

/ CHANGE AFib: IRB Process Information

CHANGE AFib is utilizing a Central Institutional Review Board (cIRB), **Advarra**.

All study sites participating in this study are welcome to utilize this centralized platform. If required, study sites may use their Institutional (Local) IRB. Please refer to the below processes based on your site's needs.

Please inform your Enrollment Site Manager of your site's IRB designation.

Central IRB Process →

- Your Enrollment Site Manager will provide information needed to help create your Advarra cIRB account. (Included below for reference)



[CIRBI™ QuickSteps \(changeafib.org\) cIRB Account Registration](#)



[CIRBI™ QuickSteps \(changeafib.org\) Submitting an Investigator Application](#)

- Once registered, each site will complete a 'Investigator Application' which will require uploading their site Principal Investigator's CV.
- Once submitted, Advarra's standard review turnaround time is approximately 1week from date of submission!! No costs are associated with the utilization of the Central IRB.
- The CHANGE-AFib study team will manage annual re-approvals and any modifications necessary on behalf of your study site.

Local IRB Process →

- Your Enrollment Site Manager will email our **IRB Starter Packet** that will contain all materials needed to successfully complete your Local IRB submission.
- Prior to submitting your application to your Local IRB, we request that all edited documents be sent to CHANGEAFibContracting@heart.org for review.
- After this review is conducting, the CHANGE-AFib team will provide the green-light to finalize your Local IRB submission application.
- Your Enrollment Site Manager will work with you and your team to manage and track your annual review and any modifications, if applicable.

Please direct all IRB (Central or Local) related questions to:
CHANGEAFibContracting@heart.org