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REVISED APPROVAL WITH MODIFICATIONS

MOD01465167

DATE:	29 Mar 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:	24 Oct 2022

It has come to our attention that the previously released Revised Approval with Modifications Notice (Dated 04 Nov 2022), did not include the LAR Determination. This notice has been revised to correct that oversight. Please retain this revised notice along with the original.

It has come to our attention that the previously released Approval with Modifications Notice (Dated 31 Oct 2022), did not include the updated Protocol Number. This notice has been revised to correct that oversight. Please retain this revised notice along with the original.

Additionally, the released Informed Consent Form (ICF) did not include the updated protocol number on page 1. The updated Informed Consent Form (Advarra IRB Approved Version 4 Nov 2022) is now electronically available on your CIRBI workspace under the "IRB Issued Documents" tab.

IRB APPROVED:

Documentation:	• Protocol Version 2.0 (Dated 17OCT2022)
Consent Template(s):	• Informed Consent Form (Advarra IRB Approved Version 24 Oct 2022)

The IRB reviewed the above referenced documentation. The IRB granted approval with the modifications listed below:

- **Modifications to the Informed Consent Form**

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

The IRB determined that the use of a Legally Authorized Representative (LAR) is approved for this study. During the course of the study, if the subject regains the capacity to consent, informed consent must be obtained from the subject and the subject must be offered the ability to leave the study if desired.

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.