eRESEARCH | REGULATORY MANAGEMENT

Date: Thursday, August 24, 2023 4:59:44 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 Review of Practice Patterns Regarding Benzodiazepine Use in Cardiac Surgery

1.1.1 Full Study Title:

Multicenter Review of Practice Patterns Regarding Benzodiazepine Use in Cardiac Surgery

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

HUM00083221 – Coordinating Center IRB
HUM00025285 is the performance center IRB

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:

Allison Janda
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?
Allison Janda	PI	MM Anesthesiology Department	Yes	no	No	no	yes	N/A	yes
Sachin Kheterpal	Co-Investigator	MM Anesthesiology Department	Yes	no	No	no	yes	N/A	yes
Michael Mathis	Co-Investigator	MM Anesthesiology Department	Yes	no	No	no	yes	N/A	yes
Graciela Mentz	Biostatistician	MM Anesthesiology Department	Yes	no	No	no	yes	N/A	yes

1.8* Project Summary:

There is remarkable variability in clinical practice and a lack of consensus amongst anesthesiologists providing care for cardiac surgery patients on a number of fronts. Some of these topics include variation in pulmonary management with utilization of lung protective ventilation strategies, neuromuscular blockade management, timing of reversal of neuromuscular blockade in the ICU, and concern for hyperoxia with 100% FiO2 administration. Regarding hemodynamic management, there are various opinions and strategies for vasopressor and inotrope selection, fluid management, transfusion thresholds, autologous blood removal, venous anterograde and retrograde arterial priming of the bypass circuit, threshold of adequate pump flow while on cardiopulmonary bypass, and placement of monitors such as a pulmonary artery catheter. Practice variation also exists amongst neurologic modulation for choice of induction agents including the role of benzodiazepines, use of BIS monitors, and neuroprotection strategies.(1–3) Describing cardiac anesthesiologist's choices of induction agents, primarily the use or lack of use of benzodiazepines, is a topic with implications for hemodynamic stability, and in neurocognitive recovery after cardiac surgery.

Conflicting evidence exists regarding the role of benzodiazepines in cardiac surgery. Some studies focusing on administration of benzodiazepines in the ICU have shown that benzodiazepines are associated with an increased risk of delirium or disrupted neurocognitive recovery surgery,(1–7) but some anesthesiologists specifically utilize benzodiazepines for their amnestic properties due to a higher than average rate of intraoperative awareness in the cardiac surgery population since there is little data on the impact of intraoperative use of benzodiazepines.(1,8–11) A survey of cardiac anesthesiologists in Canada found that 89 percent of respondents did routinely use benzodiazepines, yet, a majority believed most cardiac anesthetics could safely be performed without benzodiazepines.(1) Gaps exist in the current literature in determining the impact of benzodiazepine use on postoperative outcomes.(1,8) As emerging evidence suggests that postoperative delirium may be associated with increased morbidity, mortality, prolonged ventilation, and increased length of stay,(4–6,12–16) it is important to determine strategies to prevent delirium in the cardiac surgery population. Although work has been done in the intensive care unit regarding the impact of benzodiazepine use, and practice patterns in Canada have been identified via survey,(1) little is known about practice patterns in the United States.

In this descriptive study, we plan to investigate practice patterns regarding benzodiazepine use including incidence of use, total dosage, and context of benzodiazepine use during the perioperative period for cardiac surgical cases with data obtained from the electronic medical records from a variety of institutions across the United States. We aim to provide descriptive data from the electronic medical record regarding practice variation of benzodiazepine administration to better frame the discussion surrounding benzodiazepine use and guide future studies. As more research is done regarding the impact of intraoperative benzodiazepines on delirium, morbidity, and mortality, with randomized clinical trials, quantifying the use of benzodiazepines in the United States will contribute to any extrapolation of these findings and potential impact on current practices.

1. Spence J, Belley-Côté E, Devereaux PJ, Whitlock R, Um K, McClure G, Lamy A, LeManach Y, Connolly S, Syed S: Benzodiazepine administration during adult cardiac surgery: a survey of current practice among Canadian anesthesiologists working in academic centres. Can J Anaesth 2018; 65:263–71
2. Kassie GM, Nguyen TA, Kalisch Ellett LM, Pratt NL, Roughead EE: Preoperative medication use and postoperative delirium: a systematic review. BMC Geriatr 2017; 17:298
3. Maldonado JR, Wysong A, Starre PJA van der, Block T, Miller C, Reitz BA: Dexmedetomidine and the reduction of postoperative delirium after cardiac surgery. Psychosomatics 2009; 50:206–17
4. Saczynski JS, Marcantonio ER, Quach L, Fong TG, Gross A, Inouye SK, Jones RN: Cognitive trajectories after postoperative delirium. N Engl J Med 2012; 367:30–9
5. Riker RR, Shehabi Y, Bokesch PM, Ceraso D, Wisemandle W, Koura F, Whitten P, Margolis BD, Byrne DW, Ely EW, Rocha MG, SEDCOM (Safety and Efficacy of Dexmedetomidine Compared With Midazolam) Study Group: Dexmedetomidine vs midazolam for sedation of critically ill patients: a randomized trial. JAMA 2009; 301:489–99
6. Pandharipande PP, Pun BT, Herr DL, Maze M, Girard TD, Miller RR, Shintani AK, Thompson JL, Jackson JC, Deppen SA, Stiles RA, Dittus RS, Bernard GR, Ely EW: Effect of sedation with dexmedetomidine vs lorazepam on acute brain dysfunction in mechanically ventilated patients: the MENDS randomized controlled trial. JAMA 2007; 298:2644–53
7. Pandharipande P, Shintani A, Peterson J, Pun BT, Wilkinson GR, Dittus RS, Bernard GR, Ely EW: Lorazepam is an independent risk factor for transitioning to delirium in intensive care unit patients. Anesthesiology 2006; 104:21–6
8. Spence J, Belley-Côté E, Lee SF, Bangdiwala S, Whitlock R, LeManach Y, Syed S, Lamy A, Jacobsohn E, MacIsaac S, Devereaux PJ, Connolly S: The role of randomized cluster crossover trials for comparative effectiveness testing in anesthesia: design of the Benzodiazepine-Free Cardiac Anesthesia for Reduction in Postoperative Delirium (B-Free) trial. Can J Anaesth 2018; 65:813–21
9. American Society of Anesthesiologists Task Force on Intraoperative Awareness: Practice advisory for intraoperative awareness and brain function monitoring: a report by the american society of anesthesiologists task force on intraoperative awareness. Anesthesiology 2006; 104:847–64
10. Sebel PS, Bowdle TA, Ghoneim MM, Rampil IJ, Padilla RE, Gan TJ, Domino KB: The incidence of awareness during anesthesia: a multicenter United States study. Anesth Analg 2004; 99:833–9, table of contents
11. Orser BA, Mazer CD, Baker AJ: Awareness during anesthesia. CMAJ 2008; 178:185–8
12. Sanson G, Khlopenyuk Y, Milocco S, Sartori M, Dreas L, Fabiani A: Delirium after cardiac surgery. Incidence, phenotypes, predisposing and precipitating risk factors, and effects. Heart Lung 2018; 47:408–17
13. Samuel M: Postoperative delirium in older adults: best practice statement from the American Geriatrics Society. JMAGSEP 2015; 220:136–49
14. Koster S, Hensens AG, Palen J van der: The long-term cognitive and functional outcomes of postoperative delirium after cardiac surgery. Ann Thorac Surg 2009; 87:1469–74
15. Leslie DL, Marcantonio ER, Zhang Y, Leo-Summers L, Inouye SK: One-year health care costs associated with delirium in the elderly population. Arch Intern Med 2008; 168:27–32
16. Stransky M, Schmidt C, Ganslmeier P, Grossmann E, Haneya A, Moritz S, Raffer M, Schmid C, Graf BM, Trabold B: Hypoactive delirium after cardiac surgery as an independent risk factor for prolonged mechanical ventilation. J Cardiothorac Vasc Anesth 2011; 25:968–74

1.9* Select the appropriate IRB:

IRBMED

1.11* ***Estimated*** **Duration of Study:**

5 years

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

Study Team Detail

1.4 Team Member:

Allison Janda

Preferred email: ajanda@umich.edu
Business phone 734-936-9479
Business address: Anesthesiology CVC 4172 48109-5861

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
Janda CV 06.2023(0.03)	0.03

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:

Sachin Kheterpal

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

No

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

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

Name	Version
CV(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 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:

Michael Mathis

Preferred email: mathism@med.umich.edu
Business phone 734-936-4280
Business address: Anesthesiology UH-1H247 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.)

No

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

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

Name	Version
NIH Biosketch 2020(0.24)	0.24

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:

Graciela Mentz

Preferred email: gmentz@umich.edu
Business phone 734-936-5334
Business address: Anesthesiology Department NCRC Bldg 16, Room G023W 48109-2800

1.5 Function with respect to project:

Biostatistician

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.)

No

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

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

Name	Version
Mentz Biosketch 031122.docx(0.01)	0.01
MentzCV(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 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: 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.
☑	**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: 01-1.2 Scope of Secondary Use Research
Section: 01. General Study Information

01-1.2 Scope of Secondary Use Research

Completion of this section is required based on the response provided to question 1-1.1.

Projects involving only analysis of data and/or biospecimens require different levels of review, depending on identifiability of information accessed, identifiability of information recorded, and whether other federal regulations apply to the research. The following questions will help the IRB determine the appropriate type of review.

1* This research will involve analysis of (select all that apply):

- [x] Data [Require Section 24]
- [ ] Biospecimens [Require Section 18]

2* Does the source of the data or biospecimens require an IRB review and approval of the project - full committee or expedited review rather than an exempt or not regulated?

○ Yes ● **No**

3* Are or were any study team members on this project also involved with the direct collection of the data/biospecimens from subjects and still have access to subject identifiers either directly or via the key to the code linking to subject identifiers?
(e.g. part of another study, part of an ongoing study involving interaction/intervention with subjects, managing a repository in which the specimens are stored)

○ Yes ● **No**

4* Can subject identity be readily ascertained (directly or through links) in the data/biospecimens *accessed or received* by study team members on this project?
This means that the **information accessed or received** includes **direct identifiers** (name, address, email, phone number, social security number, student ID, medical record number), **indirect identifiers** (i.e. data elements that could be combined to identify an individual, such as dates, employment history, etc.), or a **code that can be linked back to the subject.**

● **Yes** ○ No

4.1* Will the study team members *record* direct, indirect or coded subject identifiers that could be linked back to the subject for ANY of the data/biospecimens?

● **Yes** ○ No

5* Will data from the proposed activity be submitted in an application to the FDA for an IDE (Investigational Device Exemption) or In Vitro Diagnostic (IVD) device approval? [Require Section 16]

○ Yes ● **No**

6* Does the research analysis target prisoners as the subjects of the research? [Require Section 38]

○ Yes ● **No**

7* Does the research analysis include data/biospecimens from children? [For non-exempt research require Section 33-1]

○ Yes ● **No**

8* Is ANY identifiable information to be accessed, used, and/or analyzed defined as "Protected Health Information (PHI)" protected by HIPAA? PHI is:

- information about a subject's 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 HIPAA-covered component (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).

[Require Section 25]

● **Yes** ○ No

8.1* To ascertain if ALL data are Protected Health Information (PHI) protected by HIPAA:

Answer Yes if

1. All study team members are Michigan Medicine faculty, staff, medical student(s) or professional trainee(s), and
2. All data are generated by or received from a HIPAA "covered entity, and
3. The study never involves sharing PHI outside the "covered entity" ("disclosing"), and
4. If biospecimen analysis is involved: all biospecimens were obtained with research consent and HIPAA authorization

Answer No if

1. The study team includes collaborators from outside Michigan Medicine (e.g., LSA, SPH, Business School, or outside University of Michigan), and/or
2. Not all data source(s) are HIPAA “covered entities” (data is generated by or received from source(s) not subject to HIPAA), and/or
3. Patient-level data containing HIPAA identifier(s) will be shared outside a covered entity (CE) ("disclosed"), and/or
4. Identifiable biospecimens are used, at least some of which were not obtained with research consent and HIPAA authorization.

● **Yes** ○ No

12* Provide a brief summary of your research (subjects, location of research, research methods).

If this information is detailed in your research protocol, please indicate so below and upload the research protocol in section 44.1.

This is detailed in our study protocol uploaded in section 44.1.

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

1-2.5* Is the study related to cancer, cancer risk, or cancer care delivery?

○ 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**

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 Analysis Functions
Section: 03. Performance Sites

03. UM Analysis 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.

If other, please specify.

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,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.

If other, please specify:

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: 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
MPOG data set. Please see HUM00025285 and HUM83221. There is an application process in which the study protocol and methods are evaluated and if approved, the data are securely sent to my study team after Blinded Record Index (BRI) software has de-identified PHI other than date of service.	The type of data in the dataset is age, sex, BMI, comorbidities, preoperative medications, type of surgical procedure, and benzodiazepine type and dose administered intraoperatively.

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.

MPOG data set. Please see HUM00025285 and HUM83221. There is an application process in which the study protocol and methods are evaluated and if approved, the data are securely sent to my study team after Blinded Record Index (BRI) software has de-identified PHI other than date of service.

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.

The type of data in the dataset is age, sex, BMI, comorbidities, preoperative medications, type of surgical procedure, and benzodiazepine type and dose administered intraoperatively.

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

Select all that apply:

Coded or Indirect Identifiers - data record includes a link to direct identifiers, or unique subject characteristics, or a combination of data fields that can be correlated to another dataset

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: 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

If other, please specify:

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

The only remaining PHI elements will be dates of service in order to enable research into physiological data dates/times and care provide by month or 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:

- Limited data set(s)

View: 25-4. Limited Data Set
Section: 25. Protected Health Information/HIPAA

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**

Note: if yes and 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.

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
IRB Study Summary and Protocol: Multicenter Review of Practice Patterns Regarding Benzodiazepine Use in Cardiac Surgery(0.01)	0.01

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.

View: 45. End Of Application
Section: 45. End of Application

45. End of Application

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