition includes a provision requiring the Common Rule departments and agencies to assess whether there are analytic technologies that should be considered by investigators to generate “identifiable private information.”

[Refer to 45 CFR 46.102(e) of the [revised Common Rule](#).]

Assurance Process

[NEW!] Does my institution need to revise its FWA because of the revised Common Rule?

No. At this time, the assurance process remains unchanged. The public will have a chance to comment on any proposed changes to the assurance process before they are implemented.

[Refer to 45 CFR 46.103 of the [revised Common Rule](#).]

Exemptions

How has Exemption 1 for research involving educational practices changed with the revised Common Rule?

Exemption 1 applies to research in established or commonly accepted educational settings that involves certain normal educational practices, such as research on instructional techniques already in use or classroom management. The 2018 revisions to the Common Rule have added a new restriction to the applicability of Exemption 1: the research must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.

[Refer to 45 CFR 46.104(d)(1) of the [revised Common Rule](#).]

How has Exemption 2 for research involving educational tests, surveys, interviews or observation of public behavior changed with the revised Common Rule?

There have been three primary changes to Exemption 2 in the revised Common Rule. First, the word "only" has been added to clarify that Exemption 2 applies to research that "**only** includes interactions" involving educational tests, surveys, interviews, and observation of public behavior. This clarification is consistent with OHRP's understanding of Exemption 2 in the pre-2018 rule: Exemption 2 applies to research that only involves the types of interactions listed in the exemption category. Exemption 2 is not applicable to research involving interventions.

The second main change to Exemption 2 is that a new limitation has been added to one of the applicability criteria. Prior to the 2018 revisions, Exemption 2 used to apply if (1) the information collected was recorded in a non-identifiable manner, or (2) disclosure of the subjects' responses outside the research would not reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. The revised Common Rule has retained these two applicability criteria, with an addition to the second criterion requiring that the disclosure of the subjects' responses outside the research would not reasonably be damaging to the subjects' "educational advancement."

The third main change to Exemption 2 is that it has been expanded, so that now more research can qualify for the exemption than under the pre-2018 Common Rule. Exemption 2, prior to the 2018 revisions, used to apply where the information collected was recorded in a non-identifiable manner, or where disclosure of the subjects' responses outside the research would not reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. The revised Common Rule includes another opportunity for studies to qualify for Exemption 2: where identifiable information (even if sensitive) is recorded, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

[Refer to 45 CFR 46.104(d)(2) of the [revised Common Rule](#).]

What has happened to Exemption 3 from the pre-2018 Common Rule?

The pre-2018 Exemption 3 applies to research involving educational tests, surveys, interviews, or observations of public behavior that are not exempt under Exemption 2, if the subjects are elected or appointed public officials or candidates for public office, or if there is a federal statute that, without exception, protects the confidentiality of personally identifiable information collected, throughout the research and thereafter. The 2018 changes to the Common Rule made this exemption largely unnecessary.

First, the pre-2018 Exemption 3 was often applied to activities that focused on investigating one or more specific elected or appointed public officials. The revised Common Rule explicitly clarifies that historical and journalistic activities that focus on one person do not meet the regulatory definition of research.

Second, the pre-2018 Exemption 3 applies to research that was not exempt under Exemption 2. In contrast, the revised Common Rule has expanded Exemption 2 to cover the collection of identifiable information, even if sensitive, provided that a limited IRB review determines that there are adequate privacy and confidentiality protections in the study. This expansion leaves very little research that is covered under Exemption 3 in the pre-2018 rule, which would not be covered by Exemption 2 under the 2018 rule.

The previous exemption 3 has been replaced by a new exemption applicable to certain research involving benign behavioral interventions.

[Refer to 45 CFR 46.104(d)(3) of the [revised Common Rule](#).]

What type of research is covered by the new Exemption 3 in the revised Common Rule?

The new Exemption 3 applies to research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings. The criteria for when Exemption 3 applies to such research is the same as for Exemption 2, in summary: (1) the information recorded cannot be

readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subjects; or (2) any disclosure of this information would not place the subjects at risk of certain harms, or (3) the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that , when appropriate, there are adequate privacy and confidentiality protections in the study.

The new Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research. Additionally, it applies only to research with adults; it is not applicable to research with children.

[Refer to 45 CFR 46.104(d)(3) of the [revised Common Rule](#).]

What does it mean for an intervention to be a "benign behavioral intervention"?

A benign behavioral intervention must be brief in duration (although data collection may take longer). Also, the intervention must be harmless, painless, and not physically invasive. Further, the intervention must not be likely to have a significant adverse lasting impact on subjects. The investigator must have no reason to believe that the intervention will be offensive or embarrassing to subjects, and should take into consideration the subjects' population, the context of the research, the topic, and other characteristics of the study.

[Refer to 45 CFR 46.104(d)(3) of the [revised Common Rule](#).]

How has Exemption 4 for secondary research changed with the revised Common Rule?

Exemption 4 applies to the secondary research use of identifiable private information or identifiable biospecimens. One change in the revised Common Rule is that the private information and biospecimens no longer have to be in existence prior to the start of the research. Under the revised rule, for example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future could qualify for this exemption if it meets at least one of the applicability provisions.

Another change is that if an investigator records information about individuals in a nonidentifiable manner, the investigator must not attempt to re-identify or contact the research subjects.

Also, some new provisions have been added to Exemption 4 so that more research can be exempt. In the pre-2018 Common Rule, there are two provisions for when Exemption 4 can be used: (1) when the identifiable materials are publicly available, or (2) when the information is recorded by the investigator in a nonidentifiable manner. The revised Common Rule retains these two provisions, and it also adds two new ones:

- When the investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health." Note that HIPAA does not

apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).

- When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for nonresearch purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

[Refer to 45 CFR 46.104(d)(4) of the [revised Common Rule](#).]

How has Exemption 5 for research involving public benefit or service programs changed with the revised Common Rule?

Exemption 5 has been expanded to cover more research than it does under the pre-2018 Common Rule. In the pre-2018 Common Rule, Exemption 5 applies to research that is designed to study, evaluate, improve, or otherwise examine public benefit or public service programs, if the research is conducted by a federal department or agency. This has been expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). There is also a new requirement for the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.

[Refer to 45 CFR 46.104(d)(5) of the [revised Common Rule](#).]

Has Exemption 6 for research involving taste and food quality evaluation, and consumer acceptance studies changed with the revised Common Rule?

No. The revised Common Rule made no changes to Exemption 6.

[Refer to 45 CFR 46.104(d)(6) of the [revised Common Rule](#).]

What type of research is covered by the new Exemption 7?

Exemption 7 is a new exemption in the revised Common Rule that covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for nonresearch purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

[Refer to 45 CFR 46.104(d)(7), 46.111(a)(8), and 46.116(d) of the [revised Common Rule](#).]

What are the criteria for limited IRB review for Exemption 7?

The use of exemption 7 in the revised Common Rule requires the IRB to conduct a limited review of specific requirements that pertain to the use of the exemption. The IRB is not asked to conduct a

standard IRB review using all the criteria at 46.111. For Exemption 7, the IRB review is limited to the determinations described in 46.111(a)(8), which pertain to protections for privacy and confidentiality and broad consent.

[Refer to sections 45 CFR 46.104(d)(7), 111(a)(8), and 116(d) of the [revised Common Rule](#).]

What type of research is covered by the new Exemption 8?

Exemption 8 is a new exemption in the revised Common Rule that covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for nonresearch purposes or for research other than the current proposal. There are four requirements that must be satisfied to use exemption 8: broad consent must be obtained from the subjects for the secondary research use of their identifiable materials, documentation or waiver of documentation of informed consent must be obtained, an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and investigators cannot include the return of individual research results to subjects in the study plan. Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.

[Refer to sections 45 CFR 46.104(d)(8), 111(a)(7) and 46.116(d) of the [revised Common Rule](#).]

What are the criteria for limited IRB review for Exemption 8?

The use of Exemption 8 in the revised Common Rule requires the IRB to conduct a limited review of specific requirements that pertain to the use of the exemption. The IRB is not asked to conduct a standard IRB review using all the criteria at 46.111. For Exemption 8, the IRB conducts a limited review to determine whether the following criteria are met:

- There are adequate privacy and confidentiality protections as required under 46.111(a)(7), and
- The research to be conducted is within the scope of the broad consent.

[Refer to sections 46.104(d)(8) and 46.111(a)(7) of the [revised Common Rule](#).]

If a secondary research study does not qualify for any exemption, what options are available under the revised Common Rule for conducting secondary research with identifiable private information or identifiable biospecimens?

If a secondary research study that involves human subjects does not qualify for any exemption, the study must comply with the criteria for IRB approval of research at 45 CFR 46.111 (which includes the requirement for seeking the informed consent from every prospective subject or legally authorized representative, unless informed consent is waived by the IRB).

Under the revised Common Rule, there are three options to conduct a secondary research study that involves human subjects and that does not qualify for an exemption:

1. Apply for and obtain a *waiver of the requirement for informed consent* from the IRB; or
2. Seek and obtain the *study-specific informed consent* of each potential subject or legally authorized representative for the study in question; or
3. Seek and obtain the *broad consent* of each potential subject or legally authorized representative for the study in question

Note that this third option, broad consent, is a new option added in the revised Common Rule. Each option has its own applicability requirements and implications.

[Refer to 45 CFR 46.111 and 46.116 of the [revised Common Rule](#).]

[NEW!] A study subject to the revised Common Rule meets the criteria for one of the new exemption categories. It is also eligible to be reviewed through the expedited review procedure. May the study be considered exempt?

Yes. For an activity to be considered exempt, the activity must comply with the requirements specified in one or more exemption categories. Even if the study could be reviewed through the expedited review procedure, if it meets one or more of the exemption categories, the study may be considered exempt.

[Refer to 45 CFR 46.104(a) of the [revised Common Rule](#).]

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](#).]

What is limited IRB review?

Limited IRB review is a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria in §46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

[Refer to sections 45 CFR 46.109(a) and 46.109(f)(1)(ii) of the [revised Common Rule](#).]

What types of limited IRB review are described in the revised Common Rule, and which exemptions require it?

There are four exemptions that may require limited IRB review: Exemptions 2, 3, 7, and 8.

- Exemption 2 is for research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior if at least one of the three provisions included in this exemption is met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. For this provision of Exemption 2, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
- Exemption 3 is for research involving benign behavioral interventions in conjunction with specified data collection methods if the criteria listed in one of three possible provisions are met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. For this provision of Exemption 3, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
- Exemption 7 is for the storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use, for which broad consent is required. This exemption requires limited IRB review to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained.
- Exemption 8 is for secondary research involving identifiable private information or identifiable biospecimens, for which broad consent is required. This exemption requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of

subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

[Refer to sections 45 CFR 46.104(d)(2)(iii), 46.104(d)(3)(i)(C), 46.104(d)(7), and 46.104(d)(8)(iii) of the [revised Common Rule](#).]

Who may conduct limited IRB review?

The limited IRB review process may be done either via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair, or by the convened IRB.

[Refer to sections 45 CFR 46.109(a), 46.110(b)(1)(iii), and 46.110(b)(2) of the [revised Common Rule](#).]

Do studies for which limited IRB review is required also require continuing review?

No, studies for which limited IRB review is required in order to meet an exemption do not require continuing review.

[Refer to sections 46.109(f)(1)(ii) of the [revised Common Rule](#).]

***[NEW!]** Must an IRB continue to monitor a non-exempt study for which continuing review is no longer required?*

Yes. An IRB is required to ensure prompt reporting to the IRB of proposed changes in a research activity, and to ensure that investigators conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subjects. This requirement still exists even when continuing review is not required under the revised Common Rule. IRBs also have the authority to observe or have a third party observe the consent process and the research for the life of any nonexempt research study.

[Refer to 45 CFR 46.108(a)(3)(iii) and 46.109(g) of the [revised Common Rule](#).]

***[NEW!]** After January 21, 2019 (the general compliance date for the revised Common Rule), is the 1998 Expedited Review List still in effect for studies subject to the revised Common Rule?*

Yes. Until HHS finalizes a revised expedited review list, the [1998 Expedited Review List](#) (63 FR 60364) is still in effect for research subject to the revised Common Rule. This means that until a new list is finalized, the entire 1998 list, including the “Applicability” section, remains in effect for studies subject to the revised Common Rule. Under the 1998 List, in order for research to qualify for expedited review, a determination must still be made that the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

HHS must publish any proposed revision to the expedited review list in the *Federal Register* and solicit public comment on the proposal before a revised expedited review list can be finalized.

[Refer to 45 CFR 46.110 of the [revised Common Rule](#).]

Broad Consent in the Revised Common Rule

What is broad consent?

Broad consent is a new type of informed consent provided under the revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for nonresearch purposes, such as materials that are left over from routine clinical diagnosis or treatments. Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.

[Refer to 45 CFR 46.116(d) of the [revised Common Rule](#).]

Is broad consent required?

There is no requirement to use broad consent. Other options for doing secondary research remain, such as conducting secondary research with nonidentifiable private information and nonidentifiable biospecimens without IRB review, since this is not human subjects research. Sometimes, secondary research is exempt from the requirements of the Common Rule. In fact, some exemptions have been expanded in the revised Common Rule to make them apply to a wider range of activities. For example, Exemption 4 has two new provisions under the revised Common Rule that may be applicable to secondary research. For many researchers, using the options that are available under the pre-2018 Common Rule, and that continue to be available in the revised Common Rule, may be preferable to using broad consent for future secondary research use.

[Refer to 45 CFR 46.116(d) of the [revised Common Rule](#).]

Does broad consent have to comply with all the usual elements of consent?

Not all the required elements for standard informed consent are included in broad consent. Under the revised Common Rule, broad consent includes some of the basic elements of informed consent that are required in the standard informed consent (and outlined in 45 CFR 46.116(b) of the revised Common Rule). These include disclosing: reasonably foreseeable risks; reasonably expected benefits to subjects or others; confidentiality safeguards; and that participation is voluntary and may be discontinued without penalty.

There are also additional elements of informed consent (outlined in 45 CFR 46.116(c) of the revised Common Rule) that are included in the broad consent. These are: when appropriate, a statement about commercial profit and whether subjects will or will not share in it; as well as, when appropriate, whether research might include whole genome sequencing. The basic and additional elements of informed consent that are required in broad consent are outlined in 45 CFR 46.116(d)(1) of the revised Common Rule.

Broad consent is also required to comply with most of the general elements of informed consent outlined 45 CFR 46.116(a). These include: obtaining informed consent before involving a human subject in a research activity; only seeking informed consent under circumstances that provide the prospective subject sufficient opportunity to discuss and consider whether or not to participate; providing information to potential subjects in a way that is understandable to the subject; providing prospective subjects with all of the information that a reasonable person would want to have in order to make an informed decision about participation; and not including certain types of exculpatory language in informed consent.

In addition to the elements described above, there are elements unique to broad consent found in 45 CFR 46.116(d)(2)-(7). For example, there needs to be a general description of the types of research that may be done, with sufficient information that a reasonable person would expect the broad consent would permit the types of research conducted. There also needs to be a description of the identifiable private information or identifiable biospecimens that might be used, whether they might be shared, and which types of institutions or researchers may use the information or biospecimens for research. There needs to be a description of the period of time the materials may be stored, maintained, or used. As applicable, broad consent also needs to include a statement that subjects will not be informed about specific studies and that they might have chosen not to consent to some of these studies. As applicable, broad consent needs to include a statement that clinically relevant research results might not be disclosed to the subject. Finally, broad consent needs to include an explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research related harm.

Notice that if broad consent is requested, all of the elements that are described for broad consent under section 116(d) in the revised Common Rule must be included. None of the elements can be altered or omitted.

[Refer to sections 45 CFR 46.116(a)-(d), 46.116(e)(2), and 46.116(f)(2) of the [revised Common Rule](#).]

Can an investigator ask subjects for broad consent for future research at the time of obtaining standard consent for a present study?

Yes, broad consent for secondary use may be obtained when standard informed consent is obtained for the original or initial primary research when investigators are interacting or intervening with subjects, for example, for a clinical trial. Investigators who anticipate that they or others may want to use

information or biospecimens collected through the primary research for unspecified secondary research may consider also obtaining broad consent from the subjects for the secondary use of their identifiable materials at the time of the primary research.

[Refer to sections 45 CFR 46.116(d) of the [revised Common Rule](#).]

Can the IRB waive informed consent after broad consent was refused?

If an individual was asked and refused to provide broad consent, the IRB cannot waive informed consent to the use of the subject's identifiable private information or identifiable biospecimens in a secondary study. Of note is that the use of the individual's materials in a nonidentifiable manner in secondary research continues to be permissible. This is not human subjects research and falls outside the scope of both the pre-2018 and the revised Common Rule.

[Refer to sections 45 CFR 46.116(e)-(f) of the [revised Common Rule](#).]

Informed Consent

What are the changes to the general requirements for informed consent under the revised Common Rule?

There are several major changes to the general requirements for informed consent in the revised Common Rule. The intent of these changes is to promote prospective subjects' autonomy. Informed consent serves several purposes, but an important one is letting people make their own decisions about what they really want and what best serves their interests. To do this, they need to have the necessary information conveyed in an appropriate way.

One of the new standards is that the consent form, and the consent process, should provide subjects with the information needed to make an informed decision about whether to participate. One change is introducing the requirement that informed consent must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision about whether to participate. Using this standard, informed consent remains focused on what information a reasonable person would want to have to make an informed choice about participation.

An additional change is that the information needs to be presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate.

Moreover, the informed consent should not merely be a list of isolated facts. Many consent forms are not as good as they could be in terms of aiding decision-making. The goal is to help people process the complicated information they're being given and make it easier for them to make a more informed decision.

There is also a new requirement that key information about the study must be provided at the beginning. Because consent forms can be very long, sometimes 25-30 pages, the aim is to put the really important information up front. This will likely include information about the purpose, the risks, the benefits, and alternatives, and it will explain to the person how to think about these pieces of information in terms of making a decision. It should be presented in a concise and focused manner. That way people will at least have what's most important right at the beginning. As with the other changes, the goal of this is to help participants think about why they might or might not want to participate in a study and make a decision that reflects their interests. Of note is that if information included in the key information section also satisfies the elements of informed consent under §46.116(b) and (c), this information need not be repeated later in the body of the informed consent.

[Refer to 45 CFR 46.116(a) of the [revised Common Rule](#).]

Are there changes to the basic elements of informed consent in the revised Common Rule?

There is one new element that has been added to the basic elements of informed consent at §116(b). This new element requires a notice about whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future. The purpose of this is to increase transparency by letting participants know that it might happen. If potential participants find it objectionable, they may not want to participate in the study.

Consent forms will need to say either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not happen. Note that this is only about future research use of information and biospecimens that will be stripped of identifiers. Consent for the future use of identifiable private information and identifiable biospecimens for future unspecified research is covered under the section for "broad consent," or could also occur under conditions where an IRB determines that a waiver of informed consent is appropriate.

[Refer to 45 CFR 46.116(b)(9) of the [revised Common Rule](#).]

Are there changes to the additional elements of informed consent in the revised Common Rule?

There are three new additional elements of informed consent at section 116(c). Note that these are additional elements; they may not be relevant to all studies, in which case, they wouldn't need to be included. These new additional elements are all notices. One is a notice about possible commercial profit, the second is a notice about whether clinically relevant research results will be returned to the subjects, and the third is a notice about whether research activities will or might include whole genome sequencing.

[Refer to 45 CFR 46.116(c)(7), (8) and (9) of the [revised Common Rule](#).]

Are there changes to the conditions for waiving informed consent by the IRB in the revised Common Rule?

There is a change regarding the waiver and alteration of informed consent in the revised Common Rule. There is one new waiver criterion, which applies to research with identifiable private information or identifiable biospecimens. This new criterion is that the IRB must determine that the research could not practicably be carried out without using the information or biospecimens in an identifiable form. The purpose of this additional criterion is that if the research could be done using non-identifiable information, then that is what should be done. In these cases, researchers shouldn't be using identifiable information because it increases the risk of breaches of privacy or confidentiality.

[Refer to 45 CFR 46.116(e) and 45 CFR 46.116(f) of the [revised Common Rule](#).]

What are the new flexibilities to the requirement for informed consent for screening, recruiting, or determining eligibility under the revised Common Rule?

Under the revised Common Rule, an IRB may approve a proposal for the investigator to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent. In other words, the revised Common Rule removes the pre-2018 Common Rule requirement for an IRB to approve a waiver of informed consent for these types of activities. This is applicable if (1) the information is obtained through oral or written communication with the subject or the subject's legally authorized representative, or (2) identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens.

[Refer to 45 CFR 46.116(g) of the [revised Common Rule](#).]

Are there changes to the requirements for documenting informed consent in the revised Common Rule?

There is a change regarding documentation of consent, which refers to obtaining someone's signature before they can participate in a study. This change is an expansion of the waiver of the signature requirement. In addition to waiver criteria that existed in the pre-2018 Requirements, an IRB may waive the requirement for a signed informed consent form if the subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research involves no more than minimal risk, and there is an alternative method for documenting that consent was obtained. Note that there are other requirements in the pre-2018 Common Rule about when the signature requirement can be waived, and those continue in the revised Common Rule. Also note that this waiver of documentation can be applied to broad consent.

[Refer to 45 CFR 46.117(c)(1)(iii) of the [revised Common Rule](#).]

What changes did the revised Common Rule make to the definition of legally authorized representative?

The definition of legally authorized representative has been changed to address jurisdictions in which there is no applicable law for allowing a legally authorized representative to provide consent on behalf of a prospective research subject. Under the revised Common Rule, in these jurisdictions, an individual who is recognized by institutional policy as acceptable for providing consent in the nonresearch context to the procedures involved in the research will be considered a legally authorized representative for the purposes of research.

[Refer to 45 CFR 46.102(i) the [revised Common Rule](#).]

What consent form must be posted?

This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. Under the revised Common Rule, the term “clinical trial” refers to research studies in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes. For such studies, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Federal departments or agencies may permit or require redactions as appropriate. The purpose of this requirement is to be more transparent about the consent forms being used and, over time, improve the quality of consent forms.

[Refer to sections 46.102(b) and 46.116(h) of the [revised Common Rule](#).]

Does the posted informed consent have to be reposted after every change to the form?

No. Only one IRB-approved version of a consent form that has been used in the course of the study to enroll participants needs to be posted on a public Federal website designated for posting such consent forms.

[Refer to 45 CFR 46.116(h) of the [revised Common Rule](#).]

Are social, behavioral, and educational (SBER) research studies also required to post an informed consent form?

The provision for posting informed consent forms applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. The revised Common Rule defines clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions ... to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” SBER research studies that are conducted or supported by a Common Rule department or

agency *and* that fit the definition of clinical trial as stated in 45 CFR 46.102(b) of the revised Common Rule must also comply with the posting requirement.

[Refer to sections 46.102(b) and 46.116(h) of the [revised Common Rule](#).]

[NEW!] Where should consent forms subject to the revised Common Rule's posting requirement be posted?

The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form must be posted on a publicly available federal website within a specific time frame. The consent form must have been used to enroll subjects in order to satisfy this new provision.

At this time, two publicly available federal websites have been identified that satisfy the revised Common Rule's consent form posting requirement: ClinicalTrials.gov and a specified [docket folder on Regulations.gov \(Docket ID: HHS-OPHS-2018-0021\)](#).

The awardee or the Federal department or agency component conducting the trial may choose whether to post the consent form on ClinicalTrials.gov or the designated [docket folder on Regulations.gov \(Docket ID: HHS-OPHS-2018-0021\)](#).

HHS and other Common Rule departments and agencies are developing instructions and other materials providing more information to the regulated community about this posting requirement.

[Refer to 45 CFR 46.116(h) of the [revised Common Rule](#).]

HHS Subparts

How do the updates to the Common Rule affect the HHS subparts?

Only the Common Rule (45 CFR 46, Subpart A) has been revised. The other HHS subparts have not been revised at this time. However, the revised Common Rule includes some changes to the applicability of exemptions to research that falls under the other subparts.

- The exemptions are applicable to subpart B research (research with pregnant women, fetuses, and neonates) as long as the conditions of the exemptions are met.
- The exemptions do not apply to research subject to subpart C (research with prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Exemptions 1, 4, 5, 6, 7, and 8 can apply to subpart D research (research with children) as long as the conditions of the exemptions are met. The first two provisions of exemption 2 (§46.104(d)(2)(i) and (ii)), are applicable to subpart D research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being

observed. The third provision of exemption 2 (§46.104(d)(2)(iii)) may not be applied to research with children. Exemption 3 does not apply to research with children.

[Refer to section 45 CFR 46.104(b) of the [revised Common Rule](#).]