

PRIM&R's Primer on the Revised Common Rule

In January, PRIM&R hosted PRIM&R's Primer on the Revised Common Rule, a webinar to introduce the human subjects research community to the changes present in the revised Federal Policy for the Protection of Human Subjects. Presented by P. Pearl O'Rourke, MD, and Heather Pierce, JD, MPH, this webinar provided an overview of the noteworthy changes from the current rule, as well as a discussion of various possible fates of the revised Common Rule under the new presidential administration.

Below are some of the questions discussed after the webinar that the UO human subjects research community may find helpful.

The final rule requires posting of informed consent forms for clinical trials. Who is responsible for posting the form, and does the posting have to be updated every time the form is revised?

- This posting requirement in the final rule only applies to federally conducted or federally supported clinical trials as defined in the final rule. For federally funded clinical trials, the rule requires that the form be posted by the awardee, typically the institution. Although the relevant website hasn't been created or identified yet, it appears likely from the preamble of the rule that the Department of Health and Human Services is strongly considering ClinicalTrials.gov as the appropriate place to house the forms. Only one form needs to be posted, and there is no requirement to update the posted form if it is revised, as long as the posted form was actually used to enroll subjects.

What does it mean to say that Subpart D isn't allowed for certain exemptions?

- If Subpart D is not allowed, it means that the exemptions do not apply to subjects who are children. While most of the exemptions apply to children as well as adults, the following exemptions do not apply to subjects who are children:
 - (d)(3) benign behavioral interventions
 - (d)(2) interactions including educational tests, surveys, interviews, etc. if:
 - identifiable information is recorded
 - the investigator participates in the observations being observed

When is broad consent required? When can it be waived?

- Broad consent, a key new requirement that was included in the proposed rule, is available as an option and is never required under the final rule. Broad consent is a prospective option that investigators could use to store, maintain, and conduct secondary research with identifiable data or biospecimens. The current available options of (1) deidentifying the data or biospecimens, (2) getting study-specific informed consent, or (3) getting an IRB waiver of the informed consent requirement are all still available. Because broad consent is never required, it does not need to be waived, which is why the waiver instructions don't apply to the broad consent requirements. Note that if you want to be able to use exemptions 104(d)(7) or (8) for secondary research, you must have previously obtained broad consent that includes all the elements in 116(d). Therefore, these two exemptions "require" broad consent, but if you aren't trying to use those exemptions, you aren't required to use broad consent.

What types of studies are required to use a single IRB and who decides which IRB will be the single IRB?

- The requirement to rely upon a single IRB applies to all research covered under the Common Rule “that involve more than one institution.” This requirement is not limited to clinical trials. The lead institution can propose which IRB will be the single IRB on which the other sites will rely, whether that is a central, commercial, or institutional IRB, and the funding agency will need to agree and accept that proposal.

Can the single IRB requirement be waived by a federal agency? Can this be proposed or suggested by an institution where the context may be very different due to the nature of the subject pool?

- Yes, the final rule allows any Common Rule department or agency to make and document a determination that “the use of a single IRB is not appropriate for the particular context.” Presumably that could include a situation where an institution makes a request to an agency about a particular study, but may also allow an agency to make a more sweeping determination that some types of research or studies with certain characteristics don’t ever have to rely on a single IRB.