

Subject: [PPHS] **New Human Subjects Research Regulations in January 2019: an Update**
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Attachments: Guidance.PNG



Research Guidance & Education

On January 21, 2019 the much delayed changes to the Federal regulations governing human subjects research, a.k.a. the Common Rule will go into effect. This transition is more challenging than usual because of the lack of guidance being issued by OHRP and the lack of strict concordance with FDA, HIPAA and other involved regulations.

It is important to know that if an IRB approves a new project before the 21st but responses required to secure approval (RRSA) aren't cleared up and accepted before the 21st then the project will have to comply with the new rules. This will likely force a modification for the project/the consent and cause a significant delay

- ***It is strongly suggested that teams are ready to respond with dispatch to any requests from the PPHS and other offices so that new projects in process can get approved under the old rule.***
- ***Any submission received after 12/7/18 will not be reviewed by a full board until after 1/21 and will have to comply with the new rules. Plan accordingly.***

There are three significant changes to the new rule that have generated interest in the research community that I will address:

1. **Broad consent**: This is a new approach to consenting for future use of specimens that was hoped would speed up IRB approval and subsequent use of those specimens. However, the regulations are written to force tracking of all potential subjects who refuse to participate. Their information cannot be used in any other research without their consent. In other words, their records would have to be removed from all research usually done with a waiver of informed consent, e.g. retrospective data explorations. For this reason, ISMMS and virtually all other centers that we have spoken to will **NOT BE IMPLEMENTING** the broad consent at this time.
2. **Annual reviews**: IRBs may decide that some or all expedited projects will no longer require a formal annual review by a full board or expedited non-committee review. Despite this change, we know that we still have an obligation to oversee that research. NO formal guidance has been issued. We also know that if we decide to use this "option" the project would no longer be grandfathered under the old rule but must be modified to be consistent with all aspects of the new rule. At the very least this would significantly impact projects that use a written consent. **For now, we will not change our process of annual continuations.** We will monitor the experience in the field and hopefully guidance from OHRP and we will regularly revisit the issue.
3. **Informed Consent**: The new regulations have introduced changes to the organization of the informed consent and the information that must be included.
 - If appropriate for a specific study, individuals must be told that their bio-specimens may be used for commercial profit.
 - Participants must be told whether the research may include whole genome sequencing.
 - Individuals must be told whether clinically relevant research results, including individual results, will be disclosed, and if so, under what conditions.

In addition, the new Common Rule now requires an introductory section of no more than 2 pages that should present a “concise and focused presentation of the key information.” Unfortunately, there is no official guidance as to what OHRP expects. **We will be posting our new template with the best instructions we can provide before 12/7/18.**

We will be speaking more about the transition at the Clinical Research Forum on Wednesday, 12/5/18 at Noon and will be sending our updates as available. Thank you for your understanding and support as we work through this process.

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