Yale University
Human Investigation Committee
Request for Approval of Medical Record Review
100 FR 7 (2016-2)

Questions to determine if the study qualifies as a Medical Record Review:

1. Will the medical information to be accessed be limited to only records of decedents?
☒ No ☐ Yes
(If yes, stop completing this form and complete the Request for Access to Protected Health Information for a Research Purpose located in the HIPAA website at http://www.yale.edu/ppdev/policy/5032/5032.pdf. When completed this form is to be given only to the holder of the records).

   For additional information consult the HIPAA website http://hipaa.yale.edu/

2. Will the information collected be used to create a data archive for future research?
☒ No ☐ Yes
(If yes, stop completing this form and complete the HIC Repository Application).

3. Are there plans to contact subjects for follow-up or to collect any information using assessment tools or other means to complete the information that is not currently available in the chart?
☒ No ☐ Yes
(If yes, stop completing this form and complete the HIC Protocol Application Form).

If you answered "No" to all of the above questions, complete the following form:

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Title of Research Project: Pilot analysis of the association between types of anesthetic and outcomes in transfemoral aortic valve replacement.			
Principal Investigator: Robert B. Schonberger		**Yale Academic Appointment:** Assistant Professor	
Department: Anesthesiology			
Campus Address: TMP-3 Anesthesiology			
Campus Phone: 2037852802	**Fax:** 2037856664	**Pager:** [redacted]	**E-mail:** robert.schonberger@yale.edu
Protocol Correspondent Name & Address (*if different than PI*): same			
Campus Phone:	**Fax:**	**E-mail:**	
Yale Cancer Center CTO Protocol Correspondent Name & Address (*if applicable*):			
Campus Phone:	**Fax:**	**E-mail:**	

Faculty Advisor:(required if PI is a student, resident, fellow or other trainee) ☒ **NA**		**Yale Academic Appointment:**	
Campus Address:			
Campus Phone:	**Fax:**	**Pager:**	**E-mail:**

List all other investigators and study personnel:

Name: Eric Chen Role: Co-Investigator Affiliation: Yale [redacted]

Name: Feng Dai Role: Co-Investigator Affiliation: Yale [redacted]

Name: Adambeke Nwozuzu Role: Co-Investigator Affiliation: Yale [redacted]

Name: Role: Affiliation: NetID:

Investigator Interests:

Does the principal investigator, or do any research personnel who are responsible for the design, conduct or reporting of this project or any of their family members (spouse or dependent child) have an incentive or interest, financial or otherwise, that may affect the protection of the human subjects involved in this project, the scientific objectivity of the research or its integrity? Note: The Principal Investigator (Project Director), upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

See Disclosures and Management of Personal Interests in Human Research
http://www.yale.edu/hrpp/policies/index.html#COI
Yes ☐ No ☒

Do you or does anyone on the research team who is determined by you to be responsible for the design, conduct or reporting of this research have any patent (sole right to make, use or sell an invention) or copyright (exclusive rights to an original work) interests related to this research protocol?
Yes ☐ No ☒
If yes to either question above, list names of the investigator or responsible person:

The Yale University Principal Investigator, all Yale University co-investigators, and all Yale University individuals who are responsible for the design, conduct or reporting of research must have a current financial disclosure form on file with the University's Conflict of Interest Office. Yale New Haven Hospital personnel who are listed as con-investigators on a protocol with a Yale University Principal Investigator must also have a current financial disclosure form on file with the University's Conflict of Interest Office. If this has not been done, the individual(s) should follow this link to the COI Office Website to complete the form: http://www.yale.edu/coi/

NOTE: The requirement for maintaining a current disclosure form on file with the University's Conflict of Interest Office extends primarily to Yale University and Yale-New Haven Hospital personnel. All Yale faculty, graduate students, post-docs and fellows conducting research are required complete the annual disclosure. **Whether or not they are required to maintain a disclosure form with the University's Conflict of Interest Office, all investigators and individuals deemed otherwise responsible by the PI who are listed on the protocol are required to disclose to the PI any interests that are specific to this protocol.**

A. Principal Investigator Assurance

As the Principal Investigator of this research project, I certify the following:

- The information provided in this application is complete and accurate.
- I assume full responsibility for the protection of human subjects and the proper conduct of the research.
- Subject confidentiality will be of paramount concern, and every effort will be made to protect subjects' rights and welfare.
- The research will be performed according to ethical principles and in compliance with all

federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.

- All members of the research team will be kept apprised of research goals.
- I will obtain approval for this research study and any subsequent revisions prior to initiation.
- I am in compliance with the requirements set forth in the Yale University Faculty Handbook and qualify to serve as the Principal Investigator of the project or have acquired the appropriate approval from the Dean's office or Office of the Provost, or Yale New Haven Hospital general counsel.
- My signature below provides written assurance that subjects' Protected Health Information (PHI) will not be used or disclosed except as required by law, for authorized oversight of research or for conducting secondary research only if that research has been reviewed and approved by the HIC.

Signature of PI _____ 4/14/2016 Date

B. Faculty Advisor Assurance

As the **faculty advisor** of this research project, I certify that:

- The information provided in this application is complete and accurate.
- This project has scientific value and merit and that the student or trainee investigator has the necessary resources to complete the project and achieve the aims.
- I will train the student investigator in matters of appropriate research compliance, protection of human subjects and proper conduct of research.
- The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.
- The student investigator will obtain approval for this research study and any subsequent revisions prior to initiating the study or revision and will obtain continuing approval prior to the expiration of any approval period.
- The student investigator will report to the HIC any serious injuries and/or other unanticipated problems involving risk to participants.
- I am in compliance with the requirements set forth by the University and qualify to serve as the faculty advisor of this project.

_____ _____

Signature of Faculty Advisor (If Applicable) (Print or Type Name)

_____

Date

C. YNHH Human Subject Protection Administrator Assurance Statement

Required when the study is conducted solely at YNHH by YNHH Health Care Providers

As Human Subject Protection Administrator (HSPA) for YNHH, I certify that:

* I have read a copy of the protocol and approve its being conducted at YNHH
* I agree to notify the IRB if I am aware of any real or apparent institutional conflict of interest
* The Principal Investigator of this study is qualified to serve as PI, and has the support of the Hospital for this research project.

_____ _____

YNHH HSPA Name (PRINT) and Signature Date

D. Project Information

1. Funding Source: (Specify Federal, Private, Industry or Department source, etc. If grant funded, provide the "M" number from the ProSum, and the grant number, if known.)
-Summer research fellowship from the Office of Student Research (Yale School of Medicine)

2. Purpose of the study: (describe briefly, including hypothesis, research plan and possible risks and benefits).
This study proposes to perform a descriptive analysis and pilot observational study looking at the types and quantity of anesthetic agents used and their associations with outcomes among patients scheduled to receive transfemoral aortic valve replacements (TAVR) at YNHH.
Hypothesis 1: TAVR surgery done under monitored anesthesia care are performed using some combination of the following anesthetics: dexmedetomidine, propofol, fentanyl, and midazolam.
Hypothesis 2: Age-adjusted dosing of these agents will be insufficient to account for extreme age after controlling for preoperative comorbid status.
Hypothesis 3: The rate of conversion to general anesthesia will be unrelated to the type of conscious sedation used.
Hypothesis 4: ICU length of stay, delirium, hospital length of stay, and length of hospital stay will be shorter for patients who were sedated using dexmedetomidine vs those without.

Research Plan: The research will be done via chart review and analysis of data already contained in the Multicenter Perioperative Outcomes Group databases at Yale (the latter is a research database approved under HIC# 1206010438).

The possible risks are primarily the risk to privacy that is inherent in any retrospective chart review. The benefit may be to suggest areas of future study to improve sedation practices for TAVR at Yale and elsewhere.

3. A. Will information be collected from sources other than YSM or YNHH (including Yale-New Haven Health System partners, e.g., Greenwich Hospital, Bridgeport Hospital)?
Yes ☐ No ☒

B. If yes, please indicate the location: _____

C. Has IRB approval from those sites been obtained? If so, upload the letters with this submission. Please note the Yale University HIC is not the IRB of record for Greenwich Hospital or Bridgeport Hospital NA

i. International? Yes ☐ No ☐
(please note that this may require that you coordinate with that facility for access to the records)

4. Estimated number of records to be reviewed:
200

5. Criteria for inclusion/exclusion:
Patients who underwent TAVR under conscious sedation with MAC rather than general anesthesia.

6. Probable duration of study: (Please state the expected duration of the project, including all data analysis activities).
5 years

7. Does the PI or any other member of the research team have a direct existing clinical relationship with the subjects whose records will be reviewed?

☐ Yes, all subjects
☒ Yes, some of the subjects
☐ No

If yes, describe the nature of this relationship.
The PI is a practicing cardiac anesthesiologist at YNHH. He was the anesthesiologist for some of the TAVR cases.

8. A. Is this review retrospective? Yes ☒ No ☐
a. Dates of the medical records that will be reviewed
B. Is this review prospective? Yes ☐ No ☒
a. Dates of the medical records that will be reviewed _____to _____ ___
C. Is this review both retrospective and prospective? Yes ☐ No ☒ If at all prospective, consider whether verbal or signed consent should be obtained. If consent is to be obtained see Appendix I for required additional questions.
Should consent be obtained? Yes ☐ No ■
If no, explain why not: _____

a. What information will be collected and recorded?
Information recorded will include demographic and preoperative medical assessment from prior to the TAVR, the anesthetic record, and the post-operative course of recovery for patients undergoing TAVR. These data will include age, gender, comorbidities, laboratory values, vital signs, and the results of imaging studies as well as other records potentially related to the above hospitalization.

Requests for medical records should be made through JDAT as described at
http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx

Note: Medical record data for extraction will occur via the Multicenter Perioperative Outcomes Group database and the associated EPIC record as described above and as approved under HIC# 1206010438.

List all data to be recorded from the chart (i.e., MRN, name, diagnosis). Only those items listed on this application may be requested from JDAT. Note that only the minimum information necessary to conduct the research should be used.

MRN, demographic and preoperative medical assessment from prior to the TAVR, the anesthetic record, and the post operative course of recovery for patients undergoing TAVR. These data will include age, gender, comorbidities, laboratory values, vital signs, and the results of imaging studies as well as other records potentially related to the above hospitalization.

o Identify the type of medium that will be used to record the information and the plans for maintaining confidentiality and security of the data.

Only Yale / YNHH approved computers with appropriate HIPAA compliant encryption will be used for data storage and analysis.

o Also indicate who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored.

Only the investigators will have access to the data which will be monitored by the PI.

***Note**: Investigators are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media. Identifiers and code keys must be stored in a secure manner, e.g., Yale network servers. If identifiers are stored on moveable media then investigators must use encryption methods to protect access to these files or other methods as appropriate for the types of information stored on these devices.*

b. How will the data and/or identifiers be destroyed when no longer needed for research purposes?

Data on the Multicenter Perioperative Outcomes Group database are maintained by YNHH IT, and there are no plans to destroy those records.

If it will not please explain why data must be retained, for how long and how it will be kept secured.

The data are contained in an ongoing perioperative data repository already approved by the HIC.

c. Waiver of Consent/Waiver of HIPAA Authorization: Complete the following:

a) Does the research pose greater than minimal risk to subjects?
No

b) Will the waiver adversely affect subjects' rights and welfare?

No
c) Explain why the research could not practicably be carried out without the waiver.
The number and types of patients in the MPOG database are too numerous to be possible without a waiver.

d) Are there any plans to provide subjects with additional pertinent information after their records have been reviewed? ☒ No ☐ Yes
If yes,

e) How will pertinent information be returned to subjects, if appropriate at a later date?

NA

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the "accounting for disclosures log", by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

By signing this protocol application, the investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

APPENDIX I

Waiver of signed consent: (Verbal consent from subjects will be obtained. Note that an information sheet may be required.)

If requesting a waiver of signed consent, please choose one of the following criteria:
a. Would the signed consent form be the only record linking the subject and the research?
☐ Yes ☐ No
b. Does a breach of confidentiality constitute the principal risk to subjects?
☐ Yes ☐ No

OR

a. Does the research pose greater than minimal risk? ☐ Yes ☐ No
If you answered yes, stop. A waiver cannot be granted.
b. Does the research include any activities that would require signed consent in a non-research context? ☐ Yes ☐ No

If consent will be obtained (verbal or written), please address the following:

1. **Consent Personnel:** List the names of all members of the research team who will be obtaining consent/assent.

2. **Process of Consent/Assent:** Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects' independent decision-making.

3. **Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent:** Indicate how the personnel obtaining consent will assess the potential subject's ability and capacity to consent to the research being proposed.

4. **Documentation of Consent/Assent:** List the documents that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given to subjects.

5. **Non-English Speaking Subjects:** Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. Translated copies of all consent materials must be submitted for approval prior to use.