With the general compliance date of the revised Common Rule looming, HRP would like to offer the following tips, reminders, and considerations.

1. **Develop a workplan for the management of existing studies** - While it may be appealing to convert everything over to the revised rule for the sake of consistency and to minimize confusion, there are potential downsides that you should be mindful of while planning. For exempt studies, consider that certain studies may no longer qualify for exemption and that limited IRB review may be required for others. It may be best to let some or all pre-existing exempt studies age out. For studies with waivers of consent, consider whether the study will still qualify for a waiver with the additional criterion that research using identifiable private information or identifiable biospecimens could not practicably be carried out without using the information/biospecimens in an identifiable format. For studies that are actively consenting new participants, consider the impact of the new requirements related to the consent process and the elements of consent.

   Consider the timing of transitioning studies (or if making the decision on a study-by-study basis, the timing of the evaluation) and the impact on IRB and researcher workload. Will you attempt to transition all at once or over a short interval of time? Will you evaluate/transition at the time of the next submission? At the time of continuing review? Having a written workplan that you can modify if needed as guidance emerges and as you gain experience will decrease confusion and stress.

2. **Develop a workplan for the management of new studies that are "in process" at the time of the rule change** - Will you stop accepting new study submissions for a period of time? Will you continue to accept new study submissions but withhold review and approval until the rule becomes effective? When will you roll out new forms, checklists, and templates? Will there be a grace period for researchers who may have been working on a submission at the time new forms are rolled out?

   Consider how different IRB actions may impact which rule applies to a study. For example, when a study is tabled or deferred versus when a study is approved with conditions. OHRP recently clarified the following for HRP:

   > *If a study subject to the Common Rule is approved with conditions prior to January 21, 2019 and the conditions are verified as satisfied after January 21, 2019, the study would be subject to the "pre-2018 requirements" unless and until the organization chooses to transition the study to comply with the "2018 requirements". Reason: Actual IRB approval precedes the general compliance date of the revised rule.*

Related to your question, importantly, please also refer to OHRP's 2010 Guidance "Approval of Research with Conditions," which provides an explanation of what OHRP understands by "IRB approval with conditions":

> *By IRB approval with conditions (sometimes referred to as "conditional approval" or "contingent approval"), OHRP means that at the time when the IRB reviews and approves a research study (or proposed changes to a previously approved study), the IRB requires as a condition of approval that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submit additional documents,* ***such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations at 45 CFR 46.111 and, if applicable, subparts B, C, or D of 45 CFR part 46.***

Keep in mind however, that this may be impacted if the conditions stipulated by the IRB are not satisfied (e.g., a researcher requests an alternative approach to one or more of the conditions).

3. **Publicize your workplans, revisions to SOPs, forms, and processes** and strategize on how to best communicate with and support your research community over the next year or more. Don't forget to consider other offices or departments that may be impacted by the changes in the rule and changes in your processes (e.g., who will perform grant congruency review?).
4. **Develop a quick guide or FAQs** for office reference and for researcher reference as you encounter different scenarios and decide on approach. Having a guide that you can quickly reference will save time, support consistency, and reduce frustration.
5. Remember to **maintain copies of existing SOPs, forms, and checklists**, you will need them for studies that are not transitioned and in the event of audit or inspection.
6. **Keep calm and carry on** - OHRP and AAHRPP both understand that implementing the revised rule is complex, especially given the lack of guidance and the fact that NIH, FDA, and others are also implementing changes that impact HRPPs, IRBs, and researchers. OHRP representatives have publicly commented that they intend to take an educational approach to compliance and AAHRPP has stated its intent to work with and help clients as they work through all of this.

As always, HRP is available to assist organizations as they work through these changes. Please don't hesitate to contact us if we can be of assistance. We wish you a wonderful new year.