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APPROVAL NOTICE

MOD01599192

DATE: 3 Apr 2023

TO: Devin Keating

PROTOCOL: American Heart Association-TX - 2.0, Pragmatic Randomized Clinical Trial of Early Dronedarone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation (CHANGE AFib). (Pro00057635)

APPROVAL DATE: 22 Mar 2023

IRB APPROVED:

- Documentation:**
- Protocol Version 3.0 (Dated 01MAR2023)
 - Physician Pocket Card (v.12.13.22)
 - Patient Brochure (v.12.13.22)
- Consent Template:**
- Informed Consent Form (Advarra IRB Approved Version 22 Mar 2023)

The IRB reviewed and approved the above referenced documentation.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

The Consent Template referenced above is now available on your Advarra CIRBI Platform workspace. Sites will be instructed to have new subjects and currently enrolled subjects receiving the applicable study treatment/drug sign the updated form.

Audio/visual recruitment or subject material approved in script format only must be submitted in final format for the IRB to review what potential subjects will see or hear. The IRB does not review the content found in embedded links or QR codes, therefore this content must be submitted for review and approval separately, prior to use.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.