eRESEARCH | REGULATORY MANAGEMENT

Date: Sunday, February 28, 2021 4:44:19 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:

Medical Student Perspectives on the Michigan Medicine Chaperone Policy

1.1.1 Full Study Title:

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,**
- **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:

Jill Nulle
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?
Jill Nulle	PI		N/A	yes	No	no	yes	N/A	yes
Angeline Lonardi	Co-Investigator		N/A	yes	No		yes	N/A	yes
Andrew Shuman	Faculty Advisor	MM Otorhinolaryngology Dprtmnt	Yes	no	No	no	yes	Yes	yes
Christian Vercler	Faculty Advisor	MM Plastic Surgery Section	Yes	no	No	no	yes	Yes	yes

1.8* Project Summary:

Our project aims to identify the level of student engagement with the new opt-in medical student chaperone policy at Michigan Medicine to gain an understanding of the current student body's

willingness to intervene on behalf of the patient during sensitive medical exams. Major questions to be addressed include: What percent of the medical student body currently chooses to serve as chaperones? What factors lead to students' decisions to become a chaperone or decline this responsibility? How willing are medical students to intervene on behalf of the patient during sensitive medical exams or report suspected and/or overt sexual misconduct on the part of a senior provider during a sensitive medical exam? Our hope is that the information gained from this project will help guide future policy concerning the role of medical students as chaperones and ultimately aid our institution's ongoing efforts to foster a safe environment and culture of respect.

We will obtain our initial data through templated in-person interviews with medical students at the University of Michigan. We will then construct an online survey based on these interviews. The survey document will require IRBMED review prior to the administration of the survey to students. An amendment will be submitted to IRBMED when the survey document is available and before administering the survey. Once approved, this online survey will then be distributed through the secure, Michigan Medicine brand of Qualtrics to all students at the University of Michigan Medical School. Email addresses will be obtained through class listservs.

The interview template is attached to this application. The online survey is now attached to the application as of 11/23/20. This study is entirely virtual and places participants at no increased risk of contacting COVID-19.

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:

Jill Nulle

Preferred email: jillcl@umich.edu
Business phone
Business address: 48109

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
Nulle Jill CV.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 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:

Angeline Lonardi

Preferred email: langelin@umich.edu
Business phone
Business address: 48109

1.5 Function with respect to project:

Co-Investigator

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

Yes

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

Yes

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

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

Name	Version
Angeline Lonardi CV(0.01)	0.01

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

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

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

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

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

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

Study Team Detail

1.4 Team Member:

Andrew Shuman

Preferred email: shumana@umich.edu
Business phone 734-232-0120
Business address: LSA UG: Curriculum Support 1904 Taubman Ctr 48109-5312

1.5 Function with respect to project:

Faculty Advisor

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

Yes

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

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

Name	Version
CV_Updated(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:

Christian Vercler

Preferred email: cvercler@umich.edu
Business phone 734-936-5881
Business address: Pediatric Plastic Surgery 4-730 C&W Mott 48109-4730

1.5 Function with respect to project:

Faculty Advisor

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
Vercler CV(0.01)	0.01

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

Current Disclosure Status in M-Inform: *This study team member has 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.

Does the research involve any of the following:

a. more than minimal risk to participants?
b. use of drugs or medical devices?
c. target prisoners as research subjects?
d. collection of biospecimens from subjects (including blood, saliva, cheek swabs)?

○ Yes ● **No**

Some studies involving interaction or intervention with subjects meet the criteria for exemption. Select the category that best describes your research. Detailed questions to verify eligibility are found on the next page. For some studies, you will be able to issue a self-determination.

If none of these categories apply to your research select NONE. Your application will be routed for comprehensive IRB review.

	Exemption Category
○	**Exemption 1** applies to research that is: • conducted in established **educational settings (typically schools/colleges)**; and • focuses on **normal (accepted) educational practices (e.g. instructional techniques, curricula, classroom management methods** May include use of educational data
●	**Exemption 2 applies to most research that involves collection of information using ONLY one or more of the following:** • **Surveys (with adults only)** • **Interviews (with adults only)** • **focus groups (with adults only)** • **educational tests** • **observation of public behavior** **May involve audio-visual recording but may not involve an intervention (see exemption 3) or linking to additional personally-identifiable data.**
○	**Exemption 3** applies to research with **adults only** that involves: • **benign** (not harmful) **behavioral interventions** Examples: ◦ Playing an online game ◦ Solving puzzles under various noise conditions ◦ Playing an economic game ◦ Being exposed to stimuli such as color, light or sound (at safe levels) ◦ Participating in a nutrition education program • **information collected through verbal or written responses** (including methods described in exemption 2 above) • **no physiological data collection** (e.g. blood pressure monitoring, EEG, FitBit, etc.) • **subjects' prospective agreement to participate** in intervention and information collection **May not involve deception** unless subjects are told that they will be misled

	Exemption Category
○	**Exemption 5** applies to **research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** that are **designed to study, evaluate, improve, or otherwise examine public benefit or service programs**.
○	**Exemption 6 - Taste and food quality evaluation and consumer acceptance studies**
○	**NONE** - none of the exemption categories apply to this research.

☐	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, or educational records. Includes Exemption 4 and “not regulated” projects. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")
☐	Activities **Not Regulated** as human subjects research	Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research (45 CFR 46 or 21 CFR 50/56). **IRB review is required** for the following activities **ONLY** to assess compliance with **HIPAA** or other regulations or institutional policies: • Research on existing data or specimens that have been coded before the researcher receives them, but identifiers still exist. • Research Involving Deceased Individuals Only • Pre-review of Clinical Data Sets Preparatory to Research • Standard Public Health Surveillance or Prevention Activities **IRB review is not required for the following activities**, but researchers may wish complete this brief application to generate a determination letter for funding or publication purposes, or to request IRB review to confirm the “Not Regulated” determination: • Case Studies • Class Activities • Journalism/Documentary Activities • Oral History • Quality Assurance and Quality Improvement Activities • Research on Organizations • Research using Publicly Available Data Sets
☐	Projects **lacking immediate plans for involvement of human subjects**, their data, and/or their specimens	Activities such as training grants, program projects, center grants, or multi-phase studies not involving human subjects until later years. Before release of funding, some agencies may require IRB acknowledgement of the future use of human subjects. These projects are sometimes referred to as "umbrella projects" or "dry applications."
☐	**Single-patient Expanded Access Drug or Biologic (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational drug or biologic, outside of a clinical trial, under a single-patient IND issued by the FDA for a patient faced with a serious or life-threatening disease or condition.

		• Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational drug or biologic is made. • Submission for IRB review and approval is required, prior to use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational agent.** • This includes both one-time use and continuing therapy.
☐	**Single-patient Expanded Access Device Use (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational device, outside of a clinical trial, when this is the only option available for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational device is made. • Submission for IRB review and approval is required, prior to device use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational device.** • This includes both one-time use and continuing therapy.
☐	**Humanitarian Use Device** (HUD) under a HDE	Non-research, on-label use of an HUD under a Humanitarian Device Exemption (HDE)
☐	Requesting Review by a **Non-UM IRB**	Use ONLY to request deferral of IRB oversight for UM activities to a non-UM IRB or when UM is a performance site in a multisite research project where UM is the lead site.
☐	**Multi-site Research** where U-M is a Coordinating Center and/or IRB of Record	Do not use Multi-site Research application type when U-M is **only** a performance site - select Standard application type. Select when U-M is any of the following: • Data Coordinating Center; • Clinical Coordinating Center; or • IRB of Record for non-U-M sites (for U-M to be IRB of Record you must contact your IRB for prior acknowledgement). When U-M is **also** a performance site, a separate application is required for local site considerations. Refer to special requirements at the IRB website.

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

01-2. Standard Study Information

1-2.1* Who initiated this study?

Student investigator or faculty member on behalf of a student

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.

Students

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**

1-2.8* Is this a clinical trial?

◯ Yes ● **No**

1-2.9* Would the integrity of this research study be compromised if the subject were able to view results of their research tests or medications in the Patient Portal of MyUofMHealth.org? Research results displayed to the subject in MyUofMHealth.org will include: lab results, radiology examinations and outpatient medication lists. Contracts and protocols should be assessed by the Principal Investigator for specific language regarding blinding of subjects and their research results.

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

◯ Yes ● **No**

View: 01-7. Student Research Information
Section: 01. General Study Information

01-7. Student Research Information

1-7.1* This application is being submitted by a:

Select all that apply:

Student for a mentored research project (e.g. K award)

1-7.2 Indicate course number here:

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

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.
*** Note: At least one of the following sections must be answered. Multiple forms of funding or support must be added one at a time.**

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

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

Related PAFs:

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

There are no items to display

Related AWDs:

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

There are no items to display

Related UFAs:

UFA ID	Title	PI	State	Category	Start Date	End Date

There are no items to display

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

Type	Department Sponsor	Support Type

There are no items to display

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

☑

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

○ Yes ● **No**

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

03. UM Study Functions

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

Select all that apply:
Recruitment (including screening)
Interaction (e.g., information gathering, survey, interview, focus groups, 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,Interaction,Analysis,Recruitment

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:

Recruitment (including screening)

Interaction (e.g., information gathering, survey, interview, focus groups, 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: Exemption 2
Section: 12. Exemption

Exemption 2

Completion of this section is required based on the Exemption Category selected in question 1-1.1.

Exemption 2 applies to projects that include either:

1. Observation of Public Behavior; or
2. Interactions with human subjects that involves collection of information ONLY using the follow methods:
   - Surveys
   - Interviews (including cognitive interviews)
   - Focus Groups
   - Educational tests (cognitive, diagnostic, aptitude, achievement)
   - Observation of public behavior

Audio and/or video recording of these observations or interactions is permitted.

This exemption does not apply if the research involves:

- Interventions/manipulations that are distinct from the information collection methods
- Collection of biospecimens in conjunction with surveys/interviews/educational tests
- Linking information collected via this exemption to other personally-identifiable data

1* Confirm that your research involves the collection of information ONLY using one or more of the following:

- **Surveys (information collected through questionnaires, in person or online)**
- **Interviews**
- **Focus Groups**
- **Educational Tests (cognitive, diagnostic, aptitude, achievement)**
- **Observation of public behavior**

● **Yes** ○ No

1.1* Does the research involve children?

○ Yes ● **No**

2* Does the research collect information about the subject in such a manner that their identity can be readily ascertained by the study team, directly or through identifiers linked to the subjects?

This means that the information is collected with direct identifiers (name, address, email, phone number, social security number, student ID, medical record number) or indirect identifiers, such as a code that can link back to the subject or data elements that could be combined to readily re-identify an individual (dates, employment history, etc.).

○ Yes ● **No**

3* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI) to identify eligible subjects? [Require Section 25]

○ Yes ● **No**

4* Provide a brief summary of your research (subject population, study procedures, location of research) or upload protocol below.

Our project aims to identify the level of student engagement with the new opt-in medical student chaperone policy at Michigan Medicine to gain an understanding of the current student body's willingness to intervene on behalf of the patient during sensitive medical exams. Major questions to be addressed include: What percent of the medical student body currently chooses to serve as chaperones? What factors lead to students' decisions to become a chaperone or decline this responsibility? How willing are medical students to intervene on behalf of the patient during sensitive medical exams or report suspected and/or overt sexual misconduct on the part of a senior provider during a sensitive medical exam? Our hope is that the information gained from this project will help guide future policy concerning the role of medical students as chaperones and ultimately aid our institution's ongoing efforts to foster a safe environment and culture of respect.

We will obtain our initial data through templated in-person interviews with medical students at the University of Michigan. We will then construct an online survey based on these interviews. The survey document will require IRBMED review prior to the administration of the survey to students. An amendment will be submitted to IRBMED when the survey document is available and before administering the survey. Once approved, this online survey will then be distributed through Google Forms to all students at the University of Michigan Medical School. Email addresses will be obtained through class listservs.

5* Upload documents (e.g. protocol document, survey/interview/test questions, or other documents relevant to your research).

The submission of an informed consent document is not required for studies that do not collect identifiable, sensitive data. Researchers still have an ethical obligation to ensure that participants are fully informed about the nature of a research project so that they can make an informed decision to participate.

Name	Version

Name	Version
Nulle and Lonardi CFI Student Interview Template.docx(0.01)	0.01

6* Will subjects receive payment or other incentives for their participation in the study?

(●) **Yes** ( ) No

6.1* What is the estimated maximum total payment to an individual subject?

$0.01-$25

6.2* Please indicate what information you will be collecting from subjects that will be paid for their participation:

Select all that apply:

- [ ] Name
- [ ] None
- [ ] Address
- [x] **Email**
- [ ] Social Security Number (SSN)

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.