



<b>TITLE: IMPLEMENTATION OF THE FINAL RULE</b>	<b>SOP NO.: IRB 106</b>
<b>EFFECTIVE DATE: 2/24/2025</b>	<b>REVISION NO.: 01</b>

## 1. PURPOSE

- 1.1. This policy describes the implementation of the Final Rule, or 2018 Common Rule, at UMBC.
- 1.2. SCOPE: This policy applies to the UMBC Institutional Review Board (IRB) and human subject research conducted at UMBC.

## 2. DEFINITIONS

- 2.1. IRB – Institutional Review Board
- 2.2. Final Rule – In this policy, 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 Common Rule”. The Final Rule is effective as of January 21, 2019.
- 2.3. Grandfathered - In this policy, 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.
- 2.4. Transitioned Study - In this policy, transitioned study refers to grandfathered studies which have been transitioned to the Final Rule.



### 3. POLICIES

Studies initiated before January 21, 2019, will be grandfathered and continue to be subject to the pre2018 Common Rule. Studies initiated (approved) on or after January 21, 2019, are subject to the Final Rule.

The UMBC IRB allows 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.

### 4. PROCEDURE

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

4.1.1. IRB staff evaluate grandfathered studies during the administrative 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.

4.1.2. If a study is ideal for transitioning to the Final Rule, the IRB staff member responsible for the administrative review will notify the principal 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.

4.1.3. 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 in UMBC's Quali system.

- 4.1.4. Documentation that the grandfathered study will be transitioned to the Final Rule is made in UMBC's IRB online management system, Quali. 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 designated as compliant with the Final Rule. Investigators will receive documentation of the transition determination in the approval letter.