

USA

The USA IRB will allow for a grandfathered study to transition to comply with the Final Rule. The

Procedures

- 1.0 Procedures for the Transition of Grandfathered Studies to the Final Rule
 - 1.1. IRB staff will evaluate grandfathered studies during 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:
 - 1.1.1. Studies with closed enrollment
 - 1.1.2. Studies that are in long-term follow-up
 - 1.1.3. Chart reviews
 - 1.1.4. 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
 - 1.3. Documentation that the grandfathered study will be transitioned to the Final Rule is documented in the IRB letter of approval and study protocol in IRBNet. 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.

Regulated Documentation

45 CFR 46

HISTORY

Effective Date: January 21, 2019

Revisions:

Responsible Party:

Office of Research Compliance and Assurance