

Purpose of form: This document is designed to assist institutions that have not yet joined any version of the SMART IRB Agreement, including Version 3.0 or the Legacy V2.0/1.0. For questions, please contact help@smartirb.org. For further guidance, you may review the SMART IRB User Guides. Relevant articles are linked as "Guide" in the instructions below.

SMART IRB Reliance System: New Institution Onboarding Checklist

Please complete the following steps to join the SMART IRB Agreement. This process should be completed by an individual with authority to make reliance determinations on behalf of the joining institution (e.g. senior institutional leadership).

Finding/Adding your Institutional Account

- ☐ Find your institution on the SMART IRB Reliance registration page.
 - If you see your institution listed on this page, skip to "Registering an Individual Account."
 - If you do not see your institution listed, please see the next step.
- ☐ If your institution is not listed on this page, please <u>contact us</u> and provide the following information, so that we may add the institution to the database to complete the registration process:
 - Institution Legal Name;
 - Federal Assurance (e.g. <u>FWA number</u>); and
 - E-mail address(es) of individual(s) completing the application.

Registering a New Individual Account

based on the following criteria:

Once the SMART IRB Team confirms that your institution has been added, please take the following steps. Note, if your institution was recently added (through the steps above), you will need to <u>contact us</u> after you complete the registration process, so that we may activate your account.

☐ On the <u>SMART IRB Reliance System landing page</u> , click "Register" in the upper right corner of the page.
☐ Complete relevant details, including name, email address, and institutional affiliation.
☐ You will be asked to confirm your login method, selecting from 3 possible options. Please make your selection

- **Login.gov:** This option should be used if neither the "InCommon Federation" nor "NIH" options apply; this will be the applicable option for most institutions.
 - Please note: you will need to create a Login.gov account using the same email address as the one listed in your SMART IRB account.
- InCommon Federation: This option applies only to institutions that are part of the InCommon Federation, i.e., your organization is listed in the drop-down on the SMART IRB Reliance System login page ("Search organization to log in").
 - Please note: the email used for your institutional single sign on (SSO) will need to match the email registered with your SMART IRB account.
- NIH: This option applies only to employees or contractors of the NIH with an NIH-designated email.

<u>Completing Institutional Details, Key Personnel, and Profile</u>

Once your individual account has been activated, <u>log in to the Reliance System</u> to complete the sections described below; this will populate the relevant information into your institution's Joinder Agreement.

	Complete the "Institutional Information" section (Guide), including:
	☐ Basic information about your institution (e.g., legal name, address, institution type).
	\square A questionnaire regarding federal assurance applicability and CTSA affiliation.
	☐ If your institution maintains an IRB, you will also be asked to provide information about how you have assessed the quality of your HRPP, including the assessment method and date you initiated or completed the assessment This date must have been within the past 5 years to be eligible to join SMART IRB.
	Complete the "Contact Lists" section (Guide), listing key personnel to be included on relevant institutional correspondence (e.g., Version 3.0 activation). The SMART IRB Point of Contact and Alternative Point of Contact (if applicable) will be listed on the SMART IRB Participating Institutions page. Key contacts include:
	\square SMART IRB Point of Contact: primary person responsible for communicating reliance-related decisions on behalf of the institution.
	☐ Alternative SMART IRB Point of Contact (if applicable): backup person responsible for communicating reliance-related decisions on behalf of the institution.
	\square Institutional Official: signatory official at institution authorized to sign the institution's Joinder Agreement to the SMART IRB Agreement.
	\Box Contact for Notices (if applicable): person(s) to be added on institutional correspondence (e.g., confirmation of V3.0 activation).
	(Optional) Complete the "Institutional Profile" section (Guide) to provide fellow SMART IRB Participating Institutions with important information regarding the institution, the relevant legal jurisdiction, etc.
Up	ending and Signing the V3.0 Joinder Agreement and (if applicable) optional Indemnification Addendum on completion of your institutional details, contacts, and profile, follow the steps below to send the Agreement on to our institutional official for signature. (Guide).
	☐ On the Reliance System global landing page, select "Agreements."
	☐ On the left-hand side, select "New Submissions."
	☐ (Optional) Review your institution's Joinder by selecting "Agreement PDF."
	\square Review information listed for Institutional Official; when ready, select "Request Signature."
	\square Consider adding yourself and/or other relevant individuals to be 'cc'd on the email by scrolling on the institutional official information.

The SMART IRB team will review the signed and submitted Joinder Agreement and/or optional Indemnification Addendum, typically within 1 business day. Upon resolution of any identified items, we will activate your institution's participation in the SMART IRB Agreement.