

## Revisions to the Common Rule (45CFR46) and Updated IRB Forms:

Please take a moment to review the below information regarding the revisions to the Common Rule regulations:

The new Common Rule regulations (45CFR46) are going into effect January 21, 2019. The updated IRB procedures will be uploaded to the IRB website ([www.unitypoint.org/irb](http://www.unitypoint.org/irb)) by 12/31/18. On this new version of the procedures, you will have the option to open a large pdf of the entire procedure document or you can open the section of the procedures that you need to reference.

Please note, there will be sections where you will have to follow a specific set of regulations/IRB procedures depending on the approval date of your study:

Any study approved on or before 1/20/19 will follow “pre-2018 Regulations”

Any study approved on 1/21/19 or after will follow “2018 Regulations”

In the procedure documents, I’ve included the difference in regulations in red font so you can easily identify them.

**In addition and most importantly, due to the changes in the regulations, we need to build in a transition period between studies that will follow the pre-2018 regulations and the 2018 regulations. Anything that has been submitted for review prior to January 8<sup>th</sup> will need to be approved under the pre-2018 regulations. Therefore, we are not allowing submission of any new, initial submissions between January 8-20, 2019 to work through our submitted pending approvals. Any new submissions that are submitted during this transition period may require completion of new IRB forms under the new Common Rule. Please be sure to check the IRB website for updated forms that meet the new Common Rule regulation requirements. All revised forms will be uploaded to the website by January 11, 2019. Please plan ahead and share this with your research teams so everyone is aware of this transition period.**

To learn more about the changes to the Common Rule, please watch the following YouTube videos from OHRP:

### [OHRP Revised Common Rule Videos](#)

- What's New in IRB Review under the Revised Common Rule? [[YouTube Video](#)]
- When Does the Common Rule Apply? Review of the Basics Under to Revised Rule [[YouTube Video](#)]

If you have any questions, please do not hesitate the IRB Office. Thank you!