CARDIOLOGY PHYSICIANS P.A.
Consultative and Interventional Cardiology

JOHN J. KELLY III, M.D., F.A.C.C.
GILBERT A. LEIDIG JR., M.D., F.A.C.C.
BRIAN H. SARTER, M.D., F.A.C.C., F.H.R.S.
GAETANO N. PASTORE, M.D., F.A.C.C.
ANTHONY W. CLAY, D.O., F.A.C.C.
ALAN MICKLIN, M.D., F.A.C.C.
ANTHONY B. FUREY, D.O., F.A.C.C., F.A.C.P.
KEVIN A. COPELAND, D.O., F.A.C.C.

Robin L. Elliott, Health Physicist
US NRC- Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

March 17, 2017

**Re: Request for Additional Information for License Amendment**
**Licensee: Cardiology Physicians, P.A.**
**License Number: 07-30713-01**
**Mail Control: 593063**

Dear Ms. Elliott,
This letter is in response to your request for additional information in order to facilitate the processing of our amendment request.

1. We confirm that the studies are diagnostic and not therapeutic.

2. The material requested will be used only in previously licensed areas within our facilities.

3. Per 10 CFR 35.6, we confirm that the study has the approval of an Institutional Review Board. Information regarding this board is attached for your review.

4. We confirm that a signed informed consent will be obtained for each patient involved in the study. A comprehensive consent form has been provided by G.E. for this study.

5. The study involves a diagnostic compound that has previously been in use. The radioactive material is used simply as part of the compound to allow the uptake of the compound to be imaged in a diagnostic capacity. Data is being gathered to look for other predictive information based on imaging with this agent.

6. The radioactive material is integral to the study only in the sense that it allows imaging of the radiopharmaceutical/uptake agent.

   An overview of the process is as follows. Patients that have an imaging study that shows an Ejection Fraction between 30 – 35 % will be permitted to volunteer for the study. The study will include administration of the radiopharmaceutical and imaging to follow. The imaging will compare two regions of interest for uptake. The ratio of uptake between the two regions will be used to predict candidates that will benefit from an ICD implant.

7. Unexpected events will be reported immediately to the board and guidance for what constitutes unexpected events has been provided to the practice. Reports to the board will be provided prior to the conclusion of the study or prior to requesting an extension of the study.

8. The study will involve only volunteers.

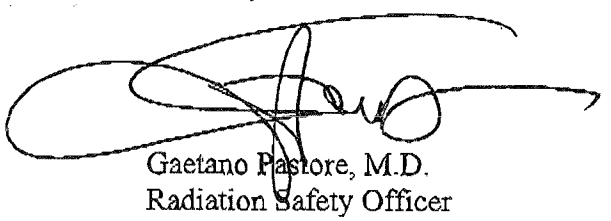
   a. The dose for the study has an acceptable range of 9 – 11 mCi per administration, as determined using industry standard protocols with a dose calibrator.

   b. Volunteers participating in the study will be evaluated prior to release to ensure that they will not be a source of radiation to members of the public in excess of the limits expressed in 10 CFR 20,1301.

All other aspects of our radiation protection program will remain the same.

Thank you for your assistance in this licensing effort. If you need any further information please feel free to contact me at: (302) 366-8600, or my health physicist, Jim Fongheiser at (610) 745-6901.

Sincerely,



Gaetano Pastore, M.D.
Radiation Safety Officer

Attachment: IRB Information

SchulmanIRB

Offices: Cincinnati, OH | Research Triangle Park, NC

www.sairb.com

CanadianREB Minimal Risk REVIEW Phase I REVIEW Central Oncology Review

**APPROVED: 02/06/2017**
**EXPIRATION DATE: 02/05/2018**

February 07, 2017

**FROM:** Schulman IRB ("Schulman" or the "Board")
**TO:** Anthony Clay, DO
**SUBJECT:** Initial Approval Documents
**SPONSOR:** GE Healthcare
**PROTOCOL NO:** GE 122-020
**PROTOCOL TITLE:** AdreView™ Myocardial Imaging for Risk Evaluation – A multicentre trial to guide ICD implantation in NYHA class II & III heart failure patients with 30%≤LVEF≤35%. ADMIRE-ICD

| The following protocol items were reviewed and approved on the dates listed below: | Review Type | Approval Date | IC Finalized |
|---|---|---|---|
| • Clinical Study Protocol, Version Number 2.0: | Full Board | 08/12/2016 | N/A |
| • Information and Consent Form (Schulman Version 1.0): | Full Board | 08/12/2016 | 09/01/2016 |
| • Administrative Letter dated 08/30/2016: | Expedited | 09/01/2016 | N/A |
| • Revised Protocol Incorporating Amendment A01 dated 11/03/2016: | Full Board | 12/16/2016 | N/A |
| **The following information is specific to the investigator referenced above:** | | | |
| • Site(s) approval to conduct this study: | Expedited | 02/06/2017 | N/A |
| • Site specific Information and Consent Form (Schulman Version 1.0): | Expedited | 02/06/2017 | 02/06/2017 |

The Board approved the items listed above. You must use only the "Schulman Approved" informed consent(s).

Please note: Effective for new studies submitted on or after 05/02/2016, Schulman has an updated informed consent versioning process. For more information, please refer to the memo available at http://www.sairb.com/ICversioncontrolmemo.

In order to participate in this research study, an adult study subject must provide his/her own written consent for participation. An adult subject is an individual who has attained the legal age for consent to treatments or the procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. The Board **has not approved** consent of subjects via a legally authorized representative for this study. Accordingly, a subject must not be enrolled in this research study via the consent of a legally authorized representative.

This approval will last 12 months.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval. You can find the Study Status Report Form at www.sairb.com.

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators (PI and Sub-Is); or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

The current Board Membership List is available to download at the link on SiteAccess at www.sairb.com. Please maintain the appropriate Board Membership List with your study binder.

**PLEASE REFERENCE IRB # 201700657 ON ALL CORRESPONDENCE FOR THIS STUDY.**

WebPortal/Paperless