Timeline 1: General Mechanics of the Transition Provision

Beginning of Delay Period

General Compliance Date of the 2018 Requirements + End of Delay Period

All studies must comply with the pre-2018 Requirements. <u>Default Rule:</u> All studies must comply with the pre-2018 Requirements.

Exception: An institution may voluntarily elect to transition a study or studies to the 2018 Requirements.*

 During the delay period, these transitioned studies comply with the pre-2018 Requirements + the three burden-reducing provisions of the 2018 Requirements.

- All studies initiated on or after this date <u>must</u> comply with the 2018 Requirements.
- All studies transitioned to the 2018
 Requirements during the delay period <u>must</u> comply with the entirety of the 2018

 Requirements on and after this date.
- On and after this date, all other ongoing studies must comply with the Pre-2018 Requirements unless an institution voluntarily elects to transition the study to comply with the entirety of the 2018 Requirements.

July 19, 2018

January 21, 2019

^{*} If an institution wishes to take advantage of the three burden-reducing provisions of the 2018 Requirements during the delay period the institution must first determine (and the IRB or institution must document) that a study or set of studies will transition to comply with the 2018 Requirements. As described above, during the delay period, studies that have transitioned to comply with the 2018 Requirements must comply with the pre-2018 Requirements + the three burden-reducing provisions of the 2018 Requirements. On and after January 21, 2019, those transitioned studies must comply with the entirety of the 2018 Requirements.

Timeline 2: Research that Transitions to the 2018 Requirements During the Delay Period

Beginning of Delay Period

General Compliance Date of the 2018 Requirements + End of Delay Period

Study A initiated.
Study A must comply
with the pre-2018
Requirements.

In order to take advantage of the three burden-reducing provisions of the 2018 Requirements during the delay period, the institution determines (and the IRB or institution documents) that Study A will transition to comply with the 2018 Requirements.

This election may not be reversed.

On and after this date, Study A must comply with the entirety of the 2018 Requirements.

Institution may not revert study compliance to the pre-2018 Requirements.

July 19, 2018

January 21, 2019

^{*} If an institution wishes to take advantage of the three burden-reducing provisions of the 2018 Requirements during the delay period the institution must first determine (and the IRB or institution must document) that a study or set of studies will transition to comply with the 2018 Requirements. During the delay period, studies that have transitioned to comply with the 2018 Requirements must comply with the pre-2018 Requirements + the three burden-reducing provisions of the 2018 Requirements.

Timeline 3: Ongoing Research that Transitions to the 2018 Requirements On or After January 21, 2019

Study Transition General Compliance Date Date for 2018 Requirements + End of **Beginning of Delay Delay Period Period** Study B's institution Study B's institution Study B must comply takes no steps to takes no steps to with the entirety of the 2018 Requirements on transition study to transition study to Study B initiated. comply with the 2018 comply with the 2018 and after this date. Study B must Requirements. Requirements. comply with the pre-2018 Institution may not Requirements. Study B continues to Study B continues to revert study compliance comply with the precomply with the preto the pre-2018 2018 Requirements. 2018 Requirements. Requirements.

July 19, 2018

January 21, 2019

Institution determines (and IRB or institution documents and dates) that ongoing study will comply with 2018 **Requirements**