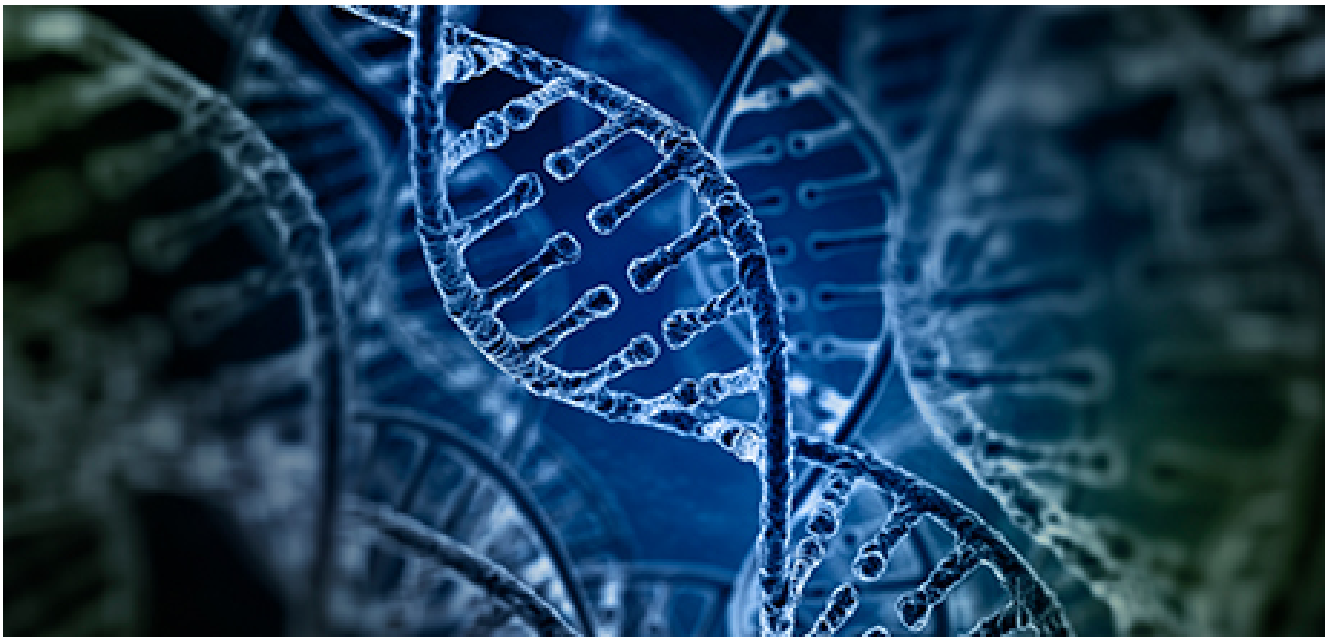

# What's new with the Common Rule? Clinical research and Common Rule updates

January 19, 2018

The updates to the Common Rule, effective July 19, 2018*, make some significant changes of which those involved in government-funded clinical research involving human subjects should be aware. These changes include:

To get your organization started, here are some action items to help with Common Rule compliance:

1. New definitions for "identifiable biospecimen," "private information," and "identifiable private information" (IPI)
2. New exemption for "Secondary Use Research" using IPI or biospecimens already obtained from the subject for other purposes (different research, clinical purposes) and the use/storage of IPI and biospecimens
3. New list of vulnerable populations: children, prisoners, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons
4. Revised informed consent requirements. The informed consent must:
    - Begin with key information most likely to assist the subject in understanding why/why not to participate
    - Be posted on a "federal website"
    - Have a statement about IPI and biospecimens, including:
        - The types of research that may be conducted in the future
        - If the IPI/biospecimens might be shared with other researchers
        - A description of the period of time allowed for storage and maintenance of the biospecimens and when the IPI or biospecimens may be used for research

        - Whether biospecimens may be used for commercial profit and whether the subject will share in such profits
        - Whether clinically relevant research results from secondary research will be disclosed to subjects and, if so, under what conditions
        - Whether research involving biospecimens might include whole genome sequencing
    - Permit researchers to seek broad informed consent that covers the subject of the current research and future unspecified research using IPI/biospecimens
    - New concept of "limited IRB review"
    - For U.S. institutions involved in cooperative (multi-site) research, they must rely on a single IRB approval unless an exception applies (effective January 20, 2020)

To get your organization started, here are some action items to help with Common Rule compliance:

1. Revise informed consent form templates.
2. Establish a process for timely posting of informed consent forms to the federal website.
3. Decide whether you will permit secondary use research and allow for broad informed consent.(If yes, institute a process for how to handle subjects who decline to give broad consent.)
4. Begin working toward the use of single IRB approval for multi-site research studies, including development of an IRB Authorization Agreement (a.k.a., Reliance Agreement) to meet the January 2020 deadline.

*The effective date of the revised Common Rule has been delayed to July 19, 2018 (originally scheduled for January 19, 2018). The federal register notice delaying the effective date and the general compliance date with the 2018 Common Rule requirements can be found here. The interim final rule (which is where the delay was published) also indicates there should be guidance on the revisions to the Common Rule forthcoming.

# Authors