

TO: David De Lurgio, MD
Principal Investigator
MedCardio

DATE: March 17, 2014



RE: **Expedited Approval**
IRB00072028

Assessment of cardiac structure and function by cardiac MRI in patients undergoing atrial fibrillation ablation

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits the regulatory category F(5) as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on DATE and granted approval effective from **03/17/14** through **03/16/15**. Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this approval:

- Complete HIPAA waiver granted: This study meets the criteria for HIPAA Authorization to be waived.
- Consent waiver granted: This study meets the criteria for all elements of consent to be waived.

Documents reviewed with this application:

- revision V1 clean, version 03/12/14
- 72028_Consent_Waiver_sk_031314
- 72028_HIPAA_Waiver_sk_031314

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, and study design), you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you

Scott S. Katz, MS

Analyst Assistant

This letter has been digitally signed