



Utilizing the SMART IRB Agreement to Document Reliance for Multiple Studies

Purpose: This guidance provides key information for institutions to utilize the SMART IRB Reliance Agreement to document reliance on a single IRB which will serve as the Reviewing IRB for multiple studies. This situation may occur within research networks, when an institution uses an external IRB to review all or most of its research, or when closely affiliated institutions have a standing reliance agreement to allow shared IRB review with each other.

A. Background

There are many situations where institutions regularly rely on a designated single IRB (sIRB) for review of multiple studies. Some institutions may also designate an outside sIRB to review all or most of its research studies. In all these scenarios, the SMART IRB Reliance Agreement (henceforth SMART IRB Agreement) may be utilized to document reliance for multiple studies.

1. sIRB Review of multiple studies within a network

Many institutions are part of a network, consortium or grant framework that coordinates multiple studies within specific fields, related diseases, or health care systems. In this guidance we will refer to these groups as “networks”. A key feature of most of these networks is use of a sIRB to review and approve all studies conducted within the network. The sIRB may be limited to one institution within the network, any IRB located at any of the network sites, or an independent IRB. Many existing networks that use the sIRB model were established prior to implementation of the SMART IRB Agreement. Because a universal agreement was not available when they originated, networks prepared their own agreements and executed them with the individual institutions. Following the availability of the SMART IRB Agreement, many networks have shifted to use of the SMART IRB Agreement for reliance among their network sites.¹

2. Shared sIRB review of multiple studies among affiliated institutions

Institutions often document reliance for multiple studies when they are closely affiliated and frequently engage in collaborative research. Historically, closely affiliated institutions with separate IRBs and Federalwide Assurances (FWAs) that collaborate on numerous studies have executed agreements so research may be overseen by one of the institution’s IRBs. This situation may exist when faculty members conduct research at an affiliated institution not owned by the university, such as a hospital or research foundation. It may also exist in a group of affiliated institutions with separate FWAs (for example, a university-hospital system, or a hospital system).

3. A designated external sIRB reviews multiple studies for an institution

Some institutions such as community-based hospitals may utilize a designated IRB outside their institution to oversee all or most of their research studies. In these situations, the Relying Institution may execute a reliance agreement with the



Reviewing IRB that covers all studies overseen by that IRB. These arrangements are often established with independent IRBs; however, they may also involve an IRB based at an institution or Federal agency.

B. Recommendations

The SMART IRB Agreement easily can be used to support and document sIRB reliance for multiple studies in each of the situations described above (i.e., networks, affiliated institutions, or external IRBs). Existing reliance agreements may be replaced with the SMART IRB Agreement. Because the SMART IRB Agreement clearly outlines roles and responsibilities of reviewing IRBs and relying institutions, transitioning to use of the agreement may enhance existing reliance relationships and improve efficiency of reliance processes.

It is recommended that organizations executing new reliance agreements for multiple studies use the SMART IRB Agreement. Utilizing the SMART IRB Agreement for new arrangements eliminates the time-consuming process of developing and executing new reliance agreements and ensures the agreement meets currently accepted standards. It also enables networks to easily expand to new sites as many organizations are already signatories to the SMART IRB Agreement.

C. Guidance on Documenting Reliance for Multiple Studies

To avoid delays in transitioning from an existing agreement to the SMART IRB Agreement or utilization of the agreement for new arrangements, it is important that institutions that will be covered by a reliance agreement are provided clear guidance on how the process will work. The process for establishing new arrangements or transitioning from an existing agreement should be initiated by the Reviewing Institution.

1. Verify whether involved sites are currently participating institutions with SMART IRB

Over 1100 institutions have joined SMART IRB and may use the SMART IRB Agreement to enable IRB reliance. This means most institutions involved in these situations are already members of SMART IRB. Each institution with a separate FWA must join SMART IRB to participate. In other words, institutions that have separate FWAs must each register and execute a SMART IRB Agreement to participate.

- a. Current participating institutions with SMART IRB can be viewed on the SMART IRB website under [Participating Institutions](#).
- b. If an institution is not a SMART IRB Participating Institution, they must join the SMART IRB Agreement in order to participate in a reliance arrangement under the agreement, instructions on how to join SMART IRB may be found at [Join SMART IRB](#).

2. Determine how reliance will be documented

In all cases where the SMART IRB Agreement will be used as the basis for reliance for multiple studies the Reviewing IRB should determine the method that makes the most sense to document reliance for their specific studies.



The following methods are examples of ways to document reliance with the SMART IRB Agreement for multiple study arrangements between institutions:

- a. [SMART IRB Letter of Acknowledgement](#) – The letter should either list all studies the reliance agreement will cover or specify that the reliance arrangement applies to all studies funded/coordinated by that network.
- b. Network Governance Documents – Many well-established networks and consortia maintain robust governance documents outlining their policies and procedures. These governance documents may be updated to include language specifying that the SMART IRB Agreement will be used to document IRB reliance for the group.
- c. Other Agreements – Some networks or institutions may require that participating institutions sign a formal agreement such as a contract or a memorandum of understanding. Institutions can incorporate information regarding reliance arrangements into these documents.

When documenting reliance between institutions for all or most research the documentation must allow for scenarios where the Relying institution may rely on a different Reviewing IRB for a specific study or studies. Each institution will need to have a process in place to ensure that institutions may enter into reliance arrangements directly with the Reviewing IRB rather than through “daisy chaining” (or an institution acting on behalf of an affiliate). This is required so that each FWA-holding institution that wishes to participate is identified and so that there is clear and simple documentation that each of them is directly agreeing to the terms of the Agreement.

It is recommended that the Reviewing IRB maintains a record of studies occurring under this reliance arrangement when the list of studies is not defined initially.

Note: At this time the SMART IRB Online Reliance System is only able to document reliance on a study-by-study basis so cannot be used to document reliance for multiple studies.

3. Implementing the flexible components of SMART IRB Agreement

Networks and institutions must determine how to best implement the flexible components of the SMART IRB Agreement for their specific studies based on their network or institutional requirements. The SMART IRB Agreement provides for flexibility related to:

- The Reviewing IRB serving as a Privacy Board
- Requiring insurance or indemnification agreement
- Requiring an auditing mechanism or who performs audits
- Whether HIPAA authorization language will be included in consent form
- Who performs Conflict of Interest analyses
- Responsibilities for reporting events/actions to federal agencies/sponsors
- What policies and procedures will apply

The flexible components may be addressed either in network governance documents, agreements or with the [SMART Agreement Implementation Checklist and Documentation Tool](#)