eRESEARCH | REGULATORY MANAGEMENT

52%

Date: Tuesday, August 10, 2021 2:40:07 PM Print Close

View: 01. General Study Information
Section: 01. General Study Information

01. General Study Information

The forms menu on the left displays all sections and pages of the application. Pages in **bold** are required. Pages in *italics* may not apply to your project. Use the "Continue" button to advance through the smartform, as it will only display the sections that must be completed.

All questions marked with a red asterisk (*) are required. Questions without a red asterisk may or may not be required, depending on their relevance to the 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)

1.1.3* Does this application include the study of COVID-19?

For example:

- **testing or studying the COVID-19 virus,**
- **exploring treatment options,**
- **studying the impact of the COVID-19 pandemic (This could included epidemiological, social, behavioral, or educational research).**

Note: Answer "Yes" only if this project includes the study of COVID-19. Inclusion of study procedures solely intended to allow the research to be conducted under pandemic constraints, such as remote interactions with subjects, remote consenting, or at-home drug delivery are not considered the study of COVID-19.

○ Yes ● **No**

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	MM Anesthesiology Department	Yes	no	No	no	yes	N/A	yes
Nirav Shah	Co-Investigator	MM Anesthesiology Department	Yes	no	No	no	yes	Yes	yes
Victoria Lacca	Study Coordinator/Project Manager	MM Anesthesiology Department	Yes	no	No	no	yes	Yes	yes

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Nicole Eyrich	Administrative Staff		N/A	no	No		yes	N/A	yes
Shelley Vaughn	Administrative Staff		N/A	no	No		yes	N/A	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 (HUM00024166). 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 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

1.11* *Estimated* Duration of Study:

10 years

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Sachin Kheterpal

Preferred email: sachinkh@med.umich.edu
Business phone 734-936-4280
Business address: Room 1H247 University Hospital Anesthesiology 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

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

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

Name	Version
CV(0.01)	0.01

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

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

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
NShah_CV_04_20_2020.pdf(0.01)	0.01

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

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Victoria Lacca

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

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
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- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Nicole Eyrich

Preferred email: nipescat@umich.edu
Business phone 734-936-4071
Business address: Anesthesiology Department 2800 Plymouth Road 48109-2800

1.5 Function with respect to project:

Administrative Staff

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

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Shelley Vaughn

Preferred email: mhousey@umich.edu
Business phone 734-936-5334
Business address: North Campus Research Complex Bldg 16 Rm 018W 48109-2435

1.5 Function with respect to project:

Administrative Staff

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
Housey_Resume(0.02)	0.02

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

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: 01-1. Application Type
Section: 01. General Study Information

01-1. Application Type

1-1.1* Select the appropriate application type.

	Application Type	Description
☑	Human Subjects research **involving interaction or intervention** *(formerly Standard, non-exempt research project - or - Exempt)*	Studies that involve either or both of the following: • Interaction, including communication or interpersonal contact between investigator and subject • Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes Interaction/Intervention studies may also have a "secondary research" component. **Does the research involve any of the following:** a. more than minimal risk to participants? b. use of drugs or medical devices? c. target prisoners as research subjects? d. collection of biospecimens from subjects (including blood, saliva, cheek swabs)? ● **Yes** ○ No
☐	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, or educational records. Includes Exemption 4 and "not regulated" projects. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")
☐	Activities **Not Regulated** as human subjects research	Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research (45 CFR 46 or 21 CFR 50/56). **IRB review is required** for the following activities **ONLY** to assess compliance with **HIPAA** or other regulations or institutional policies: • Research on existing data or specimens that have been coded before the researcher receives them, but identifiers still exist. • Research Involving Deceased Individuals Only • Pre-review of Clinical Data Sets Preparatory to Research • Standard Public Health Surveillance or Prevention Activities **IRB review is not required for the following activities**, but researchers may wish complete this brief application to generate a determination letter for funding or publication purposes, or to

		request IRB review to confirm the "Not Regulated" determination: • Case Studies • Class Activities • Journalism/Documentary Activities • Oral History • Quality Assurance and Quality Improvement Activities • Research on Organizations • Research using Publicly Available Data Sets
☐	Projects **lacking immediate plans for involvement of human subjects**, their data, and/or their specimens	Activities such as training grants, program projects, center grants, or multi-phase studies not involving human subjects until later years. Before release of funding, some agencies may require IRB acknowledgement of the future use of human subjects. These projects are sometimes referred to as "umbrella projects" or "dry applications."
☐	**Single-patient Expanded Access Drug or Biologic (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational drug or biologic, outside of a clinical trial, under a single-patient IND issued by the FDA for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational drug or biologic is made. • Submission for IRB review and approval is required, prior to use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational agent.** • This includes both one-time use and continuing therapy.
☐	**Single-patient Expanded Access Device Use (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational device, outside of a clinical trial, when this is the only option available for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational device is made. • Submission for IRB review and approval is required, prior to device use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational device.** • This includes both one-time use and continuing therapy.
☐	**Humanitarian Use Device** (HUD) under a HDE	Non-research, on-label use of an HUD under a Humanitarian Device Exemption (HDE)
☐	Requesting Review by a **Non-UM IRB**	Use ONLY to request deferral of IRB oversight for UM activities to a non-UM IRB or when UM is a performance site in a multisite research project where UM is the lead site.
☐	**Multi-site Research** where U-M is a Coordinating Center and/or IRB of Record	Do not use Multi-site Research application type when U-M is **only** a performance site - select Standard application type. Select when U-M is any of the following: • Data Coordinating Center; • Clinical Coordinating Center; or • IRB of Record for non-U-M sites (for U-M to be IRB of Record you must contact your IRB for prior acknowledgement). When U-M is **also** a performance site, a separate application is required for local site considerations. Refer to special requirements at the IRB website.

View: 01-2. Standard Study Information
Section: 01. General Study Information

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

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.

MM 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* Is the study related to cancer, cancer risk, or cancer care delivery?

○ Yes ● **No**

1-2.6* Does this study require review by the Rogel Cancer Center Protocol Review Committee (PRC)?

○ Yes ● **No**

1-2.7* 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

1-2.7.1* 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.

1-2.8* Is this a clinical trial?

○ Yes ● **No**

1-2.9* 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** https://az.research.umich.edu/medschool/guidance/guidance-blinded-studies**)

○ Yes ● **No**

1-2.10* Does the study involve administration of a cell therapy product?

○ Yes ● **No**

View: 02. Sponsor/Support Information
Section: 02. Sponsor/Support Information

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 forms of funding or support must be added one at a time.**

2.1 Please select all Proposal Approval Forms (PAFs), Awards (AWDs), and/or Unfunded Agreements (UFAs) associated with this study.

☐ **Click here to indicate that a PAF(s) has not been initiated.**

Related PAFs:

ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Related Awards

There are no items to display

Related AWDs:

Award ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Project Period	Awarded PAFs

There are no items to display

Related UFAs:

UFA ID	Title	PI	State	Category	Start Date	End Date

There are no items to display

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

Type	Department Sponsor	Support Type

There are no items to display

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

☑

2.4* Is there any other financial or non-financial sponsorship or support not covered in the sections above?

○ Yes ● **No**

View: 03. UM Study Functions
Section: 03. Performance Sites

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 and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.
- 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 (HUM00024166).

View: 03-1. Performance Sites
Section: 03. Performance Sites

03-1. Performance Sites

3-1.1* Performance Sites:

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

View: Performance Site Detail
Section: 03. Performance Sites

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 and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

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 (HUM00024166).

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	

View: 05. Research Design
Section: 05. Research Design

05. Research Design

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

● **Yes** ○ No

5.1.1* Click ADD to attach the document(s) electronically.

Name	Version
MPOG Performance Site IRB(0.01)	0.01

5.1.2* Indicate the section where each of the following are covered in the attached protocol:

Objective	Please see the Objective section in the protocol.
Specific Aim/Hypothesis	Please see the Specific Aims section in the protocol.
Background Information	Please see the Background section in the protocol.
Methodology	Please see the Methodology section in the protocol.
Statistical Design	Please see the Statistical Design section in the protocol.

5.1.3* Study team Experience: Briefly outline the experience and competence of the study team to pursue the proposed study.

Dr. Kheterpal is a 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.

5.2* 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?

99999999*(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: 999If no upper limit, enter "999"

5.8* 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. If there are none, answer "none."

None

View: 10. Informed Consent - Secondary Use
Section: 10. Informed Consent

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

View: 10-3. Informed Consent Waiver
Section: 10. Informed Consent

10-3. Informed Consent Waiver

10-3.1* This request is for:

Select all that apply:

Waiver – General - ALL of the project

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 criteria for waiver or alteration of informed consent and explain how:

☑ (i) 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

☑ (ii) 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.

☑ (iii) If the research involves identifiable private information or biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format.

Explain

The only identifiers in the MPOG repository are the date-of-service. No other PHI is included.

☑ (iv) 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.

☑ (v) Whenever appropriate, the subjects or their Legally Authorized Representative 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.

View: 11. Confidentiality/Security/Privacy
Section: 11. Confidentiality, Security and Privacy

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 study team protect research records, data, and/or specimens 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* Does either statement apply to this research:

Research has NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable sensitive information, identifiable biospecimens, individual human-level genomic data/biospecimens, or any information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

or

Research does NOT have NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable, sensitive information or identifiable biospecimens that, if revealed, might place the subjects at risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, 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.

View: 11-1. Identifiable Data
Section: 11. Confidentiality, Security and Privacy

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:

Coded or Indirect Identifiers - data record includes a link to direct identifiers (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**

View: 24. Secondary Data Analysis
Section: 24. Secondary Data Analysis

24. Secondary Data Analysis

Completion of this section is required based on the response provided to either question 1-1.2.1, 4-1.1 or 7.2.

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

Name	Identifying Info
Centricity Clinical Information System	This data set includes clinical data entered by clinicians and aggregated from automated interfaces. Subject identifiers are used since this is our electronic medical record for the peri-operative process. For a current data dictionary, please see our concept browser tool (https://mpog.org/concept-browser/) and phenotype list (https://collations.mpogresearch.org/Collations.aspx?type=general&query=na).
Collaborative Quality Initiative Registries	CQI registries include: Michigan Surgical Quality Collaborative (MSQC), Michigan Trauma Quality Improvement Program (MTQIP), Michigan Urological Surgery Improvement Collaborative (MUSIC), Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI), Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2), Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS), Michigan Bariatric Surgery Collaborative (MBSC), Michigan Spine Surgery Improvement Collaborative (MSSIC), Obstetrics Initiative (OBI), Michigan Value Collaborative (MVC). Data dictionaries for these registries are listed in section 24.5. The data dictionary for BMC2 can be found in the following sites: https://bmc2.org/pci-data-collection and https://bmc2.org/vs-data-collection. The most current data dictionary for MTQIP is listed in: https://www.mtqip.org/node/32/#data-dictionary.
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. The data dictionary for this data set is continuously updated - to view the most recent and all other versions of this data dictionary, please visit https://www.facs.org/quality-programs/acs-nsqip/participant-use
Society of Thoracic Surgeons Database	This data set includes patient comorbidities, operative characteristics and techniques, surgical and patient outcome. The data set is continuously updated - to view the most recent and all other versions of the data dictionary please see the Adult Cardiac Surgery Database Data Collection (https://www.sts.org/registries-research-center/sts-national-database/adult-cardiac-surgery-database/data-collection) and General Thoracic Surgery Database Data Collection (https://www.sts.org/registries-research-center/sts-national-database/general-thoracic-surgery-database/data-collection)
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. Please see section 24.5 for examples of data elements contained in this data set.

View: VIEW000614_customAttributes._attribute232.customAttributes._attribute0_Secondary Data Set Detail
Section: 24. Secondary Data Analysis

Secondary Data Set Detail

24.2* Name, source, and location of data set. ALSO, describe how you gain access to the data set.

Centricity Clinical Information System

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

If a data dictionary is uploaded in 24.5 or included in a separate protocol, refer to it here.

This data set includes clinical data entered by clinicians and aggregated from automated interfaces. Subject identifiers are used since this is our electronic medical record for the peri-operative process. For a current data dictionary, please see our concept browser tool (https://mpog.org/concept-browser/) and phenotype list (https://collations.mpogresearch.org/Collations.aspx?type=general&query=na).

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset.

Select all that apply:

Direct Identifiers - stored on data record (e.g. name, initials, phone number, SSN, or medical number stored on data record)

24.5 Upload

- **Any applicable Data Use or Data Sharing Agreement(DUA/DSA) - unsigned template is acceptable.** Upload is *not* necessary if this application refers to an Unfunded Agreement (UFA) in eResearch Proposal Management.
- **Data dictionary/data collection sheet/list of data variables to be accessed or received by study team and recorded for analysis.** Upload is *not* necessary if the variables are fully described in 24.3 or in a separate protocol.

Name	Version
There are no items to display	

View: VIEW000614_customAttributes._attribute232.customAttributes._attribute0_Secondary Data Set Detail
Section: 24. Secondary Data Analysis

Secondary Data Set Detail

24.2* Name, source, and location of data set. ALSO, describe how you gain access to the data set.

Collaborative Quality Initiative Registries

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

If a data dictionary is uploaded in 24.5 or included in a separate protocol, refer to it here.

CQI registries include: Michigan Surgical Quality Collaborative (MSQC), Michigan Trauma Quality Improvement Program (MTQIP), Michigan Urological Surgery Improvement Collaborative (MUSIC), Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI), Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2), Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS), Michigan Bariatric Surgery Collaborative (MBSC), Michigan Spine Surgery Improvement Collaborative (MSSIC), Obstetrics Initiative (OBI), Michigan Value Collaborative (MVC). Data dictionaries for these registries are listed in section 24.5. The data dictionary for BMC2 can be found in the following sites: https://bmc2.org/pci-data-collection and https://bmc2.org/vs-data-collection. The most current data dictionary for MTQIP is listed in: https://www.mtqip.org/node/32/#data-dictionary.

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset.

Select all that apply:

No Identifiers (De-identified, Anonymous, or Anonymized) - stored data record is stripped of all identifiers

24.5 Upload

- **Any applicable Data Use or Data Sharing Agreement(DUA/DSA) - unsigned template is acceptable.** Upload is *not* necessary if this application refers to an Unfunded Agreement (UFA) in eResearch Proposal Management.
- **Data dictionary/data collection sheet/list of data variables to be accessed or received by study team and recorded for analysis.** Upload is *not* necessary if the variables are fully described in 24.3 or in a separate protocol.

Name	Version
MARCQI Data Dictionary(0.01)	0.01
MBSC Data Dictionary(0.01)	0.01
MSQC Data Dictionary(0.01)	0.01
MSSIC Data Dictionary(0.01)	0.01
MSTCVS Data Dictionary - 1(0.01)	0.01
MSTCVS Data Dictionary - 2(0.01)	0.01
MUSIC Data Dictionary(0.01)	0.01
MVC Data Dictionary - 1(0.01)	0.01
MVC Data Dictionary - 2(0.01)	0.01
OBI Data Dictionary(0.01)	0.01

View: VIEW000614_customAttributes._attribute232.customAttributes._attribute0_Secondary Data Set Detail
Section: 24. Secondary Data Analysis

Secondary Data Set Detail

24.2* Name, source, and location of data set. ALSO, describe how you gain access to the data set.

National Surgical Quality Improvement Program

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

If a data dictionary is uploaded in 24.5 or included in a separate protocol, refer to it here.

Elements include preoperative comorbidities, laboratory values, procedural information, provider information, intraoperative information,and 30 day outcomes. Patient identifiers are used and stored. The data dictionary for this data set is continuously updated - to view the most recent and all other versions of this data dictionary, please visit https://www.facs.org/quality-programs/acs-nsqip/participant-use

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset.

Select all that apply:

Direct Identifiers - stored on data record (e.g. name, initials, phone number, SSN, or medical number stored on data record)

24.5 Upload

- **Any applicable Data Use or Data Sharing Agreement(DUA/DSA) - unsigned template is acceptable.** Upload is *not* necessary if this application refers to an Unfunded Agreement (UFA) in eResearch Proposal Management.
- **Data dictionary/data collection sheet/list of data variables to be accessed or received by study team and recorded for analysis.** Upload is *not* necessary if the variables are fully described in 24.3 or in a separate protocol.

Name	Version
There are no items to display	

View: VIEW000614_customAttributes._attribute232.customAttributes._attribute0_Secondary Data Set Detail
Section: 24. Secondary Data Analysis

Secondary Data Set Detail

24.2* Name, source, and location of data set. ALSO, describe how you gain access to the data set.

Society of Thoracic Surgeons Database

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

If a data dictionary is uploaded in 24.5 or included in a separate protocol, refer to it here.

This data set includes patient comorbidities, operative characteristics and techniques, surgical and patient outcome. The data set is continuously updated - to view the most recent and all other versions of the data dictionary please see the Adult Cardiac Surgery Database Data Collection (https://www.sts.org/registries-research-center/sts-national-database/adult-cardiac-surgery-database/data-collection) and General Thoracic Surgery Database Data Collection (https://www.sts.org/registries-research-center/sts-national-database/general-thoracic-surgery-database/data-collection)

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset.

Select all that apply:

Direct Identifiers - stored on data record (e.g. name, initials, phone number, SSN, or medical number stored on data record)

24.5 Upload

- **Any applicable Data Use or Data Sharing Agreement(DUA/DSA) - unsigned template is acceptable.** Upload is *not* necessary if this application refers to an Unfunded Agreement (UFA) in eResearch Proposal Management.
- **Data dictionary/data collection sheet/list of data variables to be accessed or received by study team and recorded for analysis.** Upload is *not* necessary if the variables are fully described in 24.3 or in a separate protocol.

Name	Version
There are no items to display	

View: VIEW000614_customAttributes._attribute232.customAttributes._attribute0_Secondary Data Set Detail
Section: 24. Secondary Data Analysis

Secondary Data Set Detail

24.2* Name, source, and location of data set. ALSO, describe how you gain access to the data set.

UMHS Data Warehouse

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

If a data dictionary is uploaded in 24.5 or included in a separate protocol, refer to it here.

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. Please see section 24.5 for examples of data elements contained in this data set.

24.4* Please confirm whether the investigators receive or record identifiers from THIS dataset.

Select all that apply:

Direct Identifiers - stored on data record (e.g. name, initials, phone number, SSN, or medical number stored on data record)

24.5 Upload

- **Any applicable Data Use or Data Sharing Agreement(DUA/DSA) - unsigned template is acceptable.** Upload is *not* necessary if this application refers to an Unfunded Agreement (UFA) in eResearch Proposal Management.
- **Data dictionary/data collection sheet/list of data variables to be accessed or received by study team and recorded for analysis.** Upload is *not* necessary if the variables are fully described in 24.3 or in a separate protocol.

Name	Version
UMHS Data Warehouse Data Dictionary Example(0.01)	0.01

View: 25. HIPAA Covered Components
Section: 25. Protected Health Information/HIPAA

25. HIPAA Covered Components

Completion of this section is required based on the response provided to question 1-1.2.8, 4-1.1, 5-1.3, 7.3, or 7-3.2.

25.1* Select all sources of HIPAA-regulated data used, received, or analyzed in the study:

Entity
Michigan Medicine hybrid covered entity

Examples: Michigan Medicine electronic medical record; Medical School Office of Research services such as Data Office for Clinical and Translational Research or Central Biorepository; University Health Service; School of Dentistry Provider Clinics; U-M Group Health Plan

View: 25-1. Protected Health Information/HIPAA
Section: 25. Protected Health Information/HIPAA

25-1. Protected Health Information/HIPAA

Completion of this section 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?

No - 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 to be approved by U-M IRB or Privacy Board
- Limited data set(s)

View: 25-2. HIPAA Authorization Waiver Request
Section: 25. Protected Health Information/HIPAA

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? (If yes review the guidelines from UM HIPAA office)

○ Yes ● **No**

View: 33-1. Children - Secondary Analysis-Only Studies
Section: 33. Children

33-1. Children - Secondary Analysis-Only Studies

Completion of this section is required based on the response provided to question 1-1.2.7 or questions in Section 6 and 9-1.1.

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.

View: 44. Additional Supporting Documents
Section: 44 Additional Supporting Documents

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 Enter any information that should show in a "Supporting Documents" list on the current submission's approval notice, such as document names and version numbers or version dates. Text entered here will AUTOMATICALLY appear word-for-word on the approval letter.