

# SMART IRB Reliance Agreement Version 3.0

# Transition Plan (Transition from Versions 1.0/2.0 to Version 3.0)

The purpose of this document is to (1) describe the circumstances when an institution must join Version 3.0 of SMART IRB Reliance Agreement (“Agreement”) and when a current Participating Institution may remain on the prior Versions 1.0/2.0; and (2) describe the effect of the new optional SMART IRB Indemnification Addendum on any existing indemnification agreements between Participating Institutions.

## Transition to Version 3.0

### Institutions New to the Agreement

All institutions that are new to (not already participating in) the Agreement must join Version 3.0.

### Current Participating Institutions

All current Participating Institutions that are added to an ongoing instance of reliance or that participate in a new reliance request now that Version 3.0 is live must join Version 3.0. In such cases, the Reviewing IRB Institution must also join Version 3.0.   
  
Additionally, for ongoing instances of reliance or new reliance requests that will involve a federal agency that is new to the Agreement (i.e., any federal agency other than NIH), all of the Participating Institutions involved in that reliance must join Version 3.0.

In all other cases, current Participating Institutions are strongly encouraged to join Version 3.0, but are not required to do so. A current Participating Institution already involved as a Relying Institution in an ongoing instance of reliance may remain on the version that institution previously joined (Version 1.0 or 2.0) as long as no new federal agencies will be involved in the reliance, and does not need to join Version 3.0 unless/until that institution becomes involved in a new reliance request.

Note that a current Participating Institution that either is required to or elects to transition to Version 3.0 in accordance with the above may, consequently, be under different versions of the Agreement with respect to different studies. A Reviewing IRB Institution may also, consequently, be under different versions of the Agreement with respect to different Relying Institutions in the same study. Participating Institutions will need to keep track of which version of the Agreement applies to each study in which they are involved, and with respect to each reliance partner in that study. A **list of operational differences** between the terms of Versions 1.0/2.0 and the terms of Version 3.0 is available in order to assist Participating Institutions in identifying the differences between the versions that they will need to manage day-to-day.

## Transition to SMART IRB Indemnification Addendum

New institutions and current Participating Institutions joining Version 3.0 have the option to also join the SMART IRB Indemnification Addendum at Exhibit C to the Agreement. Institutions can join the SMART IRB Indemnification Addendum at the same time they join Version 3.0 or at any time after they join Version 3.0.

Once joined, the SMART IRB Indemnification Addendum applies to all reliance relationships entered by the joining institution with any other institution that has joined the SMART IRB Indemnification Addendum, unless those institutions negotiate a more limited scope among themselves (e.g., agreeing to apply the SMART IRB Indemnification Addendum only to certain studies).

If joined, the SMART IRB Indemnification Addendum does not supersede any separate indemnification agreements entered by the joining institution with respect to activities initiated prior to joining. Such separate indemnification agreements will continue to apply to activities initiated under those separate agreements.

Institutions joining the SMART IRB Indemnification Addendum also remain free to enter new separate indemnification agreements with other Participating Institutions for activities outside the scope they defined for the SMART IRB Indemnification Addendum.