eRESEARCH | REGULATORY MANAGEMENT

Date: Thursday, May 7, 2020 12:39:13 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:

Antibiotic Use for TS/EEA Pituitary Adenomectomy

1.1.1 Full Study Title:

Antibiotic Use for Transsphenoidal/EEA Pituitary Adenomectomy: National Quality Data Analysis from the North American Skull Base Society (NASBS) Value-Based Healthcare Committee

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

1.1.3* Does this application include the study of COVID-19? For example: testing or studying the COVID-19 virus, exploring treatment options, or studying the impact of the COVID-19 pandemic (e.g. epidemiological, social, behavioral, or educational research).

○ Yes ● **No**

1.2* Principal Investigator:

Erin McKean
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?
Erin McKean	PI	Otorhinolaryngology Department	Yes	no	No	no	yes	N/A	yes
Amy Hurst	Study Coordinator/Project Manager	Otorhinolaryngology Department	Yes	no	No	no	yes	N/A	yes

1.8* Project Summary:

The North American Skull Base Society (NASBS) Value-Based Healthcare Committee (VBHC) reviewed data on prophylactic antibiotic use in transsphenoidal (TS), or expanded endonasal approach (EEA), pituitary adenomectomy, finding that data is sparse and inconclusive. The NASBS VBHC has put together an Excel data collection sheet on what we suggest all NASBS members performing TS/EEA pituitary adenomectomy should collect.

Information to be collected over a continuous 6 month period, either retrospective or prospective, within the last 2 years or going forward includes: institution with a number for each case (e.g. UMich1, UMich2), intraop leak, extent of resection, tumor pathology, postop leak, presence of lumbar drain, exact antibiotic(s) and duration given, size of defect, presence of packing, postop infectious complication and relevant comorbidities (diabetes mellitus, smoking, BMI >40).

Data is deidentified from patients here at UM and other institutions will be collected and analyzed here at the University of Michigan. The information collected will be used to determine what treatments are most effective for these tumors.

1.9* Select the appropriate IRB:

IRBMED

1.11* *Estimated* Duration of Study:

1 year

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

Study Team Detail

1.4 Team Member:

Erin McKean

Preferred email: elmk@umich.edu
Business phone 734-936-7633
Business address: UMH Otorinolaryngology 1904 TC SPC 5312 48109-5312

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
Erin McKean MCV 5.2019(0.09)	0.09
March 2020 CV McKean(0.01)	0.01
McKean April 2020(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 have an outside interest or a relationship* with a non-UM entity**, where the non-UM entity is:**

- Sponsoring this project;
- Supplying products purchased for this project;
- Providing a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation);
- Holding an option/license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation) that you developed; or
- Receiving a subcontract for work on this project?

*Examples of relevant interests or relationships with a non-UM entity include owning stock in, receiving income from, consulting with, serving as an officer/director/advisor to, or having some other related financial/leadership interest or relationship with that entity.

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:

Amy Hurst

Preferred email: ahurst@umich.edu
Business phone 734-998-5585
Business address: Otorhinolaryngology Department L2110 Women's Hospital 48109-5864

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
Amy Hurst-CV_20MAR2018(0.02)	0.02
CV-AH-APR2020.docx(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 not yet disclosed in M-Inform.*

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

- Sponsoring this project;
- Supplying products purchased for this project;
- Providing a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation);
- Holding an option/license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation) that you developed; or
- Receiving a subcontract for work on this project?

*Examples of relevant interests or relationships with a non-UM entity include owning stock in, receiving income from, consulting with, serving as an officer/director/advisor to, or having some other related financial/leadership interest or relationship with that entity.

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

UMOR has organized a committee to review and prioritize new or modified research projects related to COVID-19. In addition to preparation of an IRB application or amendment to study COVID-19, investigators must submit a COVID-related Research Prioritization Form. The outcome letter from the prioritization review must be uploaded into the eResearch submission in section 44 or as a posted correspondence.

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.

We will collect limited data nationwide on antibiotic prophylaxis practice and 30-day postop surgical site infection (aka meningitis and postop sinusitis requiring additional antibiotics) in transnasal/transsphenoidal pituitary adenomectomy operations in adults, age 18 and up. There is no exclusion of patients as long as they meet the above criteria.

Skull Base centers with a volume of at least 24 patients per year (average of at least 2 per month) may be candidates to participate. The requested data will be 3 consecutive months of transsphenoidal pituitary adenomectomy cases. Data requested: unique coded identifier, institution, date of operation, antibiotic(s) given intraop and periop and duration, antibiotic(s) given postop and duration, tumor/pathology, extent of resection (transsellar only, transsellar + transtubercular, transsellar + transtubercular + transplanar), intraop leak (Y/N), estimated size of dural defect if intraoperative leak is present (dropdown menu with range), lumbar drain used at primary operation (Y/N), number of days lumbar drain in place, removable/ nonresorbable packing (Y/N), resorbable packing (Y/N), postop leak (Y/N), meningitis (Y/N), bacteria isolated (type versus not identified), sinusitis requiring additional antibiotics (Y/N), BMI >40 (Y/N), diabetes mellitus (Y/N), current smoker (Y/N), immunosupression (chemo, high-dose chronic steroids, etc) (Y/N), entered by (initials), comments.

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.

Otorhinolaryngology 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)

Coordinating Center (of multiple engaged sites, e.g. statistical, data coordination, lead, or operations center)

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

If other, please specify.

If University of Michigan will be performing coordinating center activities, contact your IRB prior to continuing to ensure you have chosen the appropriate application type for your project.

3.1.1* As the Operations, Coordinating or Lead Center describe the mechanisms in place to ensure that management, data analysis, and Data Safety and Monitoring systems are adequate for each site.

All data sent will be deidentified. Data analysis will be performed here.

3.1.2* Describe the plan for communicating interim results (e.g. adverse events, unanticipated events or interim data):

Not applicable to this retrospective analysis of patients who underwent transphenoidal pituitary/sellar at multiple institutions throughout the country.

3.1.3* Describe the plan for communicating any protocol modification by the site(s):

Not applicable to this retrospective analysis of patients who underwent transphenoidal pituitary/sellar at multiple institutions throughout the country.

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
Emory U	USA	no		Secondary data collection
Institution of any other member of NASBS doing more than 24 transsphenoidal pituitary operations per year	USA	no		Secondary data collection
MD Anderson	USA	no		Secondary data collection
Northwestern University	USA	no		Secondary data collection
NY Presbyterian	USA	no		Secondary data collection
NYU Langone	USA	no		Secondary data collection
Ohio State University	USA	no		Secondary data collection
Stanford U	USA	no		Secondary data collection
Temple U	USA	no		Secondary data collection
U of Miami	USA	no		Secondary data collection
U of Pennsylvania	USA	no		Secondary data collection
U of South Florida	USA	no		Secondary data collection
UCLA	USA	no		Secondary data collection
UCSF	USA	no		Secondary data collection
University of Michigan	USA	yes		Storage,Analysis,Coordinating Center,Secondary data collection
University of Pittsburgh	USA	no		Secondary data collection

View: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

Emory U

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.)

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.

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: Performance Site Detail
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Performance Site Detail

3-1.2* Location or Institution:

Institution of any other member of NASBS doing more than 24 transsphenoidal pituitary operations per year

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.)

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.

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:

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There are no items to display	

View: Performance Site Detail
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Performance Site Detail

3-1.2* Location or Institution:

MD Anderson

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.)

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.

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: Performance Site Detail
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Performance Site Detail

3-1.2* Location or Institution:

Northwestern University

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.)

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.

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:

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Performance Site Detail

3-1.2* Location or Institution:

NY Presbyterian

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.)

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.

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:

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Performance Site Detail

3-1.2* Location or Institution:

NYU Langone

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.)

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.

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: Performance Site Detail
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Performance Site Detail

3-1.2* Location or Institution:

Ohio State University

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.)

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.

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	

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Performance Site Detail

3-1.2* Location or Institution:

Stanford U

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.)

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.

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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

Temple U

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.)

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.

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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

U of Miami

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.)

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.

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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

U of Pennsylvania

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.)

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.

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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

U of South Florida

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.)

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.

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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

UCLA

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.)

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.

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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

UCSF

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.)

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.

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: 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)
Coordinating Center (of multiple engaged sites, e.g. statistical, data coordination, lead, or operations center)
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: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

University of Pittsburgh

3-1.3 Address:

City Pittsburgh
State PA
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.)

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.

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
Subject data will be obtained from their medical record.	There will no subject identifiers in the data set collected.

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.

Subject data will be obtained from their medical record.

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.

There will no subject identifiers in the data set collected.

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
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*
External non-federal entity holding PHI *Examples: community hospital; tertiary care center; private health insurance company*

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

If other, please specify:

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

We will collect limited data nationwide on antibiotic prophylaxis practice and 30-day postop surgical site infection (aka meningitis and postop sinusitis requiring additional antibiotics) in transnasal/transsphenoidal pituitary adenomectomy operations in adults, age 18 and up. There is no exclusion of patients as long as they meet the above criteria.

Skull Base centers with a volume of at least 24 patients per year (average of at least 2 per month) may be candidates to participate. The requested data will be 3 consecutive months of transsphenoidal pituitary adenomectomy cases. Data requested: unique coded identifier, institution, date of operation, antibiotic(s) given intraop and periop and duration, antibiotic(s) given postop and duration, tumor/pathology, extent of resection (transsellar only, transsellar + transtubercular, transsellar + transtubercular + transplanar), intraop leak (Y/N), estimated size of dural defect if intraoperative leak is present (dropdown menu with range), lumbar drain used at primary operation (Y/N), number of days lumbar drain in place, removable/ nonresorbable packing (Y/N), resorbable packing (Y/N), postop leak (Y/N), meningitis (Y/N), bacteria isolated (type versus not identified), sinusitis requiring additional antibiotics (Y/N), BMI >40 (Y/N), diabetes mellitus (Y/N), current smoker (Y/N), immunosupression (chemo, high-dose chronic steroids, etc) (Y/N), entered by (initials), comments.

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

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.

For internal data, all electronic data records will be password protected and only accessed on University computers. Computers will be password protected. For data received from outside institutions, no demographics or identifiers will be given in the data set.

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.

At completion of the research, when all data analysis and publications have been completed, data will be destroyed/deleted (including the identifiers). Even during collection, the patient will be assigned an arbitrary identifier (to keep the data organized without duplication or mistakes in the data collection instrument and to allow for assessment) and no demographic or identifiable data will be shared.

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.

This information will not be reused or disclosed to any other person or entity outside the authorized research study team.

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)]?

The study relies on retrospective analysis of patients who underwent transphenoidal pituitary/sellar at multiple institutions throughout the country. There is no other feasible method of obtaining this information other than through a HIPAA waiver.

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)]?

The study relies on retrospective analysis of patients who underwent transphenoidal pituitary/sellar at multiple institutions throughout the country. There is no other feasible method of obtaining this information other than through a HIPAA waiver.

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: 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
Antibiotic Use for Transphenoidal EEA Pituitary Adenomectomy - Prospective Data Collection Instrument v4.xlsx(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.