We anticipate beginning community consultation and public disclosure activities as soon as possible after IRB review and approval of our EFIC plan, with a goal of completion by Janurary, 2017. The community consultation activities will occur over the course of about 5 months. Public disclosure will begin prior to study enrollment, will continue throughout study enrollment, and conclude with dissemination of study results after the study has concluded. We plan to initiate public disclosure activities at least 2-weeks prior to the start of the proposed trial. Public disclosure will continue beyond the end of study enrollment and through disclosure of study results, and anticipate a 1-3 year timeframe.

Analysis and Presentation of Results From Community Consultation and Public Disclosure

Reporting of community consultation results will be provided by the study team to the IRB. Summaries of the data will be reported to the FDA.

Data collected regarding CC and PD will include the following elements:

- Consultation methodology used
- Community type: geographic or condition-specific
- Participants involved: number and demographics
- Duration, content, format of information presented
- Free text log of comments, questions, and responses to open-ended questions
- Log of pre-determined closed-ended survey questions and responses

The study team will review survey responses and group meetings in summary form, and general themes will be summarized. The results of all local community consultation efforts will be summarized and submitted to IRBMED for review. If appointed and if present at the focus group discussions, an IRB liaison will provide an in-depth review of the discussions and additional feedback to the IRB as needed. Summaries of public disclosure will be reported to the IRB prior to approval, and then at least annually or upon request from the IRB.

A provision of the protocol has been made to allow participants who learn of the trial through community consultation or public disclosure or other means, and who would not want to participate if treated for a cardiac arrest, to opt-out of trial prior to such an event. Opt-out forms will be available on the Huron Valley Ambulance (HVA) and all community consultation interactions.

Contacting Legally Authorized Representatives (LAR) or family members

The federal regulations for contact of a Legally Authorized Representative (21 CFR 50.24) state:

> *(a)(7)Additional protections of the rights and welfare of the subjects will be provided, including, at least:*
>
> *(v) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if*

feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

(b) The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

A procedure for prospective informed consent will be developed as is required by 21 CFR 50.24, in the unlikely event that a LAR can be identified within the presumed short therapeutic time window for the intervention and is able to provide a meaningful prospective surrogate consent for patient enrollment. However, it is highly unlikely consent will be obtained prospectively in this EROCA trial for the reasons summarized in the scientific protocol, to delay treatment of the patient in sudden cardiac arrest long enough to identify and contact either an LAR or other family members. In circumstances in which is it impossible to identify a LAR within the therapeutic time frame, EFIC will be applied.

Participants enrolled in EROCA under EFIC procedures and unable to consent, their LAR or family member(s) will be informed of the clinical investigation, including inclusion criteria at the earliest possible opportunity.

Participants enrolled in EROCA with EFIC, or their LAR/family member(s), will be informed of study enrollment in the clinical investigation at the earliest possible opportunity. Participants admitted to the hospital will be approached in person. A study team member will speak with the senior clinician to determine the stability of the participant and the appropriate time for speaking with the participant, or if not alert and capable of making informed decisions, a LAR or family member. The study team member will approach the participant(or LAR/family) to notify them about the participant's enrollment under EFIC, provide information about the study, including continued enrollment.