eRESEARCH | REGULATORY MANAGEMENT

Date: Monday, November 30, 2020 11:54:43 AM 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 Mental Health Resource Satisfaction

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:

Lauren McGee
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?
Lauren McGee	PI		N/A	yes	No	no	yes	N/A	yes
Cayla Pichan	Co-Investigator		N/A	yes	No		yes	N/A	yes
Kirk Brower	Faculty Advisor	MM Wellness Office	Yes	no	No	no	yes	Yes	yes

1.8* Project Summary:

The University of Michigan Medical School has increased their focus on student wellness over the past few years, but there is currently no data specifically evaluating student access to, knowledge, and utilization of professional mental health resources available to them as medical students. The goal of our study is to critically assess which resources students are using and are satisfied with, and where gaps in knowledge or dissatisfaction is occurring in order to implement improvements in the future.

Additionally, we would like to evaluate the extent of mental health concerns amongst medical students, particularly any needs that have gone unmet, so that faculty administrators have a clearer idea of the number of students in need when programming decisions are made.

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

1.10* *Estimated* Study Start Date (Not required for IRBMED): (mm/dd/yyyy)

1.11* *Estimated* Duration of Study:

2 years

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

Study Team Detail

1.4 Team Member:

Lauren McGee

Preferred email: lmariemc@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
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?

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:

Cayla Pichan

Preferred email: cmpichan@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
Cayla Pichan 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:

Kirk Brower

Preferred email: kbrower@med.umich.edu
Business phone 734-936-2466
Business address: Wellness Office 5119 Med Sci I 48109-5603

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
Brower CV(0.01)	0.01
Brower CV 5-31-2020(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 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.

MM Medical School

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**

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
View	UM Institutional - Department, Pilot Grant Program, or other Institutional funding source	MM Medical School Administratn	Financial
View	UM Institutional - Department, Pilot Grant Program, or other Institutional funding source	MM Wellness Office	Non-financial

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: VIEW000593_customAttributes._attribute239.customAttributes._attribute3_Internal Sponsor Detail
Section: 02. Sponsor/Support Information

Internal Sponsor Detail

2.2.1* Department Sponsor/Support:

MM Medical School Administratn

2.2.2* Sponsor Type:

UM Institutional - Department, Pilot Grant Program, or other Institutional funding source

If other, please specify:

2.2.3* Support Type:

Financial

2.2.4* Is the support confirmed?

● **Yes** ○ No

2.2.5* Please describe the award/support:

Capstone for Impact Project Funding

2.2.6 Upload Supporting Documentation

Name	Version
Capstone for Impact Project Funding - Lauren McGee(0.01)	0.01

View: VIEW000593_customAttributes._attribute239.customAttributes._attribute3_Internal Sponsor Detail
Section: 02. Sponsor/Support Information

Internal Sponsor Detail

2.2.1* Department Sponsor/Support:

MM Wellness Office

2.2.2* Sponsor Type:

UM Institutional - Department, Pilot Grant Program, or other Institutional funding source

If other, please specify:

2.2.3* Support Type:

Non-financial

2.2.4* Is the support confirmed?

● **Yes** ○ No

2.2.5* Please describe the award/support:

Mentorship support and medical school project approval

2.2.6 Upload Supporting Documentation

Name	Version
Capstone for Impact Project Proposal with Advisor Signature(0.01)	0.01

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.)
Qualitative research (e.g., 'member checking', open-ended questions, 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		Qualitative research,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.)

Qualitative research (e.g., 'member checking', open-ended questions, 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.

The study will be disseminated to students currently enrolled at the University of Michigan Medical School, as well as the most recent graduated students (medical school class of 2020). The study is in the form of an anonymized survey. Students will be emailed the link to the survey. Their participation will be voluntary and there will be a statement prior to the beginning of the survey attesting consent to participation and future data usage for resource development or publication.

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
Mental Health Resources Survey(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?

$26-$100

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
- ☑ **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.