General Questions Relating to the Common Rule

1. WHAT IS THE COMMON RULE?
The current U.S. system of protection for human research subjects is heavily influenced by the Belmont Report, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) revised, and made as compatible as possible under their respective statutory authorities, their existing human subjects regulations.

The Federal Policy for the Protection of Human Subjects or the “Common Rule” was published in 1991 and codified in separate regulations by 15 Federal departments and agencies. The HHS regulations, 45 CFR part 46, include four subparts: subpart A, also known as the Federal Policy or the “Common Rule”; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children.

Each agency includes in its chapter of the Code of Federal Regulations [CFR] section numbers and language that are identical to those of the HHS codification at 45 CFR part 46, subpart A. For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. Human subject research conducted or supported by each federal department/agency is governed by the regulations of that department/agency.

If interested, you can see who has signed off on the Common Rule here: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

2. WHAT IS THE BACKSTORY OF THE 2018 COMMON RULE? HOW DID WE GET HERE?
On January 19, 2017, the U.S. Department of Health and Human Services (HHS) and fifteen other Federal Departments and Agencies announced revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. The Final Rule was initially anticipated to be effective January 19, 2018. On June 19th, 2018, HHS and 16 other federal departments and agencies announced an additional six-month delay in the general compliance date for changes made to the Common Rule. The general compliance date of the revised Common Rule (known as the “2018 Requirements”) is January 21, 2019.

During the delay period (July 19, 2018, through January 20, 2019), regulated entities are required to continue to comply with the requirements of the pre-2018 Requirements with the following exception. Institutions have the option to implement three burden-reducing provisions of the revised Common Rule during the six-month delay:

1. The revised definition of “research”;
2. The allowance for no annual continuing review of certain categories of research; and
3. The elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research.
Institutions who choose to implement these burden-reducing provisions for particular studies, must assure that these studies also meet all 2018 Requirements beginning January 21, 2019. The UCI IRB chose to implement one of the three provision as noted below.

Effective July 19, 2018, UCI IRB will no longer conduct federal award-to-protocol congruence reviews. Principal Investigators supported by a federal award to conduct Human Subjects Research will be required to assure that their IRB protocol matches the federal award scope of work.

3. **WHAT IS THE PRE 2018 COMMON RULE?**
The regulations under 45 CFR 46- Subpart A - in effect up until January 20, 2019.

4. **WHY IS IT CALLED THE 2018 COMMON RULE IF IT GOES INTO EFFECT JANUARY 21, 2019?**
See question # 2 above. With the allowance for the exceptions during the delay period the Common Rule went into effect - in part, in 2018.

**Transitioning**

5. **MUST STUDIES APPROVED ON OR AFTER JANUARY 21, 2019 TRANSITION TO THE 2018 COMMON RULE?**
Yes. All studies approved by the IRB on or after January 21, 2019 must transition regardless of funding.

6. **MUST STUDIES APPROVED BEFORE JANUARY 21, 2019 TRANSITION TO THE 2018 COMMON RULE?**
It depends. At the time of continuing review (both the Short and the Long Continuing Protocol Application (CPA)), the Researcher will be prompted by HRP Staff at pre-review (until the electronic CPA is updated to allow this question):

"Is this protocol associated with a new or renewal of a federal award?"

If the answer is yes, the Researcher will be asked to transition at the time of CPA.

7. **CAN YOU CLARIFY WHAT IS MEANT BY A NEW OR RENEWAL OF A FEDERAL AWARD?**
Researchers are asked to please use the table below as a quick reference to determine if their study needs to transition to the 2018 Common Rule:

<table>
<thead>
<tr>
<th>FEDERAL AWARD TYPE</th>
<th>TRAINING GRANT</th>
<th>NO COST EXTENSION</th>
<th>ADMINISTRATIVE SUPPLEMENT</th>
<th>A FLOW DOWN OF FUNDS</th>
<th>INDIRECT FUNDING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRANSITION TO THE 2018 COMMON RULE?</strong></td>
<td>Transition only if this is a new or renewal of a federal award.</td>
<td>No need to transition.</td>
<td>No need to transition.</td>
<td>Transition only if this is associated with a new or renewal of a federal award.</td>
<td>No need to transition if funds are used in the form of a service, such as through the Institute for Clinical and Translational Science (ICTS) – an institute that is federally supported. If however, the indirect funds are a grant from ICTS, and it is associated with a new or a renewal, a transition is needed.</td>
</tr>
</tbody>
</table>
8. **MY AWARD IS A FEDERAL 5 YEAR AWARD, IN ITS 3rd YEAR. IS THAT A RENEWAL? SHOULD THE RESEARCH STUDY TRANSITION?**

Researchers are asked to please refer to the below graphic. A renewal is not the same as a continuing. The research study will only need to transition to the 2018 Common Rule if it is at the time of their renewal of a federal award or are receiving a new federal award. If the award is continuing, the research study does not need to transition.

9. **MY AWARD IS A FEDERAL 3 YEAR AWARD, IN ITS 2nd YEAR. IS THAT A RENEWAL? SHOULD THE RESEARCH STUDY TRANSITION?**

Researchers are asked to please refer to the below graphic. As with the above example, the research study will only need to transition to the 2018 Common Rule if it is at the time of their renewal of a federal award or are receiving a new federal award. If the award is continuing, the research study does not need to transition.

10. **HOW DOES A RESEARCHER TRANSITION THEIR RESEARCH STUDY?**

At the time of CPA, Researchers will be asked to complete a new section of the Protocol Narrative, depending on which version of the document has already been completed (exempt, social-behavioral or biomedical) as well as reorder elements of consent in their consent documents so that key information is provided “up front.” Additional consent elements may be required. Researchers will be provided with the updated Consent templates and asked to review/add in elements as applicable. Additional questions may be posed relating to waiver of consent criteria (see question # 12 below). This may include completion of a revised Appendix (O). The Human Research Protections (HRP) Staff will work with Researchers on this process.

11. **WHAT NEW SECTIONS OF THE PROTOCOL NARRATIVE WILL RESEARCHERS NEED TO COMPLETE?**

If the study involves screening of identifiable information or identifiable biospecimens to determine eligibility of prospective subjects, then the following section is required.
- Section 3D is a new section in the biomedical Protocol Narrative.
- Section 3C is a new section in the social behavioral version.
- Section 9 is a new section in the exempt version.

12. **(From OHRP) 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 practically 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 transitioned 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).

13. I NEED TO SUBMIT A MODIFICATION (MOD). I THINK I ALSO WILL NEED TO TRANSITION. WILL I BE REQUIRED TO TRANSITION AT THE TIME OF MY MOD?
No. Transitioning through a modification for studies initially approved prior to January 21, 2019 that are either at their time of federal renewal or a new award—is not required. Researchers can wait until their CPA to transition.

14. I WANT TO TRANSITION NOW. WHAT ARE MY OPTIONS?
Researchers can choose to transition via a MOD or a new IRB Application (APP). If via a MOD, please refer to question # 10 above. HRP Staff will work with the Researcher to ensure that their study documents are updated. If an APP, Researchers can use the IRB templates available on the IRB Apps & Forms page. All posted templates (including appendices) have been updated to accommodate the 2018 Common Rule.

15. I AM DUE FOR A DE-NOVO REVIEW AT TIME OF CPA. I DO NOT HAVE A NEW OR RENEWAL OF A FEDERAL AWARD. WILL I BE REQUIRED TO TRANSITION TO THE 2018 COMMON RULE?
Researchers who conduct greater than minimal risk research are required to update their study documents with the latest IRB templates every 7 years. Even though the research study will now have on file updated study documents (IRB templates), this does not mean that the study has transitioned to the 2018 Common Rule.

16. (From OHRP) IF A RESEARCH STUDY TRANSITIONS, DOES THE 2018 COMMON RULE APPLY RETROSPECTIVELY OR PROSPECTIVELY?
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.

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 re-consent 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.

IRB Review & Approval Processing

17. (From OHRP) UNDER WHICH VERSION OF THE COMMON RULE SHOULD THE IRB REVIEW A MOD?
MODs will be reviewed and evaluated under the version of the Common Rule to which a study is subject, regardless of when the MOD is made. For example, if a study initiated before January 21, 2019 is not transitioned to the 2018 Requirements, any change to that study must be evaluated under the pre-2018 Requirements regardless of when the change is made. Thus, a MOD submitted and reviewed 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 MOD for this activity would be reviewed under the pre-2018 Requirements. On and after April 5, 2022 (i.e., the study's transition date), MODs would be evaluated under the 2018 Requirements.

18. (From OHRP) 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).

19. IF A RESEARCHER ADDS IN SOME OF THE NEW ELEMENTS OF CONSENT TO THEIR CONSENT DOCUMENTS, DOES THIS MEAN THAT THE RESEARCH STUDY HAS TRANSITIONED TO THE 2018 COMMON RULE?
No. A Researcher may add in elements of consent as applicable to their study on their own or per the request of the IRB, as appropriate. This does not mean that the study has transitioned to the 2018 Common Rule.

20. IF A STUDY WAS GRANTED MINOR CHANGES BEFORE JANUARY 21, 2019, AND THEN IS REVIEWED AND APPROVED ON OR AFTER JANUARY 21, 2019, DOES THE 2018 COMMON RULE APPLY?
No. A protocol that received a “minor changes” memo from the IRB prior to January 21, 2019 has been given a conditional IRB approval. The final approval date could be on or after January 21, 2019, and the 2018 Common Rule would not apply.

21. IF A STUDY WAS TABLED BEFORE JANUARY 21, 2019, AND THEN IS REVIEWED AND APPROVED BY THE IRB ON OR AFTER JANUARY 21, 2019, DOES THE 2018 COMMON RULE APPLY?
Yes. A tabled protocol is not IRB approved (not even conditionally approved). The final approval date is on or after January 21, 2019, so the 2018 Common Rule applies.

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22. IF A RESEARCH STUDY TRANSITIONS, WILL THE IRB APPROVAL LETTER BE UPDATED TO INDICATE THAT THE STUDY HAS BEEN REVIEWED PER THE 2018 COMMON RULE?
Yes. A notation will be made on the approval letter to reflect that the study was reviewed / transitioned to the 2018 Common Rule.

Exempt Research

23. FOR EXEMPT STUDIES, ARE ALL THE NEW CONSENT ELEMENTS REQUIRED?
We encourage Researchers to use our new exempt template which we updated to include some provisions of the 2018 Common Rule as it was felt they are informative for participants. At this time, we want to encourage use but we / the IRB can be flexible if not all elements work for that particular submission.

24. HAS KEY INFORMATION BEEN INCORPORATED INTO THE FOLLOWING EXEMPT CONSENT / STUDY INFORMATION SHEET TEMPLATES?
   a. Survey
   b. Interview
   c. Focus Group
Yes, this change only required re-organizing the study information sheet/s in the order in which OHRP has suggested that key information be provided up front.

Vulnerable Populations

25. NOW THAT PREGNANT WOMEN ARE OFFICIALLY NO LONGER CONSIDERED VULNERABLE, DOES SUBPART B STILL APPLY?
Yes. Although the regulations now no longer refer to pregnant women as vulnerable, completion of Appendix B as part of addressing Subpart B will be required when pregnant women, fetuses and neonates are a target enrollment population.