

# Introduction

Clinical trial sites, sponsors and investigators conducting government-funded research have some new rules to follow now that the revision of the Federal Policy for Protection of Human Subjects, known as the Common Rule, is complete.

While the Common Rule technically doesn't apply to the FDA, which has its own human subject protection regulations in 21 CFR Parts 50 and 56, the requirements of the different regulations are very similar. And there has been talk of bringing the FDA into the fold and replacing its regulations with equivalent Common Rule regulations, according to healthcare regulation attorney Carrie Hanger of Nelson Mullins Riley & Scarborough. The purpose of the Common Rule, Hanger says, is to create a uniform body of regulations across various federal agencies that might have a hand in human subject research.

So now is the time for clinical researchers under FDA oversight to take note of the key developments in the governmentwide rule.

Those developments include the addition of identifiable biospecimens to the definition of “human subject” and provisions that address this rapidly developing area of research. In particular, the revised rule updates informed consent requirements to include explanation of what, if anything, will be done in the future with any biospecimens collected during a study.

The revision also includes a section on broad consent, which allows study subjects to sign off on future, secondary research that may be conducted with their identifiable information or identifiable biospecimens.

Another change involves the addition of new carve-outs under the definition of “research.” These activities—including scholarly and journalistic activities, public health surveillance and collection of biospecimens data for criminal justice and law enforcement purposes—do not count as research per the Common Rule, and thus are not subject to its regulatory dictates.

Other key changes include:

- Procedures for limited Institutional Review Board (IRB) reviews;
- Changes to the policy for continuing IRB review, including new scenarios in which continuing review will no longer be required;
- A new rule that requires cooperative research to be overseen by a single IRB; and
- A stipulation that independent IRBs can be held directly accountable for certain compliance lapses during an institutional study.

This report will walk readers through the ins and outs of the changes to the Common Rule, explaining what those changes mean in practical terms, and laying out next steps and

action items for both institutions and IRBs to take between now and the compliance date. The report will also clarify the sometimes confusing compliance dates for different parts of the Common Rule—what provisions go into effect immediately, what provisions will take effect in 2019, and what provisions won't be enforced until 2020.

*Portions of this report were adopted from a June 2018 webinar sponsored by FDAnews and featuring Carrie Hanger and Jennifer Mallory, both partners in the law firm Nelson Mullins Riley & Scarborough.*