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Terminology

Terms Related to the Revised Common Rule

Pre-2018 Requirements: The term "pre-2018 Requirements" refers to subpart A of 45 CFR part 46 (i.e., the Common Rule) as published in the 2016 edition of the Code of Federal Regulations. 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."

2018 Requirements: The term "2018 Requirements" refers to the Common Rule as published in the July 19, 2018 edition of the e-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."

Transition provision: The term "transition provision" refers to 45 CFR 46.101(l) of the 2018 Requirements. This provision outlines which studies must comply with the pre-2018 Requirements and which studies must comply with the 2018 Requirements. It also describes how an institution can voluntarily transition a

study subject to the pre-2018 Requirements (i.e., a study initiated before January 21, 2019) to instead be subject to the 2018 Requirements. Finally, it describes the regulatory requirements that apply during the delay period (i.e., from July 19, 2018 through January 20, 2019) to a study that has been transitioned to the 2018 Requirements before January 21, 2019. .

Initiated: Consistent with 45 CFR 46.101(l) of the 2018 Requirements, references to "initiated" research encompass research activities (1) initially approved by an institutional review board (IRB), (2) waived pursuant to § 46.101(i), or (3) for which a determination was made that the research was exempt.

Ongoing research or ongoing study: These terms refer to research that was initiated before January 21, 2019 and that continues on or after January 21, 2019.

Delay period: This term refers to the time period of July 19, 2018 through January 20, 2019.

Three burden-reducing provisions of the 2018 Requirements: As described in the transition provision at 45 CFR 46.101(l)(4)(i)(A), if an institution elects during the delay period to transition a study to comply with the 2018 Requirements, beginning on the date that the transition determination is documented, through January 20, 2019, such studies must comply with the pre-2018 Requirements, except that the studies will comply with the three burden-reducing provisions instead of or in addition to the comparable pre-2018 Requirements (specified in § __.101(l)(4)(i)(A)(1)-(3)):

- Pursuant to § __.101(l)(4)(i)(A)(1), § __.102(l) of the 2018 Requirements (definition of research) will apply instead of § __.102(d) of the pre-2018 Requirements).
- Pursuant to § __.101(l)(4)(i)(A)(2), § __.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) will apply instead of § __.103(f) of the pre-2018 Requirements.
- Pursuant to § __.101(l)(4)(i)(A)(3), § __.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) will apply instead of § __.103(b) of the pre-2018 Requirements (as related to the requirement for continuing review) and in addition to § __.109 of the pre-2018 Requirements.

Transition date: The date that an institution determines, and an IRB or institution dates and documents, that a study initiated before January 21, 2019 will comply with the 2018 Requirements instead of the pre-2018 Requirement. This determination may be made on a per-study basis or with respect to a broader group of studies conducted at an institution.

If the institutional determination occurs prior to the documentation, the date of the documentation is the transition date.

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