Baystate Health

Local Considerations and Single IRB (sIRB) Review

When conducting multisite research under the single IRB (sIRB) model, gathering local considerations is essential. SMART IRB recently released "Recommendations for the Harmonization of Local Considerations" which recommends a standardized approach to identifying and communicating local requirements.

What are Local Considerations?

SMART IRB describes local considerations as aspects of a relying institution that could affect the reviewing IRB's determinations including any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews relevant to the research that would affect the conduct or approval of the research at the Relying Institution. These considerations are distinct from standard IRB review activities, which apply across all sites.

Local Considerations throughout the Lifecyle of a Study

Local considerations are not just reviewed at the initiation of a study. They should be evaluated throughout the entire lifecycle. Changes to the study may affect site-level implementation such as adding new populations, recruitment changes, addition of certain testing (genetic testing or infectious disease), consent language changes or other modifications may have specific local factors that would need to be assessed. SMART IRB has provided a checklist of items that may trigger new or updated local considerations (Appendix 8). We encourage you to review the checklist and keep these items in the back of your mind when there are changes to multisite research that you are involved in.

SMART IRB has developed a table that highlights the difference between Standard IRB Review Practice and items that are local considerations (TABLE 1). This resource helps HRPP professionals, study teams, and relying institutions better understand what information may still be needed from participating sites, even when another institution serves as the reviewing IRB. While the reviewing IRB is responsible for the regulatory review, each site remains responsible for ensuring compliance with its own laws, policies, and institutional requirements.

A clear understanding of local considerations helps support efficient reliance processes while ensuring that site-specific requirements continue to be addressed throughout the conduct of multisite research.