IMPORTANT DATES REGARDING IRB PROTOCOL SUBMISSION
TO PREPARE FOR IMPLEMENTATION OF
the Revised Policy for the Protection of Human Subjects
(aka Revised Common Rule).

For simplicity, we will refer to the current regulations as the "Current Common Rule" and the January 21, 2019 regulations as the "Revised Common Rule."

TEMPORARY FREEZE ON NEW INITIAL IRB APPLICATIONS

To manage the transition given the volume of initial submissions, the ORI, IRB, and Research Information Service are implementing a freeze on new Full IRB applications effective December 5, 2018 and a freeze on new Expedited/Exempt applications effective December 14, 2018. The freeze will remain in effect until the January 21, 2019 implementation date of the Revised Common Rule.

If your submitted protocol cannot be approved by January 21, the submission will be canceled and ORI will provide you with a PDF version for use in resubmitting after January 21 when the Revised Common Rule is implemented in E-IRB.

Ongoing Approved Research:

During this period, investigators will need to continue preparing and submitting modifications, violations, reports, and continuations to maintain compliance for existing studies approved under the Current Common Rule.

CAUTIONARY NOTICE

BEGINNING November 14, 2018 Investigators are strongly encouraged to delay the creation of New Initial Review submissions until on or after January 21, 2019. If your submitted protocol cannot be approved by January 21, the submission will be canceled and ORI will provide you with a PDF version for use in resubmitting after January 21 when the Revised Common Rule is implemented in E-IRB.

- **Initial Full Review Submissions:**

  MINOR REVISIONS: If revisions are minor, investigators are expected to provide prompt responses in order for the IRB to review revisions and issue approval before January 21.

  MAJOR REVISIONS: Substantive revisions must be reviewed at a convened meeting. Initial applications requiring substantive changes are unlikely to be approved prior to January 21, 2019.

- **Initial Expedited or Exempt Submissions:**

  Investigators are expected to provide prompt responses in order for the IRB to review revisions and issue approval before January 21.

REASON FOR TEMPORARY FREEZE - NO FEDERAL GRACE PERIOD

January 21, 2019 is both the effective date and the compliance date for the Revised Common Rule. This means that the institution cannot implement the revised rule before the effective date. It also means the regulation provides no grace period for which to transition to become compliant with the revised rule.

- All initial applications submitted under the current rule, must obtain approval prior to January 21, 2019.
- All initial applications submitted after the effective date must comply with the new elements and regulatory requirements of the revised rule.

Due to the federal delay, the effective and general compliance date of the Revised Common Rule is January 21, 2019.

- Research approved prior to January 21, 2019 may continue through completion based on the Current Common Rule regulations.
- Research approved on and after January 21, 2019, will need to comply with the Revised Common Rule. The Revised Common Rule regulatory changes will be incorporated into the version of E-IRB that will be released January 21, 2019.
- FDA-Regulations have not yet harmonized with all of the Revised Common Rule provisions. However, we will implement those changes that do not conflict with current FDA regulations.