

# New Human Subjects Regulations

## What Is Yet to Come

### From the Federal Government

09.03.2018

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- The effective date of the New Rule is January 21, 2019.
- We refer to “Pre-2018” and “2018 Regulations” because the original effective date of the New Rule or Revised Common Rule was January 19, 2018.

Once the New Rule becomes effective:

- Within the first year and then at least every four years, the Department of Health and Human Services (DHHS) will consult with experts to:
  - Re-examine the meaning of identifiable private information and identifiable biospecimens
  - Assess whether there are analytic technologies or techniques that generate identifiable private information or identifiable biospecimens
- DHHS is required to review the list of expedited review categories every 8 years and to amend the list if needed following consultation with agencies and an opportunity for public comment.
- DHHS is required to provide guidance regarding what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of the data (provisions required under “limited review”).