



## SOP 106: IMPLEMENTATION OF THE FINAL RULE

### DEFINITIONS

- a) Final Rule In this policy, the term “Final Rule” refers to the Common Rule as published in the July 19, 2018 edition of the Code of Federal Regulations. The 2018 Requirements were originally published on January 19, 2017 and further amended on January 22, 2018 and June 19, 2018. The 2018 Requirements may also be referred to as the “revised Common Rule” or “2018 Requirements”. The Final Rule is effective as of January 21, 2019.
- b) Grandfathered In this policy, the term “grandfathered” refers to research approved under pre-2018 requirements. The pre-2018 requirements were originally promulgated in 1991, and subsequently amended in 2005. The pre-2018 requirements may also be referred to as the pre-2018 Common Rule.
- c) Transitioned Study In this policy, the term “transitioned study” refers to grandfathered studies which have been transitioned to the Final Rule.

### POLICY

Studies initiated before January 21, 2019 will be grandfathered and continue to be subject to the pre-2018 Common Rule. Studies initiated (approved) on or after January 21, 2019 are subject to the Final Rule.

The University of Utah IRB (UUIRB) did not elect to transition any studies during the delay period of July 19, 2018 through January 20, 2019.

The UUIRB will allow for a grandfathered study to transition to comply with the Final Rule. The IRB must document the date and the determination to transition a study to the Final Rule. Transitioned studies must adhere to all aspects of the Final Rule, not individual components.

The FDA intends to harmonize, to the extent possible, the FDA’s regulations with the Final Rule but has not yet done so as of date of this policy (see version date). Until such a time when harmonized regulations have been finalized, the UUIRB will review studies subject to FDA regulations as follows:

- **Informed Consent**

The informed consent requirements related to the content, organization and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Final Rule are not inconsistent with the FDA’s current policies and guidance. The UUIRB may approve a consent process for an FDA-regulated study that is consistent with the Final Rule.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



- **Expedited Review**

The FDA regulation 21 CFR 56.110(b) allows for expedited UUIRB review procedures for certain kinds of research appearing on the published list in the Federal Register, 1998<sup>1</sup>. In order to use the expedited review procedure, the IRB reviewer must find that the research involves no more than minimal risk.

The Final Rule changed the expedited review procedures in 45 CFR 46.110(b). The Final Rule states that the IRB may use expedited procedures for research appearing on the published list unless the IRB determines that the study involves more than minimal risk. Because the FDA has not revised its regulations, the UUIRB must continue to comply with the FDA's regulation (21 CFR 56.110(b)) for FDA-regulated studies, including studies that are subject to both HHS and FDA regulations.

- **Continuing Review**

The FDA regulation 21 CFR 56.109(f) states that IRBs are required to conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

The Final Rule eliminated the requirement to conduct continuing review in certain circumstances (45 CFR 46.109(f)(1)). Because the FDA has not revised its regulations, the UUIRB must continue to comply with the FDA's regulation (21 CFR 56.109(f)) for FDA-regulated studies, including studies that are subject to both HHS and FDA regulations.

## PROCEDURES

### 1. Procedures for the Transition of Grandfathered Studies to the Final Rule

1.1. IRB staff will evaluate grandfathered studies during the pre-review of continuing review applications to determine whether the study is recommended for transition to the Final Rule.

Factors that will influence recommendation to transition include but are not limited to:

- Studies with closed enrollment
- Studies that are in long-term follow-up
- Chart reviews
- Expedited studies with no consent document

1.2. If a study is ideal for transitioning to the Final Rule, the IRB staff member responsible for the internal review will notify the investigator. If necessary, guidance will be provided to the investigator about compliance to the Final Rule. Investigators are not compelled to transition a grandfathered study to the Final Rule and may decline the invitation to transition the study.

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<sup>1</sup> Federal Register – November 9, 1998 (Volume 63, Number 216, page 60364-60367)

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- 1.3. Investigators may request that a grandfathered study be transitioned to the Final Rule. Requests to be transitioned to the Final Rule may be made via an amendment application or in a continuing review application.
  
- 1.4. Documentation that the grandfathered study will be transitioned to the Final Rule is made in the internal checklist and study record in ERICA. The date of transition determination is the approval date of the continuing review or the amendment. The date of transition determination also serves as the date the study is in compliance with the Final Rule. Investigators will receive documentation of the transition determination in the approval letter.

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