Resuscitative TEE Collaborative Registry
Frequently Asked Questions

May 13, 2021

Before answering each of these questions individually, the following clarification should be made, as it is highlighted in multiple questions:

For the sake of your IRB, you should consider the template protocol we have provided as a study *within* your institution. Therefore, it is our deliberate approach following the recommendations of other successful registries to establish this Registry as a collaboration of multiple single-center studies. This is in contrast to the alternative, more complex approach of establishing the Registry as a multi-center study.

After the IRB has approved your protocol, the DUA allows you the ability to share the data from your study with the Resuscitative TEE Collaborative Registry, housed at the University of Pennsylvania. The only caveat to this line of reasoning is that when you collect the data, you will be inputting it directly into the Registry database housed at UPenn (which is why you should complete the DUA prior to collecting data). We are aware that this approach might not work for every institution participating in the Registry, in which case the IRB may and can be modified to align with local needs.

Questions (**yellow highlight designates new questions/answers**):

A44. For how long will you store research data generated by the study?

In our IRB template, we specify a local study duration of 1 year (although we plan to extend our study with our IRB at UPenn. However, if you intend on collecting data for greater than a year, you may extend the local study duration to 2 or even 3 years. We suggest the 1-year timeline to ensure prompt IRB/Ethic committee approvals.

The Resuscitative TEE Registry will follow a 3-year trajectory, followed by an approximate 6-month authorship phase. However, a second data collection phase may be implemented. Please refer to our Authorship Plan for more details.

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Data will be stored on a password-protected web platform called REDCap. Here is a modified excerpt describing the data-protection process from a fellow participating institution's IRB:

Patient names will not be sent off-site and will remain only in the local application database. Medical record numbers will similarly remain at the site with a master list linking the study ID with the patient ID. with only the pseudo-ids sent offsite. All data being sent off-site will be transferred over a secure, strongly encrypted HTTPS connection via REDCap and stored on the coordinating centers database server. The database server is cordoned off from the Internet by our corporate firewall, and is only accessible from the secure internal network. Additionally the database itself require either an active Active-Directory account that has been granted permissions, or an application-specific account with a strong password to connect. Connections from application accounts are restricted to specific server IP

addresses, and all connection attempts are logged. Besides any relevant applications, only user accounts specifically related to this study and administrators will be granted permission to the database. The databases are databases are backed up three times per day, the database server is backed up every night, and backup tapes are periodically rotated between secure on-site storage and secure off-site storage at Iron Mountain via a courier in a locked container.

Although you may not require all of this detail, it could be helpful for particularly strict IRBs.

The plan for data storage is to keep data for at least the 3-year data collection period and the 6-month authorship period until all publications have been completed. After this period, all the data will be destroyed. That said, there is potential to extend the timeline of the Registry. In both cases, institutions that have contributed data to the Registry will be notified about data destruction or retainment at this that juncture.

A56. How have the statistical aspects of the research been reviewed?

Please refer to the updated IRB template protocol.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their careers, or members of the public?

Patients for which TEE is being used for care are unable to provide consent. Our IRB at UPenn provides a means by which exemption from informed consent can be obtained. Attached are our **Request for Waiver of HIPAA Authorization** and **Notice of Exemption**. As detailed in the Request document, there are a number of criteria that must be fulfilled for exemption, and our answers will likely help with answering many questions asked by traditional IRBs. These answers may be especially helpful for those groups that do not have a formal exemption process.

Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The Registry will not be collecting any personal health information or identifiable data. As is customary with most registries of this kind, all data is de-identified by site investigators prior to data entry. That includes all clinical data as well as TEE images.

A50-1. Will the research be registered on a public database?

No, The Registry is not a public database.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

You will not be using identifiable personal data. All clinical information, patient characteristics and TEE images should contain no identifiers prior to entry into the database.

A53. How and when will you inform participants of the study results?

We do not plan to inform all patients about the results of this registry. It is unclear whether the 'participants' here refers to patients or participating research centers.

As part of the structure of the Registry, we plan to generate and share reports containing benchmark data that will be available on the Resuscitative TEE Collaborative Website.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below*

Please refer to the updated IRB template protocol for more details.

As a descriptive, convenience sample study aimed to characterize the current practice, clinical impact, and safety profile of TEE in these clinical settings, it is necessary to collect as many of the cases being routinely performed as part of the standard clinical practice. In order to characterize the safety profile/complications and clinical impact, it is also of critical importance to collect as many as possible.

For our institution, we stated a goal of 100 cases over a 12 month period, which is based on the total number of TEEs performed in the clinical; you should modify this based on frequency of TEE use in critically ill patients at your institution. You should aim for a sample representative of your patient population that will allow the research data to have validity in terms of representing the practice and the outcomes from patients in whom TEE is performed in critical care scenarios. As a general goal, and following the standards set by other international, recognized registries collecting observational data, we will aim for enrollment of over 90% of cases of TEE performed.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

No formal sample size calculation was made because this is a convenience sampled, observational/descriptive study on TEE, which is routinely used as a standard of care. Sample size was estimated based on the frequency of TEE in our institution. It is important that the sample size not limit the extent to which you enroll subjects.

74. What arrangements are in place for monitoring and auditing the conduct of the research?

Research projects will be assessed by the chairs and interdisciplinary scientific oversight committee of the Resuscitative TEE Collaborative Registry. These leaders are clinicians that are experts in both this modality and research methodology knowledge relevant to the research project. For a list co-chairs and scientific oversight committee, refer to this website. The operational and research infrastructure of the Resuscitative TEE Collaborative Registry is housed by the Center for Resuscitation Science at University of Pennsylvania.

The Scientific Oversight Committee (SOC) will work in the development of the registry dataset, define areas of high priority for research in this field, coordinate registry reports, review data requests for new research proposals, and promote and disseminate scientific product from the Resuscitative TEE Collaborative Registry.

The SOC will also assist in the development of strategies to engage new participating institutions and establish procedures to ensure that research is conducted with integrity and with the highest scientific quality standards.