METROWEST MEDICAL CENTER
Framingham Union Hospital • Leonard Morse Hospital

January 30, 2019

Douglas Laidlaw M.D.
Saint Vincent Medical Center
123 Summer Street
Worcester, MA 01608

RE: 2019-015: Predictors of Recurrence of Atrial Fibrillation in Patients with Paroxysmal Atrial Fibrillation Following Cryoablation

Jurisdiction: Medical Records from Saint Vincent Medical Center, 123 Summer Street, Worcester, MA 01608
Dates: from 01/01/2015 through 01/31/2018
MWMC IRB: 002845

Dear Dr. Laidlaw

This is to inform you that on January 30, 2019 MetroWest Medical Center Institutional Review Board (IRB), via Expedited Review by the IRB Chair, has approved the above-referenced research protocol and the participation of the above-referenced investigative site in the research. Your study number is 2019-015. Please be sure to reference this number and the name of the principal investigator in any correspondence with MetroWest Medical Center IRB.

Specifically your request was approved as "expedited review" under the following category:

- Secondary research uses of identifiable private information or identifiable biospecimens that are not exempt under §__.104(d)(4) because (a) the identifiable private information or identifiable biospecimens are not publicly available; (b) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained directly or through identifiers linked to the subjects, or the investigator intends to contact the subjects or will re-identify subjects; (c) research use of identifiable health information not regulated under 45 CFR parts 160 and 164, subparts A and E.

RE: 2019-015: Predictors of Recurrence of Atrial Fibrillation in Patients with Paroxysmal Atrial Fibrillation Following Cryoablation

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Continued approval is conditional upon your compliance with the following requirements:
A waiver of documentation of consent was approved in accordance with 45 CFR 46.117(c).

- The following must be promptly reported to the IRB: changes to the study site, and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.

- Approval is valid for enrollment of the number of subjects indicated on your submission form.

- All protocol amendments and changes to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate hazards to the study subjects.

- Advertisements, letters, internet postings and any other media for subject recruitment must be submitted to the IRB and approved prior to use.

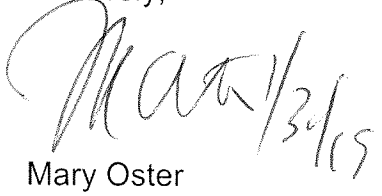
- Compliance with all federal and state laws pertaining to this research, and with MetroWest Medical Center IRB's SOPs.

- All publications and communications related to this research are subject to Tenet Policy AD 2.16 related to the substantiation of all data/claims with reliable scientific evidence

Additionally, a HIPPA Waiver of Authorization has been approved as it relates to the conduct of the above named study.

Please call me if you have any questions about the terms of this determination at 508-383-8786 or e-mail me at mary.oster@mwmc.com .

Sincerely,



Mary Oster
IRB Administrator