

Date: Wednesday, March 15, 2006 9:29:20 AM

1. General Study Information

1.1 * Study Title *(limited to 256 characters)*:

Retrospective Data Analysis--Non-Exempt with Waiver Sample Application for Training

1.1.1 Full Study Title *(if applicable)*:

1.2 * Principal Investigator:

[June Insko](#)

1.3

Study Team Members: *(Note: PI is listed below and other study team members must be added one at a time)* 

Study Team Member	Study Team Role	Accepted Role	Conflict of Interest	Edit Rights
June Insko	PI			yes

1.8 3rd party services: *(e.g., transcriptionists, lab work, data analysis. etc.)*

1.9 * Estimated Study Start Date: *(mm/dd/yyyy)* 4/8/2006

1.10 * Estimated Study End Date: *(mm/dd/yyyy)* 9/29/2006

1.11 * Select the appropriate IRB:

[IRBMED](#)

1.12 * Type of Application:

Research project involving human subjects, their data, and/or their specimens, including requests for exemption

* Required

1-1. Standard Study Information

1-1.1 * Who initiated this study? 

Investigator

If other, please specify:

1-1.2 * This application is being submitted by a:

Note: Student submissions require a Faculty Advisor be included on the study team in question 1.3.

Select all that apply:

Not Applicable to this study

1-1.2.1 Indicate course number here:

1-1.3

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.*

Medical School Administration

1-1.4 *

Has this study been previously submitted to this or any other UM or non-UM IRB for approval? (*Note: select "No" if this study has been previously approved by a UM IRB.*)

no

1-1.4.1 If yes, list all IRBs.

Attach the IRB documentation outlining the previous review outcome.



name

version

There are no items to display

Check here if the documentation is not available electronically.

***Note:** Study Teams are encouraged to scan and upload documents. [See Help](#) for a list of sites with scanning facilities.*

1-1.5 Will the study utilize resources from the following centers?

- UM Health System General Clinical Research Center (GCRC)
- Michigan Alzheimer's Disease Research Center (MADRC)

1-1.6 *

Does this study require review by the UM Health System Comprehensive Cancer Center Protocol Review Committee or Cancer Prevention and Control Protocol Review Committee (PRC/CPC-PRC)? 

no

1-1.7 *

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

no

1-1.7.1 If yes, list the peer-review organization(s).

* Required

2. Sponsor Information

The following sections request details about the sponsorship of this study. Consider all of the choices below and complete the appropriate sections.

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

2.1 External Sponsor(s):

Only key fields are displayed. Click on the link below to view all details.

Type	Name	Other Direct Sponsor	Support Type
------	------	----------------------	--------------

There are no items to display

2.5

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

Only key fields are displayed. Click on the link below to view all details.

Type	Department Sponsor	Support Type
There are no items to display		

2.8

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

* Required

3. University of Michigan 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.)

Analysis (data/specimen)


Storage (data/specimen)

If other, please describe:

* Required

3-1. Performance Sites

3-1.1 *


Based on the information provided in 3.1, "University of Michigan" is listed below as a performance site. Click ADD to list non-UM locations (both domestic and foreign) where UM-related research activities are conducted including subject recruitment, interaction, intervention, study coordination, and/or data analysis. *This section may or may not apply to certain industry/corporate sponsor locations -- see Help for important instructions.* 

Location	Country	"Engaged" in the research?
University of Michigan	USA	yes

* Required

4. Non-Technical Study Abstract

4.1 *

Non-Technical Study Abstract (400 words or less): *Use non-technical language that someone without a scientific background could understand. Include a summary of the significance, scientific objective or research question, and specific aims.* 

This study will review the records of newborns treated in the UM intensive care unit (NICU) between January 2000 and February 2006 to see which of two drugs works better when babies are taken off the breathing machine.

Currently doctors use either dexamethasone or hydrocortisone to treat premature infants with low blood pressure that have not responded to other treatments. Our aim is to determine which babies have better outcomes.

Currently, due to limited number of studies as well as methodological difficulties, there is no established clinical standard of practice. Results of this protocol will provide us with a good sense of how well each medication reduces potentially detrimental physiological stress in neonates. The findings of this study may help to establish a standard of practice for neonates.

* Required


5. Research Design

This section covers the overall research design of the project. Later sections will ask more specific questions about benefits, risks, special review considerations, targeted populations, recruitment strategies, and experimental methodologies/procedures.

In this section, you will be able to answer the specific questions by:

- Submitting a stand-alone scientific protocol and/or research plan, then referencing the relevant sections in questions 5.2 through 5.7;
- Submitting a stand-alone scientific protocol and/or research plan, then augmenting it with additional information in questions 5.2 through 5.7; or
- Providing a detailed response to each question below.

5.1 *

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

yes

If yes, click **ADD** to attach the document(s) electronically, OR check below if the document is not available electronically. 

See [Help](#) for more information about working with documents (e.g. uploading, downloading, editing).

name	version
 Data Collection Sheet 3-11-06	0.01
 Dexamethasone vs hydrocortisone Protocol	0.01

Check here if the documentation is not available electronically.

Note: Study Teams are encouraged to scan and upload documents. [See Help](#) for a list of sites with scanning facilities.

5.2 *

Objective: What is the overall purpose of this research study? (*Limit response to 1-2 sentences. If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application.*)

Section I A

5.3 *

Specific Aim(s): What is (are) the specific aim(s) of this study and/or what hypothesis (hypotheses) is (are) to be tested? (*If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application.*)

Section I B

5.4 *

Background: What prior information or knowledge exists to support the conduct of this study? (*Limit response to 5,000 characters, including references. If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application.*)

Section IV

5.5 *

Study team expertise: Briefly outline the special expertise and qualifications of the PI, Co-Investigators and/or Faculty Advisors to conduct and/or oversee this particular study. (*If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application. This will supplement information provided in study team CVs.*)

Appendix II

5.6 *

Methodology: Describe the design and procedures to be used to accomplish the specific aims of the study. Describe the advantages of any innovative methodologies. *Include a sequence or timetable of research activities. (If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application.)*

Section III

5.7 *

Statistical Design: Describe the statistical design of the research study, including methods used to analyze data. *Include (as appropriate) statistical or interpretive analysis methods, study stopping rules, etc. (If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application.)*

Section IV

* Required

6. Benefits and Risks

6.1 * Are there potential direct benefits of this research to the subjects?

no

6.1.1

If yes, describe the potential direct benefits. Indicate if all, or only some, of the subject groups may derive this potential benefit.

6.2 *

Describe the potential benefits of this research to society (e.g., how might the research lead to improvement in management of a particular illness; health care cost reduction; increased knowledge of a social issue; improved safety; better health; technological advancement?).

Results of this study will benefit future neonates suffering from pressor resistant hypotension by providing data on the safety and efficacy of dexamethasone and hydrocortisone.

6.3 *

Provide a description of the foreseeable risks to the subjects (*include physical, psychological, social/reputation, legal, financial, privacy, etc.*).

For EACH identified risk, include:

- **likelihood of the risk,**
- **seriousness to the subject; and**
- **what measures will be taken to minimize the risk.**

If possible, please use the following categories to assess the likelihood

- **"Common" (i.e., approximate incidence > 25%)**
- **"Likely" (i.e., approximate incidence of 10-25%)**
- **"Infrequent" (i.e., approximate incidence of 1-10%)**
- **"Rare" (i.e., approximate incidence < 1%):**

Because this is a retrospective study, breach of confidentiality is the only identified risk subjects. This risk is considered rare and non-serious. The research records will not include data that is potentially stigmatizing. Because the research records will not include any information not already part of the medical record a breach should not impact subjects' financial insurability or pose other financial risk.

Electronic records will be maintained on password protected computers and servers, in password protected files. Paper records will be stored in locked file cabinets in the Mott Offices of the

6.4 *

Describe any direct risks to the public or community, which could result from this research (*e.g. potential dissemination to others of transferred genetic material, exposure of others to radiation from radioisotopes administered to a subject.*)?

None.

6.5 *

What is the highest level of risks of harm to the subjects, resulting from this research? 


No more than minimal risk

6.6 *

Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits.

The risks are non-serious and the chance of them occurring are rare while a greater understanding of the safety and efficacy of dexamethasone and hydrocortisone will reduce mortality and morbidity of neonates.

6.7 *

What specific criteria will be used to prematurely end a particular subject's participation in the study (*e.g., predetermined safety endpoints, unexpected clinically significant findings, situations of distress or adverse events*)? (*If covered in attached document, indicate specific location. Failure to do so may result in delays in the review process or return of the application.*) 

Not applicable.

* Required

7. Special Considerations

 Help

7.1 *

Will subjects receive payment or other incentives for their participation in the study? (*e.g., free parking, course credit, health-care procedures provided at no charge, etc.*) [Require Section 13]

no

7.2 *

Will subjects undergo healthcare-related treatments or procedures as part of the study (*e.g., medical, dental, therapeutic, psychological, etc.*)? [Require Section 14]

no

7.3 *

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

no

7.4 *

Will genetic analysis be performed on any specimens acquired in conjunction with this study? [Require Section 20]

no

7.5 *

Does this study involve the **secondary analysis** of a **pre-existing data set**? (*Studies that are limited to retrospective review of medical records ARE considered secondary data analyses. Consultation of medical record*

information in conjunction with a study involving interaction/intervention (e.g., screening for eligibility) is not necessarily considered secondary data analysis. In either case, a request for full or partial waiver of informed consent may be required.) [Require Section 24]

yes

7.6 *

Does this study utilize protected health information (PHI)? *PHI is identifiable patient health information maintained by a HIPAA-covered entity (e.g., healthcare provider, healthcare plan, or healthcare clearinghouse) and/or the creation of information that will be placed into patient health records maintained by a HIPAA-covered entity. [Require Section 25]*

yes

7.7 *

Is this study considered epidemiological or public health research? [Require Section 26]

no

7.8 *

Does this study involve the deception of subjects? [Require Section 27]

no

7.9 *

Excluding routine email correspondence, does this study involve the use of the Internet or email as an integral part of the research design? [Require Section 28]

no

7.10 *

Will the study survey or interview individuals, households, businesses, or organizations or hold group meetings/focus groups to collect data? [Require Section 29]

no

7.11 *

Does this study involve UM-related research activities

conducted or coordinated at sites outside of the United States? *[Require Section 30]*

no

7.12 *

Does this study require subjects to listen to an audio recording or view images (e.g. *photographs, artwork, sketches, videos, etc.*)? *[Require Section 31]*

no

7.13 *

Is the intent of the study the development of a commercial product that may bring financial benefit to the investigators and/or the University?

no

If yes, please consult with the [University of Michigan Technology Transfer Office](#), request opinion on the rights of the subject and inform the IRB of that opinion.

* Required

7-1. Special Considerations (continued)



7-1.1 *

Will any drugs, biologics, nutritional (e.g., *herbal or alternative medication*) supplements or other material be administered, implanted, or applied to the subjects as the object of the study? *(Please note, a fee applies if using UMHS IDS services)* *[Require Section 15]*

no

7-1.2 *

Will any devices be used, administered, implanted, or applied to the subjects? *[Require Section 16]*

no

7-1.3 *

Will the study involve a placebo (*drug, device, procedure, intervention, surgery, etc.*) control group? *[Require Section 17]*

no

7-1.3.1

If yes, is the placebo for a drug? *[Require Section 15]*

Yes No

7-1.4 *

Will the study involve human embryonic stem cells (hESCs), human embryonic germ cells derived from fetal tissue, or hESC- or germ cell-derived test articles? *[Require Section 19]*

no

7-1.5 *

Will the subjects be exposed to any ionizing radiation during the course of this study? (e.g., x-rays, CT-scans, PET-scans, beta-rays, gamma-rays, neutrons, and other high-speed atomic particles. Magnetic Resonance Imaging (MRI) is NOT ionizing radiation.) *[Require Section 21]*

no

7-1.6 *

Will any organs, tissues, or cells from other humans (including fetal tissue) or animals be administered to the subjects for the purposes of this study? *[Require Section 22]*

no

7-1.7 *

Does this study involve a gene transfer intervention or an intervention based on recombinant DNA technology? *[Require Section 23]*

no

7-1.8 *

Will the study have a Data and Safety Monitoring Plan (DSMP)? *A DSMP is required for:*

- *GCRC-sponsored research,*
- *FDA-regulated research,*

- *research where adverse events (AEs) are expected (e.g., physical, social, psychological, confidentiality/privacy, etc), and*
- *NIH-sponsored research involving human subjects.*

In addition, research projects involving identifiable sensitive data are strongly recommended to have a DSMP. [Require Section 32]

Note: For Dental School Applications, [See Help](#) for more information.

no

* Required

8. Subject Description



8.1 *

Will the involvement of any subjects in this study be limited to their existing data or specimens (*i.e., other than any potential informed consent process, there is no direct interaction/intervention with subjects; subject interaction/intervention is limited to databases, data sets, medical records, specimens from bank or repository*)?

yes

8.1.1

If yes, how many subjects are represented in the data to be analyzed?

100000 (*do not enter commas, dots, or special characters*)

8.2 *

Will the study involve recruitment and/or participation of subjects in order to produce new data (*e.g., surveys, interaction, intervention*)?

no

8.3 *

List the inclusion and exclusion criteria for this study population and/or data set. (*If covered in attached*

protocol, indicate section)

Protocol section III-A

8.4 *

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

Minimum Age: 0

Maximum Age: 1 If no upper limit, enter "999"

* Required

10. Informed Assent for Children and Parental or Guardian Consent/Permission -

10.2 *

What types of informed assent for children and parental consent/permission will be obtained?

NOTE 'Parent' or 'Parental' below refers to parent or guardian. [See Help for important instructions on selecting the appropriate category.](#)

Select all that apply:

Request for waiver of parental informed consent/permission requirement (e.g., some retrospective studies, screening portion of a study)

10.2.1 *

Describe the process to seek and obtain informed assent for children and parental consent/permission (e.g., setting, timing, personnel involved, arrangements for answering subject questions before and after the consent is signed).

None

10.2.2 *

What criteria will be used to determine whether or not a child's assent to participate will be obtained, whether that assent will be oral or written, and whether documentation of the child's assent (e.g., signature on the assent form) will be obtained?

NA

10.2.3 *

Are any of the following changes expected in the status of child subjects during the study?

Check all that apply:

Expect no change in status of child subjects

10.2.3.1

If applicable, describe the plan to re-assent or obtain consent for the subject if any of the changes occur.

* Required

10-3. Informed Consent Waiver

10-3.1 * This request is for:

Select all that apply:

Waiver of informed consent for ALL of the project

10-3.1.1

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

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

10-3.2

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

10-3.2.1 The research involves no more than minimal risk to the subjects.

*



Explain:

Data analysis only.

10-3.2.2

*

The waiver or alteration will not adversely affect the rights and welfare of the subjects.

**Explain:**

Identified risk is rare and non-serious.

10-3.2.3

*

Research could not practicably (i.e., feasibly) be carried out without the waiver or alteration. 

**Explain:**

We will be accessing the records of over 8000 patients, many of whom may have died or are not being followed by UM. We would not be able to locate a statistically significant subject pool without the waiver.

10-3.2.4

*

Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Explain:**

If in the course of the research we uncover any information that would be pertinent to the on-going care of a subject, we will attempt to contact the patient's primary care physician.

* Required

11. Confidentiality/Security

11.1 *

Will any component of the research involve data that is linked to a subject's identity by name or other identifier? 

yes

If yes, answer the following three questions.

11.1.1 Indicate how subjects are identified in the research records.

Select all that apply:

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

11.1.2

Explain the necessity for maintaining data linked to subjects' identities.

We will validate collection methods by comparing data collection sheets to subjects' records.

11.1.3 How long will the identifiers be retained?

The document linking the subject number and the subject CPI number will be destroyed when the validation is complete. This step is estimated to take place 6 months after initiation of the study.

11.2 *

How will the research records and data be protected? *This includes informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, etc.*

Select all that apply:

Locked office

Locked cabinet or storage unit

Limited access

Restrictions on copying study-related materials

Secure laptop

Password protection

Routine electronic back up

Network restrictions

Dedicated server

11.2.1

Describe any other (e.g., additional) measures that will be taken to protect the study records and identifiers from improper use and disclosure.

11.3 *

Will the research generate information which, if revealed, might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation? (e.g. sexual matters, use of alcohol or drugs, stigmatizing or discriminating medical or mental health information)

no

If no, skip to 11.4

11.3.1 **Will a Certificate of Confidentiality be obtained for this research?** 

If yes, upload the certificate here.

name version

There are no items to display

Check here if the documentation is not available electronically.

Check here if the Certificate of Confidentiality is pending.

Note: All obtained Certificates must be forwarded to the Office of the Vice President for Research for signature by an appropriate institutional official. Principal investigators are not authorized signers.

11.3.2

Describe any measures or procedures that will be employed to prevent others from learning about subjects' participation in this study.

11.4 * Will the research involve the use of focus groups?

no

11.4.1

If yes, how will the identity of individuals participating in the groups be protected?

11.5 *

If a participant withdraws from the research, what is the plan to use, store, or destroy the participant's data?

NA

11.6 *

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

Select all that apply:

Retain for study recordkeeping purposes - requires 11.6.2

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 (*e.g., destruction of research records; removal of identifiers; destruction of linkage code information*). If the information is covered in the attached protocol, please indicate section.

11.6.2

If the data and/or specimens will be retained for study recordkeeping purposes, describe the storage arrangements (*e.g., expected duration, location, security, storage conditions, and monitoring*). If the information is covered in the attached protocol, please indicate section.

Protocol section IV-c

* Required



12. Exemption

Research that exposes participants to no more than minimal risk MAY be considered exempt from the need for ongoing IRB review and approval. Federal law details 6 categories of exempt research.

The study does NOT qualify for an exemption, if the research involves:

- Incarcerated subjects
- FDA-regulated agent or the off-label use of an FDA approved agent

Research limited to the following activities MAY qualify for an exemption determination by the IRB:

- Studying educational methods
- Interviewing public figures
- Use of publicly available data sets
- Use of existing data and/or specimens stripped of identifiers


[View Exemption Category Guidance](#)

IMPORTANT INFORMATION:

Exemption categories are very narrow in their scope and the entire research project must clearly fall within the boundaries of the definition. If the IRB determines that the study does not qualify for an exemption, the application will be routed for the appropriate expedited or full committee review.

Please contact the IRB Office if you have further questions about qualifying for an exemption.

12.1 *

Does the proposed research study qualify for exempt IRB review status? 

no

12.1.1

If yes, which of the following six exemption criteria applies to the study?

* Required

Special Consideration Details

You have now completed the general sections of the initial application for research

involving human subjects.

In Section 7 *Special Considerations*, you indicated that the research involved one or more elements that require special review consideration. You will now be asked to complete detailed questions about each element specified.

24. Secondary Data Analysis

Completion of this section is required based on the response provided to question 7.5.

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

Only key fields are displayed. Click on the link below to view all details.

Name	Identifying Info	Is Publicly Available
UMHS Medical Records including Careweb and the Data Warehouse	Records include medical history, name, address, CPI#, and possibly social security numbers	no

* Required

25. Protected Health Information (PHI) / HIPAA

Completion of this section is required based on the response provided to question 7.6.

Under Health Insurance Portability and Accountability Act (HIPAA), Protected Health Information (PHI) is defined as: information (including demographic information) about a patient that:

- (i) is created or received by a health care provider;
- (ii) relates to the past, present, or future physical or mental health of the patient; provision of health care to the patient; or payment for the provision of health care to the patient; and
- (iii) identifies the patient or with respect to which there is a reasonable basis to believe it could be used to identify the patient.

25.1 * Identify the PHI to be used.

Select all that apply:

Hospital/doctor's office records, including test results

Any records relating to condition, the treatment received, and response to the treatment

If other, please specify:

25.2 *

Affirm that the PHI indicated above is the minimum necessary to conduct the study (i.e., additional PHI will not be accessed or used).



25.3 *

Indicate the extent to which HIPAA authorization for access to the PHI will be obtained:

HIPAA authorization will not be obtained from any subjects

25.3.1

If HIPAA authorization for access to the PHI will be obtained from some or all subjects, indicate the document/process to be used:

If other, please specify:

25.3.2

If HIPAA authorization for access to the PHI will NOT be obtained from some or all subjects/candidates for recruitment, indicate why: 

Select all that apply:

Request for waiver of HIPAA authorization

* Required

25-1. HIPAA Authorization Waiver Request

Completion of this section is required based on the response provided to question 25.3.2.

25-1.1 * Waiver of HIPAA authorization requested for:

Select all that apply:

Entire Project

If other, please specify:

25-1.2 *

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 disclose [45 CFR 164.512 (i)(2)(ii)(A)(1)]

Paper documents will be in locked storage. Electronic records will be securely stored and password protected as previously described.

25-1.3 *

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 [45 CFR 164.512 (i)(2)(ii)(A)(2)].

Linking documents will be destroyed when the validation process is complete, expected 6 months after initiation.

25-1.4 *

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., 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 [45 CFR 164.512 (i)(2)(ii)(A)(3)].

Information will not be reused or disclosed.

25-1.5 *

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

We will be accessing the records of over 8000 patients, many of whom may have died or are not being followed by UM. We would not be able to locate a statistically significant subject pool without the waiver.

25-1.6 *

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

what

25-1.7 * Will data containing PHI be shared outside of the covered entity?

no

25-1.7.1

If yes, affirm that disclosures of PHI outside the covered entity will be tracked and reported according to guidelines published by institutional privacy officials.

no

* Required

The application is almost complete . . .

Three additional steps are required to submit this application for review:

1. **Click "Finish" to save the application and return to the Study Workspace.**
2. **All Co-investigators and Faculty Advisors must review the study and click "Accept Role" in the Study Workspace (if they have not already done so).**
3. **The PI must then click the "Submit" button.**

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

After the steps above are completed, the application will be sent to any required compliance committees and the IRB for review.

Study Team Detail

1.4 Team Member:

name: [June Insko](#)

Department: [Medical School Administration](#)

Preferred email: insco@umich.edu

Business phone: [734/762-1768](tel:7347621768)

Business phone: 734/763-4768
 Business address: IRBMED 4550 Kresge I 0570

PEERRS Human Subjects Module Completed	Expiration Date
Conflict of Interest	6/19/2006
Human Subjects - Biomedical Sciences	1/4/2007
Research Administration	6/19/2006
Human Subjects - Health Sciences	1/4/2007
Conflict of Interest	6/19/2006
Pre-test	1/4/2007
Human Subjects - Behavioral Science	1/4/2007
Animal Subjects	6/19/2006

The PI and any Co-Investigators and/or Faculty Advisors involved in this study must complete at least one of the PEERRS Human Research training modules.

1.5 Function with respect to project:

PI

1.6

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

yes

1.7

Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions. Co-investigators and faculty advisors are required to receive this information.)

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 PI, Co-Is and Faculty Advisors

C1

Do you receive income greater than \$10,000/year or have any other significant financial interest (stock, stock options, debt, security, or capital

holdings, etc.) in or manage:

- a business commercializing a product that the research is intended to evaluate or f develop, or
- a party whose financial interests would be directly and significantly affected by the research?

C1.1 Where have you submitted a disclosure of Conflict of Interest?

C1.2 Has a management plan been formalized?

C1.2.1 If yes, attach the management plan here.

name	version
There are no items to display	

C1.2.2

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

Performance Site Detail

3-1.2 * Location or Institution:

University of Michigan

3-1.3 Address:

Street	
City	
State	
Postal Code:	
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.)

Analysis (data/specimen)

Storage (data/specimen)

If other, please specify:

3-1.5 *


Will this site be "engaged" in the conduct of the research? *Note: "engaged" in this context refers to the regulatory definition and NOT the use of the "Engage" portal website. See Help for important information about responding to this question.* 

Yes No

3-1.5.1

If yes, indicate the IRB or its regulatory equivalent that has reviewed or will review this research and provide its approval.

3-1.6


If applicable, provide the Federalwide Assurance (FWA) number for this location. (*Note: If federally sponsored, FWA is required for site in addition to IRB approval.*) 

FWA00004969

3-1.7

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

3-1.8

Upload any location site approval documentation here : *IRB approval documentation and/or approval letters from the appropriate administrative authority (e.g, school district office, prison official, nursing home administrator) as indicated above.* 

name version
There are no items to display

Check here if the documentation is not available electronically.

***Note:** Study Teams are encouraged to scan and upload documents. [See Help](#) for a list of sites with scanning facilities.*

Secondary Data Analysis Data Set Detail



24.2 * Name of data set:

UMHS Medical Records including Careweb and the Data Warehouse

24.3 *

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

Records include medical history, name, address, CPI#, and possibly social security numbers

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

no

If yes, scroll to the bottom of this page and click OK. If no, answer the rest of the questions.

24.5 What was the original purpose for the collection of data in this set?

Clinical care.

24.5.1

If collected in conjunction with a different study, provide the IRB approval documentation.

name version
There are no items to display

24.6


Was prior consent from the subjects obtained to utilize the data set for this study?

--

no

24.6.1

If yes, describe the terms of the consent as it relates to this study, include relevant excerpts from the consent.

If available, upload the prior consent documents here. 

name	version
There are no items to display	

24.6.2

If no, indicate intention to obtain a waiver of informed consent or describe the plan to re-establish the identifying links and re-consent individuals.

Waiver of informed consent requested.