

USA is Prime - Review by External IRB

When USA is Prime and Arranging Single IRB Review

Initial Review includes both the initial review by the independent IRB as the single IRB, as well as the initial review (administrative review) conducted by the Relying IRB. Each stakeholder has responsibilities during this stage of review.

The PI and Lead Study Team are responsible for communicating with the independent IRB and making the initial submission of the overall protocol to the independent IRB. This follows the same process for when **USA is Participating Site - Rely on External IRB.**

The Lead Study Team should work with the independent IRB to ensure communication occurs between the independent IRB and the Participating Study Teams.

During the initial review stage, the Participating Study Teams are responsible for completing all of the non-IRB requirements at their local institution (Relying IRB requirements) and obtaining that information to the independent IRB as required by that independent IRB.

The independent IRB will communicate with the Lead Study Team and Participating Study Teams regarding IRB-related decisions and determinations that are part of the initial review and ongoing reviews.

Specific details about additional requirements required of the independent IRB will be communicated by the designated independent IRB.