eResearch M REGULATORY MANAGEMENT

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01. General Study Information

All questions marked with a red asterisk (*) require a response. Questions without a red asterisk may or may not require a response, depending on those questions' applicability to this study.

1.1* Study Title:

Multicenter Perioperative Outcomes Group (MPOG) and Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) Performance Site

1.1.1 Full Study Title:

Multicenter Perioperative Outcomes Group (MPOG) and Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) Performance Site

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

HUM00024166 - Multicenter Perioperative Outcomes Group (MPOG) and Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE)

1.2* Principal Investigator:

Sachin Kheterpal
Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Sachin Kheterpal	PI	Anesthesiology Department	Yes	no	No	no	yes	N/A	yes
Nirav Shah	Co-Investigator	Anesthesiology Department	Yes	no	No	no	yes	Yes	yes
Victoria Lacca	Study Coordinator/Project Manager	Anesthesiology Department	Yes	no	No	no	yes	Yes	yes
Amy Shanks	Study Coordinator/Project Manager	Anesthesiology Department	Yes	no	No	no	yes	Yes	yes

1.8* Project Summary:

The Multicenter Perioperative Outcomes Group (MPOG) is a consortium of anesthesiology departments of academic medical centers with electronic perioperative information systems. The purpose of MPOG is to allow multi-institutional collaboration for the purpose of accelerating outcomes research in perioperative medicine. The Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) is a sub-group of MPOG and is focused on using data to assess variation in practice, identify local/regional best practices, measure process adherence and patient outcomes, create programs for quality improvement, and enable collaboration among anesthesiologists, surgeons, and CRNAs. ASPIRE will also develop research topics which will lead to quality assurance research projects.

MPOG was developed so that institutions across the globe can join together to pool their electronic perioperative data into a common research database. These limited datasets are to be used for clinical outcomes and quality assurance research purposes by the physicians of the institutions. The database also includes administrative information and outcomes data from these institutions. MPOG will have a coordinating center that receives a limited dataset (only date of service will be uploaded into the repository) which will merge the data into one centralized database.

This IRB is for the University of Michigan to become a performance site for MPOG and ASPIRE to upload the University of Michigan limited dataset from our anesthesia electronic information systems to the MPOG coordinating center repository. MPOG has a Perioperative Clinical Research Committee (PCRC) which is comprised of members of institutions who are contributing data. The PCRC serves as the publication committee of MPOG and ASPIRE responsible for reviewing, refining, and modifying any research proposals and manuscripts created by researchers at active/contributing institutions. All proposed research studies using data from the central MPOG database must pass a peer-review process by the PCRC prior to submission for publication.

Patients included will be from all age groups and all medical conditions. There are no exclusions. All

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data will be scrubbed for any identifiable information prior to sending to MPOG central repository for merging into a MPOG database. There will be no patient identifiers stored in the MPOG central repository and no members of the research team will ever have access to identifiers. Automated database extraction process will be performed on secure UMHS servers. The only PHI element collected will be date of service.

1.9* Select the appropriate IRB:

IRBMED

1.10* *Estimated* Study Start Date (Not required for IRBMED): *(mm/dd/yyyy)*

5/1/2009

1.11* *Estimated* Duration of Study:

10 years

01-1. Application Type

1-1.1* Select the appropriate application type.

Standard, non-exempt, research project

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

If other, please specify:

1-2.2* Are you or any students working on this project being paid from a federally funded training grant?

Yes **No**

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

Anesthesiology Department

1-2.4 Will the study utilize resources from the following centers?

Select all that apply:

There are no items to display

1-2.5* Does this study require review by the UM Health System Comprehensive Cancer Center Protocol Review Committee (PRC)?

Yes **No**

1-2.6* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

Yes No

1-2.6.1* List the peer-review organization(s).

Peer Review Organization

Other (explain below)

The MPOG Perioperative Clinical Research Committee (PCRC) will review all research proposals for scientific validity.

1-2.7* Is this a clinical trial?

Yes **No**

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1-2.8* Would the integrity of this research study be compromised if the subject were able to view results of their research tests or medications in the Patient Portal of MyUofMHealth.org? Research results displayed to the subject in MyUofMHealth.org will include: lab results, radiology examinations and outpatient medication lists. Contracts and protocols should be assessed by the Principal Investigator for specific language regarding blinding of subjects and their research results.

(NOTE: Additional actions are required in order to limit the subject's view into their electronic medical record. Contact the IRB for additional information or see additional guidance for blinded studies at http:// medicine.umich.edu/ medschool/ research/ office-research/ institutional-review-boards/ guidance/ blinded-studies)

○ Yes ◉ **No**

Study Team Detail

1.4 Team Member:

Sachin Kheterpal

Preferred email:	sachinkh@med.umich.edu
Business phone	734-936-4280
Business address:	UMH Anesthesiology 1H247 UH SPC 5048 48109-5048

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/ stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: *(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)*

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Kheterpal CV 2-2015 | History	0.01
SachinKheterpalCV | History	0.01

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

C1 Do you, your spouse, domestic partner, or dependents have any outside interests or relationships to companies or entities related to this research that the IRB should consider?

Examples of outside interests include, but are not limited to the following:

- receiving compensation whose value could be affected by the study outcome
- IN THE AGGREGATE, expecting to receive compensation from the sponsor of the research of $10,000 or greater in the next year
- having a proprietary interest in the sponsor of the research or a product tested by this research including but not limited to, a patent, trademark, copyright, or licensing agreement, or the right to receive royalties from product commercialization
- individually or collectively, having an ownership interest (equity or stock options) in the sponsor of the research or product being tested whose value cannot be readily determined through reference to public prices
- individually or collectively, having an ownership interest (equity or stock options) in a company or product whose value could be affected by the study outcome
- IN THE AGGREGATE, having an ownership interest (equity or stock options) in the sponsor of the research that exceeds $10,000 or 1% when the sponsor is a publicly traded entity
- receiving significant payments of other sorts with an aggregate value of $10,000 or more (or payment of ANY amount to medical school or hospital employees) made directly by the sponsor of this research for unrestricted research or education, equipment, consultancy, or honorarium
- holding a position of management or leadership in company or entity related to this research including, but not limited to, officer, director, or member of an advisory board.

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- providing consulting services or serve on a Speaker's Bureau, either paid or unpaid, to the financial or non-financial sponsor of this study
- when the sponsor is a publicly traded entity, having any ownership interest (equity or stock options) in the sponsor
- expecting to receive any loans, educational support, contributions of in-kind for equipment, or any other non-compensatory payment from the sponsor of the research in the next year

C2 Please provide a detailed description of the outside interest in the box below.

C2.1 Where have you submitted a disclosure of this outside interest?

C2.2 Has a management plan been formalized?

C2.2.1 Click the View Management Plan in M-Inform button below to see your management plan for this study.

C2.2.2 If no, describe the financial interest in sufficient detail to permit the COI Ancillary Committee and the IRB to determine if such involvement represents a potential conflict-of-interest and/or should be disclosed to potential research subjects in the informed consent form.

Study Team Detail

1.4 Team Member:

Nirav Shah

Preferred email:	nirshah@umich.edu
Business phone	734-936-4280
Business address:	Anesthesiology 1H247 UH SPC 5048 48109-5048

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
NiravShah_CV_6_06.doc | History	0.01
Shah CV 2-2015 | History	0.01

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Study Team Detail

1.4 Team Member:

Victoria Lacca

Preferred email:	lacca@umich.edu
Business phone	734-936-8081

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Business address: Anesthesiology 1H247 UH SPC 5048 48109-5048

1.5 Function with respect to project:

Study Coordinator/Project Manager

1.6 Allow this person to EDIT the application, including any supporting documents/ stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Study Team Detail

1.4 Team Member:

Amy Shanks

Preferred email: amysha@umich.edu
Business phone 734-936-0063
Business address: Anesthesiology Dept 1H247 UH SPC 5048 48109-5048

1.5 Function with respect to project:

Study Coordinator/Project Manager

1.6 Allow this person to EDIT the application, including any supporting documents/ stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
CURRICULUM VITAE.doc | History	0.03

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

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02. Sponsor/ Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.

* Note: At least one of the following sections must be answered. Multiple sponsors or sources of support must be added one at a time.

2.1 External Sponsor(s)/ Support:

Type	Name	Other Direct Sponsor/Support	Support Type	Has PAF?

There are no items to display

2.5 Internal UM Sponsor(s)/ Support: [Including department or PI discretionary funding]

Type	Department Sponsor	Support Type

There are no items to display

2.8 Check here if the proposed study does not require external or internal sponsorship or support:

☑

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:

- Secondary data collection (e.g., medical chart review, data abstraction from existing records, etc.)
- Primary or secondary analysis (data/specimen)
- Storage (data/specimen)
- Other

If other, please specify.
UM is both the clinical coordinating center and an enrolling site. A separate application exists as UM as a coordinating site.

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Site Function
University of Michigan	USA	yes	Storage,Other,Analysis,Secondary data collection

Performance Site Detail

3-1.2* Location or Institution:

University of Michigan

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

- Secondary data collection (e.g., medical chart review, data abstraction from existing records, etc.)
- Primary or secondary analysis (data/specimen)
- Storage (data/specimen)
- Other

If other, please specify:

UM is both the clinical coordinating center and an enrolling site. A separate application exists as UM as a coordinating site.

3-1.5* Will this site be "engaged" in the conduct of the research?

Yes No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

FWA00004969

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

05. Research Design

5.1* Is there a stand-alone scientific protocol document and/ or research plan associated with this application?

Yes **No**

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

Yes No

5.2.1* How many subjects are represented in the data or specimens to be analyzed?

1000000 *(do not enter commas, dots, or special characters)*

5.3* Will the study involve recruitment and/ or participation of subjects in order to produce new data *(e.g., surveys, interaction, intervention)*? *[Require sections 8-1 and 11-3]*

Yes **No**

5.4* List the inclusion and exclusion criteria for this study population and/ or data set. *(If covered in attached protocol, indicate section)*

Inclusion: All adult and pediatric patients undergoing perioperative services at the University of Michigan Health System. There are no exclusion criteria.

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

None

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 0
Maximum Age: 999 If no upper limit, enter "999"

05-1. Research Design

In its review of research applications, the IRB considers whether research procedures are consistent with sound research design in order to yield the expected results. Scientific merit is examined in relationship to the risks and benefits of the research. This section covers the overall research design of the project. Later sections will ask more specific questions about benefits, risks, special review considerations, targeted populations, recruitment strategies, and experimental methodologies/ procedures.

5-1.1* Objective: What is the overall purpose of this research study?

To identify the perioperative adverse events, and changes in resource utilization associated with variation in perioperative management. Create quality measures focusing on quality improvement and as a result will include quality focused research.

5-1.2* Specific Aim(s): What is (are) the specific aim(s) of this study and/ or what hypothesis (hypotheses) is (are) to be tested?

Specific Aim 1: To aggregate patient data enabling investigation of infrequent adverse events, patient conditions, and operations

Specific Aim 2: To allow our institution to gain access to a large, international limited dataset necessary for observational and quality research

Specific Aim 3: To combine detailed physiologic data and anesthesiology interventions with long term outcomes recorded in surgical outcomes, administrative, and financial databases

5-1.3* Background: What prior information or knowledge exists to support the conduct of this study?

The traditional prospective, randomized controlled trial (RCT) is a mainstay of medical research. However, although RCTs are regarding as the gold standard of medical research, there are many clinical conundrums that cannot be effectively addressed by a prospective RCT. Observational studies are often the only option for research into
- Infrequent adverse events associated with a medication
- Emergency operations challenging conventional consent and randomization systems
- Generic medications without a reliable pharmaceutical funding sources
- Safety studies of medical procedures
- Ethnic and racial groups that are not appropriately represented in prospective RCTs
- Rare perioperative events
- Efficacy and safety of a treatment once applied to a broad patient population as opposed to specifically targetted group in an RCT

For these and many other clinical questions, the only practical research structure is a large observational dataset based upon existing information system data elements. By combining point-of-care clinical information systems with clinical registries, financial data, laboratory information systems, radiology information systems, administrative datasets, and scheduling datasets, one can address previously unanswerable clinical questions. Though causality cannot be concluded, these hypothesis generating studies are crucial to the advancement of clinical science.

Specifically, the field of perioperative medicine has witnessed a major improvement in safety over the last few decades. As a result, many of the morbidity endpoints (death, myocardial infarction, pulmonary complications, nerve injury) previously followed are now occurring with a frequency far too low (< 1%) for prospective enrollment in controlled trials. However, the importance of these morbidity endpoints cannot be diminished for the patients and families experiencing them. Alternative study techniques must be used to continue the necessary improvements in patient safety and satisfaction.

Recent literature has demonstrated the value of large dataset research in altering clinical practice. The widespread use of beta blockers for moderate risk patients and the routine use of aprotinin for cardiac surgery have both been called into question as a result of large clinical dataset research. These landmark hypothesis generating studies then led to large RCT that eventually identified an unacceptable risk profile for certain patients, leading to major changes in the perioperative use of these drugs.

5-1.4* *Briefly* outline the special expertise and qualifications of the PI, Co-Investigators, and/or Faculty Advisors to conduct and/or oversee the particular procedures or activities involved in *this particular study*. This will supplement information provided in the study team CVs.

Dr. Kheterpal is an assistant professor in the Department of Anesthesiology with expertise in perioperative clinical outcomes research. He has served as a systems designer, database architect, and data warehouse architect for over 15 years, creating a deep information technology and clinical informatics knowledgebase. He has previously used retrospective analysis of clinical documentation databases to publish studies in leading peer-reviewed anesthesiology journals. In addition, he has served as a representative to the anesthesia patient safety foundation.

Dr. Shah is an assistant professor in the Department of Anesthesiology with expertise in medical informatics and quality. He is the Director of Informatics and Systems Integration for the Department of Anesthesiology and the University of Michigan Health System. He has served as a systems designer, database architect both in industry and at academic institution for over 10 years. He brings a technical and medical background that will help to integrate the software and analytic system.

5-1.5* Methodology: Describe the design and procedures to be used to accomplish the specific aims of the study. Describe the advantages of any innovative methodologies.

The perioperative clinical information system, several UMHS surgical outcome databases, laboratory data, administrative data, and financial data will be merged together by data analysts at our institution. The original data already exists in clinical or administrative information systems and was collected by clinical providers and administrative processes as part of routine care. No additional data will be collected or requested. The clinical care delivered and documentation will remain unchanged. The standard data extract and submission will not involve a review of individual patient records for additional data items. All patient identifiers (name, DOB, address, etc) will be automatically removed once the data merging at our institution is complete.

Data will be stored on UMHS MCIT-approved and secured equipment. No patient identifiers will be stored. The existing information system architecture completely separates patient identifiers from clinical data. These enables automated, facile, and error-proof removal of patient identifiers.

All data will be encrypted using standard relational database management system storage techniques. On a regular basis (semi-annual or annual), new data will be transmitted to the coordinating center. These data will not contain any patient identifiers. The only PHI included will be date of service / surgery. The transmission will be using a secure-socket-layer / transport-layer-security encryption to ensure that data 'eavesdropping' is avoided during transmission of the data to the coordinating center.

After data is received by the coordinating center, a centralized process will be used to map and cleanse the raw data into tables that are more usable for large dataset research purposes. This process will not require the use of any protected health information. It will be impossible to identify the identity or a patient from the centralized database. The data will be stored on secured servers, with multiple password security layers for access. The data will be stored behind a firewall that eliminates access to/from the internet, with the resulting improvement in data security.

Only performance site data interface servers will be given access to the database server through the firewall. All other internet traffic and communication will be excluded.

In rare situations, research investigators using the centralized or performance site database may observe a rare clinical event that requires additional data extraction. Every case in the centralized repository and at each performance site will have a distinct patient system number (that is randomly generated) that is NOT a patient identifier. This system number is NOT related to or derived from any PHI (ie, name, reg num, DOB, etc). The centralized MPOG repository has no way of using this random system number to link to any patient identifiers. If a rare clinical event that requires additional data extraction is observed, this non-PHI system number will be provided to a performance site. Technical staff at the performance site can access their own source databases in an attempt to link the system number to PHI. This linkage exists in the source clinical information system, not in any research database proposed by this project. If they choose to, the performance site may use this system number to extract and provide additional de-identified clinical data to the coordinating center investigators. No patient contact will occur. All additional data extracted would be from existing clinical and administrative data sources.

The Coordinating Center will be the University of Michigan Health System

5-1.6* Statistical Design: Describe the statistical design of the research study, including methods used to analyze data.

A variety of statistical techniques often used for large dataset research will be used. Each approved research question may use distinct techniques, so it is beyond the scope of this document to prospectively delineate a complete statistical plan. Logistic regression modeling (GEE and standard), propensity score matching, cox proportional hazard modeling, and basic univariate comparisons are a few of the many techniques that will be used. Descriptive and inferential statistical techniques will be employed.

06-1. Benefits and Risks - Secondary Use

Completion of this section is required based on the response provided to questions 1-1.1, 5.2 and 5.3.

6-1.1 * Describe the potential benefits of this research to society.

There are many critical potential benefits of this research to society. Currently, perioperative mortality due to anesthesia is extremely rare: 1 / 200,000 cases. However, there are several perioperative complications that have devastating long term impact upon patients:
1) failure to secure an adequate airway resulting in hypoxic brain injury
2) epidural hematoma and/or abscess resulting in permanent paraplegia
3) bilateral ischemic optic nephropathy causing permanent complete blindness
4) intraneural injection of local anesthetic during peripheral nerve blockade causing permanent motor deficit
5) pulmonary injury general anesthesia causing acute respiratory distress syndrome
6) immunosuppresive effects of erythrocyte administration causing infections and cancer progression
7) perioperative renal and cardiac ischemia causing permanent renal failure or ischemic cardiomyopathy

There are limited or NO data regarding which perioperative management techniques can decrease the likelihood of these rare events. As a result, anesthesiologists, surgeons, and intensivists are currently forced to adopt theoretically practice patterns that optimize the medicolegal safety. For example, subcutaneous heparin is held in patients with an epidural because of concerns of paraplegia from epidural hematoma. There are no data to support this widespread practice, which many believe is resulting in more frequent DVTs and pulmonary emboli.

The goal of this research and quality project is to help every patient undergoing a procedure. The aggregation of large numbers of patient records is essential to identify the specific patients and risk factors responsible for these devastating events. Papers by Lindenauer and Mangano in NEJM have demonstrated that hundreds of thousands of records must be aggregated to use the sophisticated statistical techniques necessary (propensity score matching, etc).

The complications listed above are just a sampling of the outcomes that will be addressed by this project. All of these outcomes are rare (< 1% to < 0.01%). As a result, prospective enrollment is impossible. Some researcher choose to enroll high risk patients only, resulting in new knowledge that is inappropriately applied to the population at large. An example of this major error is the use of beta-blockers to decrease the risk of perioperative myocardial infarction or aprotinin to decrease operative bleeding. Small, prospective studies (funded by pharma) in high risk patients were then applied to patients at large. Years later, large, de-identified patient data research demonstrated that the data were not applicable to the general population and that thousands of patients were harmed by the use of these drugs.

We hope to help avoid the repetition of such clinical errors.

6-1.2 * Will results of the research be communicated back to the subjects?

○ Yes ◉ **No**

6-1.3 * Are multiple benefit or multiple risk levels applicable?

○ Yes ◉ **No**

6-1.4 * Benefits and Risks:

Click "Add" to begin entering the benefit and risk level detail information associated with this study.

	Name	Risk Level	Direct Benefit
View	HUM00025285	No more than minimal risk	no

Benefits and Risk Level Detail - Secondary Use

If the study involves multiple arms or phases that pose different levels of risks or direct benefits to subjects, then create an entry for each arm or phase using the "OK and Add Another" option at the bottom of this page. Only one entry is necessary if the risk level and the direct benefit to subjects is the same for the entire project, even if the study involves multiple arms or phases.

6-1.4.1 * Name of Arm.

HUM00025285

6-1.5 * Are there potential direct benefits of this research to the subjects?

Yes **No**

6-1.6 * The primary risk of conducting research with secondary data or specimens is a breach of confidentiality or privacy, which may cause psychological, social/ reputation, legal, or financial harm. Indicate any risks to subjects other than these risks from a breach of confidentiality or privacy.

Clinical / Physical / psychological / social / reputation / financial Risk
- Likelihood: None
- There will be no care interventions, no process changes, no documentation changes, and no alterations to a patient's clinical experience. Providers will not experience any changes in their roles, responsibilities, or care. De-identified data will be extracted months AFTER the clinical care episode is complete. The database servers employed are not production servers and no application performance changes will be experienced

Privacy
- Likelihood: None to Extremely Rare
- Theoretically, since patient data is being extracted, there exists a non-zero privacy risk. However, since the data extraction process is automated and the data structures involved separate patient identifiers from the data being extracted, the likelihood is EXTREMELY rare. Patient identifiers (DOB, Name, MRN, Insurance account numbers, SSN) are NOT stored or transmitted at any point during the data extraction or transmittal process.
- To further mitigate this risk, all data extraction processes are automated to eliminate the possibility of human error. No research personnel are required to 'match' or review identifiers.
- All database work is performed on UMHS-MCIT approved and secured servers that are physically located in the UMHS computing environment and maintained by MCIT security standards
- No patient identifiers will ever be stored or transported on portable computing devices (laptops, USB drives, CD, DVD, etc) that can be lost or misplaced

6-1.7 * What is the level of risk of harm to the subjects, resulting from this arm of the research? For studies involving multiple arms or phases, enter the level of risk for this arm or phase only.

No more than minimal risk

07. Special Considerations

7.1* Does this study involve human tissue or biological specimens (use, collection, or secondary analysis) *(e.g. blood, urine, bone marrow, skin, etc.)? [Require Section 18]*

Yes **No**

7.2* Does this study involve the secondary analysis of a pre-existing data set, including data associated with any specimens identified in response to question 7.1? *[Require Section 24]*

Yes No

7.3* Will the research involve the access, collection, use, maintenance, or disclosure of University of Michigan protected health information (PHI)? PHI is:

- **information about a subjects past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **maintained by a University of Michigan school, department, division, or other unit that is part of the University's HIPAA-covered component (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).**

[Require Section 25]

Yes No

09-2. Subject Populations - Secondary Use

9-2.1* Is the research designed to include or allow the following populations?

Select all that apply

- [x] **Normal, healthy subjects**
- [x] **Adults** *age 18 and older*
- [x] **Minors able to consent** *to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (e.g. emancipated minors or minors seeking treatment for certain conditions.)*
- [x] **Children and/ or Viable Neonates** *(i.e. persons who have not yet reached the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) [Require Section 33-1.]*
- [ ] **Neonates of uncertain viability and/ or nonviable neonates** *(do not check this box if the research is solely retrospective. For retrospective research regarding neonates of uncertain viability, check the box for "Children'. See Help for additional information.) [Require Section 34]*
- [ ] **Individuals and/ or products involving human in vitro fertilization**
- [x] **Pregnant women and/ or fetuses** *[Section 35-1]*
- [ ] **Lactating women**
- [x] **Women of child-bearing potential**
- [ ] **Prisoners** *(If the research includes a study population that is likely to become incarcerated during the conduct of the research, also select this category) [Require Section 38]*
- [x] **Cognitively impaired adults**
- [x] **College students**
- [ ] **Economically or educationally disadvantaged persons**
- [ ] **Patients of the study team**
- [ ] **Employees, students or trainees of the study team**
- [ ] **Family members of the study team**
- [ ] **Unknown, unspecified population**

10. Informed Consent - Secondary Use of Existing Data/ Records/ Specimens

Completion of this section is required based on the response provided to questions 1-1.1, 5.2 and 5.3.

10.3* What type of informed consent will be obtained from subjects for the use of their data, records and/ or specimens?

Select all that apply:

Request for waiver of informed consent/parental permission/legally authorized representative consent

10-3. Informed Consent Waiver

10-3.1* This request is for:

Select all that apply:

Waiver of informed consent for ALL of the project (Note: Consent cannot be waived if the study is subject to FDA oversight)

10-3.1.1 If this request is for PART of the project, identify the specific research procedures *(e.g., screening interview)* and/ or the specific subject populations *(e.g., parents of child-subjects)* involved.

10-3.1.2 Explain any requested alterations to the informed consent process.

10-3.2* Check below to affirm that this study meets each of the following four criteria for waiver or alteration of informed consent and explain how:

- [x] The research involves no more than minimal risk to the subjects.

  Explain:
  Clinical / Physical / psychological / social / reputation / financial Risk
  - Likelihood: None
  - There will be no care interventions, no process changes, no documentation changes, and no alterations to a patient's clinical experience. Providers will not experience any changes in

their roles, responsibilities, or care. A limited dataset will be extracted months AFTER the clinical care episode is complete. The database servers employed are not production servers and no application performance changes will be experienced

Privacy Risk
- Likelihood: None to Extremely Rare
- Theoretically, since patient data is being extracted, there exists a non-zero privacy risk. However, since the data extraction process is automated and the data structures involved separate patient identifiers from the data being extracted, the likelihood is EXTREMELY rare. Patient identifiers (DOB, Name, MRN, Insurance account numbers, SSN) are NOT stored or transmitted at any point during the data extraction or transmittal process.
- To further mitigate this risk, all data extraction processes are automated to eliminate the possibility of human error. No research personnel are required to 'match' or review identifiers.
- All database work is performed on UMHS-MCIT approved and secured servers that are physically located in the UMHS computing environment and maintained by MCIT security standards
- No patient identifiers will ever be stored or transported on portable computing devices (laptops, USB drives, CD, DVD, etc) that can be lost or misplaced

☑ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
Explain:
The welfare of the patient is not be adversely affected whatsoever.

The rights of the patient will not be adversely affected because the risk of the right to privacy is extremely low. In fact, creating an informed consent (written or informational sheet) process would invariably decrease the patient's right to privacy and welfare. As currently proposed, no research personnel would ever access or use the patient identifiers or information. The patient would be completely unaffected by the conduct of the study.

If an informed consent or opt-out process were required, then research personnel would need access to the patients name, reg num, operation, diagnoses, etc. The risk of privacy loss would INCREASE due to the consenting / opt-out process rather than decrease. Maintaining a list of patients that opted-out would require the storage of their identifiers in either paper or electronic format. The privacy risk would increase as a result.

☑ Research could not practicably (i.e., feasibly) be carried out without the waiver or alteration.
Explain:
There are two major reasons the research would not be feasible:

1) selection bias introduced by a consenting or opt-out process. Because of the low frequency nature of the events being studied, the selection bias introduced by a signed informed consent or informational sheet would make the research impossible to perform. For example, some of the events we hope to study have an incidence of 0.16% and require the collection of data on 15,000 patients to observe only 37 events. A single patient opting out would significantly impact the ability to gain new knowledge in such clinical areas. More importantly, the patients most likely to opt out may be focus of specific rare event research (eg, uncontrolled postoperative pain in chronic pain patients)

2) Secondly, it is not practicable to consent the hundreds of thousands of patients required to study these conditions. Acquiring written consent, documentation of consent, or opt-out capability for several hundred thousand patients would eliminate the ability to perform research on these low-frequency events. Because it is unknown which patients will have an event prior to the event occuring, all perioperative patients must be included in the dataset. The events and situations being evaluated are often extremely low incidence (ie, < 1%), making prospective enrollment prohibitive. The infrastructure necessary to manage even a simple informational sheet / addition to surgical consent would be massive and manual. If the patient has the ability to opt-out (assumed if there is an informational sheet / surgical consent change), then a manual process to record the medical record number, date of service, etc would have to be created. Study personnel would have to deployed 24 x 7 in the operative suite (since all surgeries are being evaluated) and a manual process to record the opt-outs would have to be funded. Furthermore, the manual recording of opt-outs would increase the privacy risk of the patient.

☑ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Explain:
NA. The information will be useful for future surgical patients, not for a specific patient.

11. Confidentiality/ Security/ Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? *[Require Section 11-1]*

◉ **Yes** ○ No

11.2* Explain how the subjects' privacy will be protected.

- Theoretically, since patient data is being extracted, there exists a non-zero privacy risk. However, since the data extraction process is automated and the data structures involved separate patient identifiers from the data being extracted, the likelihood is EXTREMELY rare. Patient identifiers (DOB, Name, MRN, Insurance account numbers, SSN) are NOT stored or transmitted at any point during the data extraction or transmittal process.
- To further mitigate this risk, all data extraction processes are automated to eliminate the possibility of human error. No research personnel are required to 'match' or review identifiers.
- All database work is performed on UMHS-MCIT approved and secured servers that are physically

located in the UMHS computing environment and maintained by MCIT security standards
- No patient identifiers will ever be stored or transported on portable computing devices (laptops, USB drives, CD, DVD, etc) that can be lost or misplaced

The statisticians, clinical researchers, and manuscript writers will not have access to the protected health information. Only a limited dataset (only identifier will be date-of-service) will be stored or sent to the coordinating center. Centralized resources would never be able to identify a specific patient.

11.3* How will the research records, data and/or specimens be protected against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:

- Restricted access
- Destruction of source data immediately after data collection (e.g., to preserve anonymity of a vulnerable population)
- Access rights terminated when authorized users leave the project or unit
- Individual ID plus password protection
- Routine electronic back up
- Encryption of digital data
- Network restrictions
- Security software (firewall, anti-virus, anti-intrusion) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project
- Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media)

If other please specify:

11.4* Will the research generate information that, if revealed, might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation [Require Section 11-2]

○ Yes ◉ **No**

11.5* Will data be provided to a repository as part of a data sharing agreement?

○ Yes ◉ **No**

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:

- Destroy

11.6.1* If the data and/or specimens will be destroyed, describe the specific plan that will be employed following the required retention period.

The identifiers will be removed during the data collection process and will be absent at the conclusion of the study and during the statistical analysis phase.

11-1. Identifiable Data

Completion of this section is required based on the response provided to question 11.1.

11-1.1* Indicate how subjects are identified in the research records.

Select all that apply:

- Indirectly -- linked to data record but stored separately (e.g., name, initials, phone number, SSN, or medical record number linked to data record but stored separately)

11-1.2* Explain the necessity for collecting or maintaining data linked to subjects' identities. If the information is covered in the attached protocol, please indicate section.

In order to combine disparate electronic data sources, the automated data extraction processes will use MRN (medical record number) and date of surgery to merge data. Laboratory, financial, perioperative CIS, outcome registry data is being merged together using an automated process that does NOT reveal PHI to any human or require manual data aggregation.

Once the query is completed, NO identifier information is retrieved, stored, or used. The only PHI element stored is date of surgery. This is essential to enable research into variation in quality by day of week or season of year.

Once the data are extracted from the source database, all identifiers are removed and destroyed and cannot be recreated

Only the database mining automated processes will have visibility to the patient identifier and not the statistical team, manuscript authors, or any members of coordinating center.

11-1.3* How long will the identifiers be retained?

The identifiers will not be retained. They will be accessed in the source databases (data warehouse, perioperative CIS, etc) during the query process, but not stored in the research database extract itself.

11-1.4* Will individually identifiable sensitive data be accessed, collected, used, maintained, or disclosed in the study?

(•) **Yes** ( ) No

11-1.4.1* Will a continuous, periodic, or automatic feed of sensitive data be set up to provide data directly from any University information system *(e.g., M-Pathways, U-M Data Warehouse, CareWeb)*?

(•) **Yes** ( ) No

11-1.4.2* Will sensitive data be accessed by individuals who are not University employees?

( ) Yes (•) **No**

11-1.4.3* Will sensitive data be stored on or accessed from computer equipment that is not maintained and supported by a University IT services provider (e.g., ITS, MCIT, MSIS) - such as home computers, grant-funded computers, etc.?

( ) Yes (•) **No**

11-1.4.4* Will sensitive data be stored on portable devices (e.g., laptops, PDAs, flash drives) in unencrypted form?

( ) Yes (•) **No**

24. Secondary Data Analysis

Completion of this section is required based on the response provided to either question 4-1.1 or 7.2.

24.1* List each pre-existing data set that will be used in the study.

Name	Identifying Info	Is Publicly Available
Centricity Clinical Information System	clinical data entered by clinicians and aggregrated from automated interfaces. Subject identifiers are used since this is our electronic medical record for the peri-operative process.	no
National Surgical Quality Improvement Program	Elements include preoperative comorbidities, laboratory values, procedural information, provider information, intraoperative information,and 30 day outcomes. Patient identifiers are used and stored.	no
Society of Thoracic Surgeons Database	patient comorbidities, operative characteristics and techniques, surgical and patient outcome	no
UMHS Data Warehouse	Financial charges, reimbursements for professional and facility fees. Also contains date of death, basic demographic information, and specialty specific databases: trauma registry, percutaneous coronary intervention, pulmonary function testing, electronic order entry orders and medication administration.	no

Secondary Data Set Detail

24.2* Name and source/ location of data set:

Centricity Clinical Information System

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

clinical data entered by clinicians and aggregrated from automated interfaces. Subject identifiers are used since this is our electronic medical record for the peri-operative process.

24.4* Is the data set you are analyzing publicly available?

( ) Yes (•) **No**

24.5* Does the data set contain:

Identifier
Direct Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

No

24.7.1* Indicate intention to obtain a waiver of informed consent (and, if applicable, HIPAA authorization) or describe the plan to re-establish the identifying links and re-consent individuals.

We are requesting a waiver of informed consent and waiver of HIPAA authorization. All date is de-identified after linking has occurred.

Secondary Data Set Detail

24.2* Name and source/ location of data set:

National Surgical Quality Improvement Program

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

Elements include preoperative comorbidities, laboratory values, procedural information, provider information, intraoperative information,and 30 day outcomes. Patient identifiers are used and stored.

24.4* Is the data set you are analyzing publicly available?

Yes **No**

24.5* Does the data set contain:

Identifier
Direct Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

No

24.7.1* Indicate intention to obtain a waiver of informed consent (and, if applicable, HIPAA authorization) or describe the plan to re-establish the identifying links and re-consent individuals.

We are requesting a waiver of informed consent and waiver of HIPAA authorization. All date is de-identified after linking has occurred.

Secondary Data Set Detail

24.2* Name and source/ location of data set:

Society of Thoracic Surgeons Database

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

patient comorbidities, operative characteristics and techniques, surgical and patient outcome

24.4* Is the data set you are analyzing publicly available?

Yes **No**

24.5* Does the data set contain:

Identifier

Direct Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

No

24.7.1* Indicate intention to obtain a waiver of informed consent (and, if applicable, HIPAA authorization) or describe the plan to re-establish the identifying links and re-consent individuals.

We are requesting a waiver of informed consent and waiver of HIPAA authorization. All date is de-identified after linking has occurred.

Secondary Data Set Detail

24.2* Name and source/ location of data set:

UMHS Data Warehouse

24.3* Describe the type of information contained in the data set, including any potential subject identifiers.

Financial charges, reimbursements for professional and facility fees. Also contains date of death, basic demographic information, and specialty specific databases: trauma registry, percutaneous coronary intervention, pulmonary function testing, electronic order entry orders and medication administration.

24.4* Is the data set you are analyzing publicly available?

○ Yes ◉ **No**

24.5* Does the data set contain:

Identifier

Direct Identifiers

24.6 Upload any Data Use Agreement, letter of permission, or other access documentation for this data set

Name	Version
There are no items to display	

24.7* Was prior consent from the subjects obtained to utilize the data set for this study (or for unspecified future research)?

No

24.7.1* Indicate intention to obtain a waiver of informed consent (and, if applicable, HIPAA authorization) or describe the plan to re-establish the identifying links and re-consent individuals.

We are requesting a waiver of informed consent and waiver of HIPAA authorization. All date is de-identified after linking has occurred.

25. HIPAA U-M Covered Components

Completion of this section is required based on the response provided to question 4-1.1, 5-1.3, 7.3, or 7-3.2.

25.1* Select all University of Michigan HIPAA-covered component schools, departments, division or other units for which either of the following is true about this study:

- **One or more study team members is a regular employee (faculty or staff), contractor, student, or trainee assigned to the school, department, division, or**

- **other unit (whether full-time, partial, or dry appointment); OR**
- **The school, department, division, or other unit discloses any information about individual subjects to any member of the study team, or, permits study team members to access information. This includes information that has been or will be de-identified.**

Entity
University of Michigan Health System (including hospitals and health centers, medical school, Michigan Visiting Nurses, Michigan Health Corporation, joint ventures)

25-1. Protected Health Information/ HIPAA

Completion of this seciton is required based on the responses to questions 4-1.1, 5-1.3, 7.3, or 7-3.2 and question 25.1.

25-1.1* Identify the PHI to be used.

Select all that apply:
Hospital/doctor's office records, including test results and dental records
Any records relating to condition, the treatment received, and response to the treatment
Billing information
Demographic information
Personal identifiers

If other, please specify:

25-1.2* Explain why the PHI listed above is the minimum necessary to conduct the study.

In order to link the databases, basic PHI is necessary but only for the original database linking. After the database is extracted, the patient identifiers are destroyed and cannot be recovered.

The only remaining PHI will be date of surgery in order to enable research into perioperative quality associated with day of week and season of year.

25-1.3* Will HIPAA authorization for access to the PHI be obtained for all or some subjects?

HIPAA authorization will not be obtained from any subjects

25-1.3.2* If HIPAA authorization for access to the PHI will NOT be obtained from some or all subjects/ candidates for recruitment, indicate what alternative(s) will be used:

Select all that apply:
Request for full or partial waiver of HIPAA authorization
Limited data set(s)

25-2. HIPAA Authorization Waiver Request

Completion of this section is required based on the response provided to question 25-1.3.2

25-2.1* Waiver of HIPAA authorization requested for:

Select all that apply:
Entire project

If other, please specify:

25-2.2* To ensure that this research use of the PHI involves no greater than minimal risk to privacy, describe the plan to protect patient-subject identifiers from improper use or disclosure.

- Theoretically, since patient data is being extracted, there exists a non-zero privacy risk. However, since the data extraction process is automated and the data structures involved separate patient identifiers from the data being extracted, the likelihood is EXTREMELY rare. Patient identifiers (DOB, Name, MRN, Insurance account numbers, SSN) are NOT stored or transmitted at any point during the data extraction or transmittal process.
- To further mitigate this risk, all data extraction processes are automated to eliminate the possibility of human error. No research personnel are required to 'match' or review identifiers.
- All database work is performed on UMHS-MCIT approved and secured servers that are physically located in the UMHS computing environment and maintained by MCIT security standards
- No patient identifiers will ever be stored or transported on portable computing devices (laptops, USB drives, CD, DVD, etc) that can be lost or misplaced
- No patient identifiers will be stored in any research databases

25-2.3* To ensure that this research use of PHI involves no greater than minimal risk to privacy, describe the plan to destroy patient-subject identifiers at the earliest opportunity consistent with the research. Indicate at what point in the research the

patient-subject identifiers will be destroyed. If applicable, provide a health, research or legal justification for retaining the identifiers.

Only the automated processes responsible for creating the database will have access to identifiers. All identifiers will be destroyed prior to any members of the study team seeing the data. All files are stored on a password protected, encrypted database, housed on UMHS-MCIT servers.

An internal perioperative clinical information system number for each operations that is completely unrelated to the patient medical record number or name remains in the data extract. This system number cannot be used to ascertain any PHI regarding the patient unless the perioperative clinical system database is accessed by a database specialist. In rare cases, additional info about a patient may be requested. In that case, a separate IRB application will be submitted to link the internal system number to the perioperative clinical information system.

25-2.4* To ensure that this research use of the PHI involves no greater than minimal risk to privacy, provide assurance that this information will not be reused or disclosed to any other person or entity (i.e., outside the research study team), except as required by law, for authorized oversight of the research study, or for other research for which the IRB has granted a waiver of the HIPAA authorization.

No patient identifier information will be disclosed. Only date of surgery will be used.

25-2.5* Why could this research not practicably be conducted unless the waiver of HIPAA authorization is granted [45 CFR 164.512 (i)(2)(ii)(B)]?

This research could not be carried out because access to the patient identifier during database creation is necessary. Please see section on informed consent waiver for further details.

25-2.6* Why could this research not practicably be conducted without access to and use of the PHI [45 CFR 164.512(i)(2)(ii)(C)]?

This research could not be carried out because access to the patient identifier during database creation is necessary. Please see section on informed consent waiver for further details.

25-2.7* Will data containing PHI be shared outside of the U-M covered component?

○ Yes ◉ **No**

25-4. Limited Data Set

Completion of this section is required based on the response provided to question 25-1.3.2.

The Principal Investigator is responsible for proper use of the limited data set. Only the PI and/or the study team members named on this application ("Authorized Parties") are authorized to use any or all of the limited data set. By submitting this application, the PI and each Authorized Party agrees to comply with this Statement on Use of Limited Data Set. The limited data set may not be disclosed outside the University of Michigan except with a separate Data Use Agreement.

25-4.1* Affirm that the limited data set will NOT include ANY of the following information about subjects, or their relatives, employers or household members.

Affirm all:
Names
Postal address information other than city, town, state, or zip code
Telephone, fax numbers, e-mail addresses, web URL addresses, IP addresses
Social security number, medical record number, health plan beneficiary number, any account number, certificate, or license number
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Biometric identifiers (e.g., fingerprints, voice prints) -- *DNA is not considered a biometric identifier for HIPAA purposes*
Full-face photographs and any comparable images

25-4.2* Affirm that only the Authorized Parties will access, use or disclose information in the limited data set ("LDS"), and that they will comply with all of the conditions listed below:

☑

- The LDS will be used or disclosed only for the research project described in this application.
- The LDS will be used or disclosed consistent with the IRB-approved protocol or as required by law.
- Appropriate safeguards will be used to prevent use or disclosure of LDS information other than as provided for by this application and the IRB approval.
- Any use or disclosure not permitted under the IRB-approved protocol will be promptly reported to the HIPAA Privacy Office.
- No attempt will be made to re-identify or contact individuals whose information is included in the LDS.

25-4.3* Will the limited data set be shared outside the U-M covered component?

◉ **Yes** ○ No

25-4.3.1* If yes, affirm that a Data Use Agreement will be obtained prior to its release.

(•) Yes ( ) No

Note: if a DUA has not been signed at the time of the application, a signed copy must be forwarded to the HIPAA Privacy office at 7319 Medical Science I, 1301 Catherine Street, Ann Arbor, MI 48109-0626 before disclosing the limited data set.

25-4.3.2* Upload the Data Use Agreement here. The Data Use Agreement form for UMHS (IRBMED) is available for download from the UMHS policy on Limited data sets (*level 2 password required; if you don't have level 2, contact UMMS-RegAffairs@med.umich.edu to ask for the tip sheet for setting up an account*).

Name	Version
There are no items to display	

33-1. Children - Secondary Analysis-Only Studies

33-1.1* Permitted Categories of Research: The federal policy and regulations governing human subject protections specify that research involving children must fall into one of the following permitted categories. Check all categories of permitted research that apply to this study. The information provided here must be consistent with the information provided in Section 6.

Regulatory Category	Criteria
The research does not involve greater than minimal risk [45 CFR 46.404].	

33-1.1.1* Provide a justification for how the study complies with the selected requirement.

It is a retrospective electronic data review and involves no patient interaction or intervention.

35-1. Pregnant Women and/ or Fetuses - Secondary Analysis-Only Studies

Completion of this section is required based on the response provided to questions in Section 6 and 9-1.1.

35-1.1* Permitted Categories of Research: The federal regulations governing human subject protection specify that research involving pregnant women or fetuses may be conducted in only the following permitted categories. The information provided here must be consistent with the information in Section 6.

Select all that apply:
None of the above categories applies to this research.

35-1.1.1* If none of the above categories applies to this research, justify the use of pregnant women in this study.

It is a retrospective data review and involves no patient interaction or intervention.

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
There are no items to display	

44.2 If the study sponsor requires that the IRBMED approval letter contain a list of supporting documents, list the names of the documents in the box below as they should appear on the IRBMED approval letter:

This synopsizes the decision making process of the IRB. This cover sheet may be used by other research performance sites' IRBs as they perform their independent review and decision.

45. End of Application

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.