

CIRB Workflow Using SMART IRB Exchange

Lead Study Team (LST)/
Coordinating Center (CC)

Single or Central IRB (CIRB)

SMART IRB Exchange

Participating Site (PS)
PI

PS HRPP

Initial CIRB Approval for Participating Sites

**Lead Study Team (LST)/
Coordinating Center (CC)**

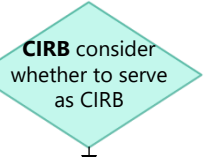
Single or Central IRB (CIRB)

SMART IRB Exchange

**Participating Site (PS)
PI**

PS HRPP

LST/CC requests CIRB support



CIRB communicates reliance process and requirements to LST/CC

LST/CC notifies participating sites of next steps *(can be done after step below)*

PIs submit request to rely on sIRB to local HRPP

HRPPs ensure all required agreements are complete

LST/CC submits to CIRB

CIRB creates study in Exchange

Exchange notifies HRPPs about study

An FYI notification sent if site is signed onto Exchange agreement

HRPPs consider whether to rely

LST/CC notified of Exchange access

CIRB uploads Lead Site Approval to Exchange

Exchange stores approval

Participating Site HRPPs confirm site engagement; indicate willingness to rely, and add local study teams.

LST/CC monitors sites' progress in Exchange

CIRB emailed confirmation of reliance

PI notified of Exchange access

HRPP confirmation of reliance

HRPPs complete local context and enter into Exchange

LST/CC emailed when site registers and confirmation of reliance

LST/CC notified of local context completion

Exchange captures local context from participating sites

PI completes local context

LST/CC exports participating site local context from Exchange

LST/CC submits PS site local context + ICF to CIRB

CIRB reviews and approves participating sites local context

CIRB (or CC) uploads participating site approval to Exchange

Exchange notifies participating sites of CIRB approval

PIs notified of CIRB approval

HRPPs notified of CIRB approval