

IRB #: IRB-FY2024-56

Title: Exploring self-directed learning readiness in medical students after first semester of being in medical school: a comparison between pathway program experienced and non-experienced medical students

Creation Date: 9-5-2023

End Date:

Status: Approved

Principal Investigator: Akshata Naik

Review Board: OU IRB

Sponsor:

Study History

Submission Type	Initial	Review Type	Exempt	Decision	<span>Exempt</span>
-----------------	---------	-------------	--------	----------	---------------------

Key Study Contacts

Member	Akshata Naik	Role	Principal Investigator	Contact	anaik@oakland.edu
Member	Akshata Naik	Role	Primary Contact	Contact	anaik@oakland.edu
Member	Deidre Hurse	Role	Investigator	Contact	dhurse@oakland.edu
Member	Cameron Davidson	Role	Investigator	Contact	cjdavidson@oakland.edu
Member	Kyeorda Kemp	Role	Co-Principal Investigator	Contact	kyeordakemp@oakland.edu

## 0. General Instructions

### Cayuse IRB:

- Cayuse IRB is an interactive application system. Based on your answers, new sections relevant to the type of research being conducted will appear on the left hand side. Based on your responses, some numbered sections may not appear.
- As you respond to questions, the length of the green progress bar will change.
- Once the section is completed, a green check mark (✓) will appear. When all of the sections have the green check marks, you will be able to access "Routing- Complete Submission" at the bottom of the left bar.
- When ready to route the submission to the next stage, click on "Routing- Complete Submission," then on the blue "Certify" button that will appear on the next screen. When you "certify" (approve) the submission, it will be routed to be certified by others [i.e. Co-PI, Faculty Advisor (when applicable), and Chairs or Deans (Organizational Approvers) of the PI and Co-PI].
- If one of the sections is missing a green check mark and you don't know why, search the section for any required questions (with red \*) that you may have missed.
- For an outline of the Initial submission form and additional instructions regarding Cayuse, please see the "Cayuse Instructions" document and the "Instructions in Using Cayuse" PowerPoint presentation available in [espace IRB Forms and Templates Library](#) (see below for additional instructions regarding accessing IRB documents in espace).

### Important Notes:

- You do not have to finish the application in one sitting.
- Save your work frequently. The system will save your answers as you complete each page, but save just in case of a loss of internet connection. The save button will disappear after work has been saved, and will only reappear whenever information is changed or new information has been added.

- The application can only be edited by the person who creates the project in Cayuse (Primary Contact- PC). CO-PI and Faculty Advisor can make comments after each question in the application and return the submission pack to the PC to make the changes.
- Initial submission requires certification by the PI (and Faculty Advisor/Sponsor, when applicable), and Co-PI and Organization (Chair/Dean) of the PI and Co-PI. The All certifications must be done before Cayuse can advance the study to be submitted to the IRB.
- Organization Approvers (Chair/Dean) may need to change their role from "Researcher" to "Org Approver" by clicking on the "Role" option on the top right of the screen. To certify (approve) the study, click on "Complete Submission" at the bottom of the left column.
- Cayuse email notifications (including instructions as what needs to be done) are sent at every stage of the submission and review process of the study. When you submit the study, if you do not receive a confirmation email from Cayuse, please check your email Spam folder and move the email to your inbox. By doing so, subsequent Cayuse emails should appear in your inbox.

#### CITI Training in Human Subject Research:

- All researchers are required to complete [CITI training in Human Subjects Research](#)
- CITI training that is completed using [oakland.edu](#) account will be automatically linked to Cayuse application submission.
- CITI training that is completed without using oakland.edu account or through outside institution needs to be attached to the Cayuse submission in Section 2 on the left of the screen.
- Training other than CITI needs to be attached to the Cayuse submission in Section 2.
- For additional information regarding CITI training courses, visit the [IRB webpage](#).

#### IRB Additional Forms and Templates Library in espace

All additional forms (e.g., COI Disclosure, Special Permission, Key Personnel Roles and Qualifications Table, etc.), and templates (e.g., consent form, information sheet, child assent, parental permission, advertisement, etc.) can be accessed and downloaded from [espace IRB Forms and Templates Library](#)

### Directions to access documents in espace:

- Click on [espace IRB Forms and Templates Library](#);
- Log-in with your OU email (including the @oakland.edu) and NetID password; and
- Click the "Enroll Me" button.
- If you're a first time user of espace, then you will get a 'tour' of the site.

### Attachments:

If you receive an error message while trying to attach a document using the ATTACH button, please shorten the name of the document and try again.

### Human Subject Research:

- The Code of Federal Regulations ([45 CFR 46](#)) mandates that certain types of research involving human subjects must be reviewed by the Institutional Review Board (IRB) in order to protect the study participants.
- Human Subject research may be determined exempt if it fits one or more of the exemption categories ([45 CFR 46.104](#)).
- Human subject research may be reviewed through an expedited review if it fits one or more of the expedited categories and involve no more than minimal risk to participants ([45 CFR 46.110](#)).
- Research will be reviewed by the full board at a convened IRB meeting if it is non exempt research that does not fit under any of the expedited categories or if the research involves more than minimal risk to participants.

---

\*required

### Getting Started

---

Are you ready to proceed?

✓ Yes



## 1. Principal Investigator

\*required

### PRINCIPAL INVESTIGATOR

---

The Principal Investigator (PI) is the person with primary responsibility for the design, conduct, monitoring, and reporting of the research.

If you are preparing this submission on behalf of someone else who is the PI, put your name in the field as the Primary Contact near the bottom of this section.

\*required

### Principal Investigator (PI)

---

**Who will be the PI for this project?**

**Please select that person's name from the people finder below.**

**Note:** If you do not find the name you are looking for in the list, please send an email to the IRB Staff to add the name to the Cayuse database. In the email, please provide the name, Oakland.edu email address, status (Faculty, Staff, Student) and Department/School.

Name: Akshata Naik

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive O'Dowd Hall Room 408, Rochester, MI 48309-4482

Phone: 248-370-3887

Email: [anaik@oakland.edu](mailto:anaik@oakland.edu)

\*required

### Principal Investigator Status

---

**Note:**

- If the PI is a student or trainee, an OU faculty advisor must also be identified below. The faculty advisor must be a tenured or tenure-track member of the OU faculty or have obtained special permission from the Chief Research Officer to serve as a faculty advisor.
- OU faculty not on the tenure track or OU staff who are serving as PIs must either identify an OU faculty advisor or obtain special permission from the Chief Research Officer to serve as PI.

- Investigators not employed by OU must identify an OU faculty advisor and obtain special permission from the Chief Research Officer to serve as PI.
- In all cases, the faculty advisor must certify the Faculty Adviser's Assurance Statement at the end of this application.
- The submission must also be certified by the Organizational Approver (Chair/Dean) of the PI or the Faculty Advisor, when applicable, before it is submitted to the IRB.

### What is the PI's status?

#### ✓ OU Tenured or Tenure-Track Faculty

Tenure track individuals are those who likely have the following titles:

- Assistant Professor
- Associate Professor
- Professor

---

OU Non-Tenure-Track Faculty

OU Staff

OU Student

Non-OU Employee

\*required

### PRIMARY CONTACT PERSON

---

**Designate the individual who is to be the primary contact for this project.**

**If the Primary Contact is the PI, please enter the principal investigator into this section as well as in the PI section above.**

**Please select from the FIND PEOPLE below the name of the person**

*Note:*

- *All communications from the IRB related to this study will be directed to the individual named here.*
- *If you are filing an application on behalf of someone else, put your name here and make sure the PI's name is listed above for Principal Investigator.*

Name: Akshata Naik

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive O'Dowd Hall Room 408, Rochester, MI 48309-4482

Phone: 248-370-3887

Email: [anaik@oakland.edu](mailto:anaik@oakland.edu)

\*required

### **Principal Investigator Emergency Contact Phone Number**

---

**Provide a telephone number to contact the PI in case of an emergency related to this project.**

The number chosen should be for a phone that the PI is always likely to have access to, such as a personal cell phone.

2489824088



## 2. Type of Applications and Training

\*required

### TYPE OF APPLICATIONS

---

**What type of application are you interested in?**

✓ **Initial Human Subject Research Study Application (Exempt, Expedited, or Full Board).**

**Not Research or Not Human Subject Research Determination**

(To determine if the project meets the regulatory definition of Research or Human Subjects and/or if a determination letter is needed from the IRB).

**IRB Reliance/Authorization Agreement or Report of Exempt Determination for Domestic Research**

(For collaborative projects that have been approved/exempted by a domestic IRB outside of Oakland University. International research must be submitted as Initial).

**Reporting the Conduct of Human Subject Research Activities without an IRB Approved Application**

\*required

### TRAINING IN HUMAN SUBJECT RESEARCH

---

**Select one of the following:**

**N/A- No training is required because:**

- **I am not conducting research and seeking a Not Research letter; or**
- **I am not conducting Human Subjects Research and seeking a Not Human Subjects Research letter; or**
- **I am submitting a blanket IRB Reliance/Authorization Agreement**

All of the researchers in my project, including myself have used oakland.edu email addresses to complete CITI training.



**Note:** *No action is required by you; all training is automatically attached to your submission.*

**Note:** If for some reason the CITI training is not showing properly in the table by the name of the researcher(s), please attach the training documentation for all members of the research team by clicking on the ATTACH button below.  
(Researchers need to email their training to the Primary Contact to be able to attach it here)

---

[citiCompletionCertificate\\_2397155\\_56261109.pdf](#)

[citiCompletionCertificate\\_2397155\\_56261108.pdf](#)

[citiCompletionCertificate\\_2397155\\_56261107.pdf](#)

[citiCompletionCertificate\\_2397155\\_56261106.pdf](#)

[citiCompletionCertificate\\_2397155\\_56261105.pdf](#)

[citiCompletionCertificate\\_2397155\\_56261104.pdf](#)

Not all of the researchers in my project used oakland.edu email addresses to complete CITI training. Some researchers used one of more of the following:

- A Non-oakland.edu email address
- CITI training affiliated with a different institution
- Other human subject research training (not through CITI)

### 3. Key Personnel

Oakland University defines Key Personnel as any individuals involved in conducting human subjects research. Such involvement may include obtaining informed consent, interacting or intervening with individuals, collecting identifiable private information from individuals, or studying, interpreting, or analyzing identifiable private information or data for research purposes.

For NIH funded projects, key personnel are defined differently. Please contact the IRB Office for more information.

---

\*required

#### OTHER PROJECT PERSONNEL

---

Does this project include other personnel?

✓ Yes

\*required

Check all that apply:

---

✓ Co-Principal Investigator:

\*required

Select his/her name from FIND PEOPLE.

---

**Note:** Please be aware that the Co-PI and Organizational Approver (Chair/Dean) of the Co-PI need to certify this submission before it is submitted to the IRB.

Name: Kyeorda Kemp

Organization: Foundational Medical Studies

Address: 403 O'Dowd Hall , Rochester, MI 48309-4482

Phone:

Email: kyeordakemp@oakland.edu

✓ Key Personnel from Oakland University

\*required

**Select his/her name from FIND PEOPLE.**

---

Name: Deidre Hurse

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive O'Dowd Hall, Rochester, MI 48309-4482

Phone:

Email: dhurse@oakland.edu

Name: Cameron Davidson

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive 400 O'Dowd Hall, Rochester, MI 48309-4482

Phone:

Email: cjdavidson@oakland.edu

**Non-Oakland University Key Personnel**

\*required

**KEY PERSONNEL ROLES AND QUALIFICATIONS**

---

**Please attach the completed Key Personnel Roles and Qualifications Table** by clicking on the ATTACH button below.

Key Personnel Roles and Qualifications Table can be accessed and downloaded from [espace IRB Forms and Templates Library](#)

Directions to access documents in espace are in the "0. General Instructions" section of this application. (Left side of the screen).

**Note:** If you receive an error message while trying to attach the document using the ATTACH button, please shorten the name of the document and try again.

[Section 3 Key Personnel Roles and Qualifications Table.pdf](#)

No

\*required

## ALTERNATE EMERGENCY CONTACT

---

Is there someone else we should contact in an emergency related to this project?

✓ Yes

\*required

**Alternate Emergency Contact**

---

Please select from the FIND PEOPLE below the name of the person to be contacted in the event of an emergency related to this project if neither the PI nor the Primary Contact is available.

*Note: If you do not find the name you are looking for in the list, please contact the Research Office to have them added to the Cayuse database.*

Name: Kyeorda Kemp

Organization: Foundational Medical Studies

Address: 403 O'Dowd Hall , Rochester, MI 48309-4482

Phone:

Email: kyeordakemp@oakland.edu

\*required

**Alternate Emergency Contact Phone Number**

---

Please provide a telephone number to contact the alternate emergency contact in case of an emergency related to this project. The number chosen should be for a phone that the alternate emergency contact is always likely to have access to, such as a personal cell phone.

5174202447

No

## 4. Conflict of Interest

### Conflicts of Interest

Conflicts of interest are defined by federal and state laws, University policies, and/or sponsor guidelines.

#### Oakland Universities Conflicts of Interest Policy (# 406)

##### Article II:

Conflicts of interest are those personal and financial interests, whether actual, apparent or possible, the could lead someone to:

- (a) compromise or lose their own independence, impartiality or judgment in connection with an arrangement with the university;
- (b) propose or support an arrangement with the university that is not in the university's best interest;
- (c) results in personal or financial gain to that person;
- (d) involves preferential treatment to the person's family or business associates; or (e) would damage the university's reputation or erode the public's confidence in the university.

##### Activities related to the project that may involve COI:

Such conflicts may be real or apparent, and may include some or all of the following involving anyone working on the project or any person with whom that person has a familial or other close personal relationship (e.g., spouse, domestic partner, parent, natural or stepchild, etc.):

- Receipt of sponsored or compensated travel related to the project or to an individual's University activities related to the project;
- Receiving income for conducting the project (including, but not necessarily limited to, royalties, consulting fees, salary, dividends, etc.) of \$5,000 or more from a publicly or privately owned business entity;
- Having an equity interest or ownership stake valued at \$5,000 or more in any publicly owned/traded business entity related to the project;
- Having an equity interest or ownership stake valued at any amount in a privately owned/traded business entity related to the project;
- Holding a seat on a board of directors or advisory board for a business entity related to the project;

- Holding an executive position in a business entity (e.g., owner, president, chief executive officer, chief operating officer, chief technology officer, treasurer, etc.) related to the project; and
- Providing professional services related to your University activities to an outside organization that are related to the project.

**Note: Researchers' salaries, benefits and other financial gains that are not related to conducting this specific study do not constitute a COI in this research.**

---

\*required

## **CONFLICTS OF INTEREST**

---

**Do you, your spouse and/or dependent children or does any of the the Co-PI(s) or key personnel or their spouse(s) and/or dependent children have a potential and/or real conflict of interest with this research as described above?**

**Yes**

☒ **No**

## 5. External Funding

\*required

### EXTERNAL SPONSOR

---

Is this project funded by an *external sponsor*? i.e., are you receiving grant funding (not gifts) from an institution other than OU to support this research?

Yes

✓ No



## 6. Background and Purpose

\*required

### BACKGROUND AND RATIONALE

---

**Provide a brief (not to exceed 500 words or 3,000 characters) narrative summary of the background and rationale for the research, written in language that a layperson can understand. No citations should be included here.**

Post-baccalaureate premedical (PBPM) certificate and degree granting programs have emerged as a pathway for individuals seeking to enter medical schools. Oftentimes students, either from non-traditional backgrounds or those with a need to improve their academic records, attend these programs. However, PBPM programs are also important for diversifying medical school applicant pools by targeting populations that are historically underrepresented in medicine (Andriole, 2015; McDougale, 2015), with 18% of them having diversity-based missions (AAMC, 2018). Recent scholarship shows that students who complete PBPM programs go on to be successful in medical school and beyond (Johnson, 2021; Ripa, 2022; Schneid, 2022). While these studies at individual institutions are informative, we are interested in exploring the global effect of these programs on students' development of skills and the behaviors needed to succeed in the field of medicine.

Learning strategies, such as self-directed learning (SDL), allow healthcare professionals to keep pace with the ever changing medical field. SDL refers to the individual's ability to take the initiative to identify one's learning needs and goals, implement their own learning activities, and evaluate learning outcomes with or without help from others to be successful (Knowles, 1975). Interestingly, SDL is shown to positively correlate with academic self-efficacy (Hwang, 2021; Saeid, 2016), defined as an individual's belief in their ability to succeed academically (Artino, 2012). Importantly, self-efficacy affects decisions regarding learning and can impact an individual's performance (Guntern, 2016; Hayat, 2020; Zhang 2018).

PBPM programs provide foundational knowledge by offering appropriate courses and/or clinical experiences to participants; however, it is critical that learners also develop SDL and self-efficacy skills while in these programs. Due to their engagement with historically underrepresented populations, we believe PBPM programs are uniquely positioned to cultivate these crucial skills prior to entry into medical school. Therefore, it is imperative that the field of education explores the impact of and ways to increase the utility of PBPM programs.

\*required

### PURPOSE AND HYPOTHESIS

---

**Briefly (not to exceed 500 words or 3,000 characters) state the purpose(s) of your research, written in language that a layperson can understand, and any hypotheses related to those purposes, if applicable. No citations should be included here.**

Our overall goal is to explore how PBPM program participation impacts learners who matriculate into medical school. We have two objectives: Objective 1) Measure SDL readiness (SDLR) and self-efficacy in individuals during the first semester after matriculating into medical schools that complete a PBPM program (known as PBPM program learners, or PBPM-PL) and compare them to those graduating from a baccalaureate degree granting institution (known as traditional learners, or TL) in addition to students matriculated into medical school only after taking one year of gap year.

## 7. Research Population

\*required

### RESEARCH POPULATION

---

The research involves the following populations:

✓ Adults

Children: 17 years of age and under

\*required

### INCLUSION CRITERIA

---

Describe the inclusion criteria for participation in the research including the age or age range of potential participants:

- Medical students within their first year of medical school who are currently enrolled in an M.D. or D.O. program within the United states.

\*required

### EXCLUSION CRITERIA

---

Describe the exclusion criteria for participation in the research including possible age exclusion:

- Not a first year medical student  
- Medical students outside of United States  
- Individuals who cannot read or write english

\*required

### EXCLUSION OF SPECIFIC GROUPS

---

Will your research exclude specific groups from participation (including, but not necessarily limited to, exclusion on the basis of gender, ethnicity, race, or age)?

Yes

✓ No

\*required

## POPULATION NUMBERS

---

Provide the approximate number of participants to be enrolled, the number of records to be reviewed, and/or the number of biospecimens to be collected. Check all of the following categories that apply to your research, and indicate the total number of participants, records, and/or specimens, as appropriate. You must check at least one category.

**Note:** The number of participants, records, and/or biospecimens is defined as the number of individuals who agree to participate (i.e., those who provide consent or assent, or whose records have been or will be accessed, or whose biospecimens have been or will be obtained, etc.), even if all of them do not prove to be eligible or complete the study.

✓ Participants

\*required

Total Participants

---

Indicate the total number of participants who will be involved in the research, as defined above:

400

Records

Specimens

\*required

## USING YOUR STUDENTS AS RESEARCH PARTICIPANTS

---

Will you be using your own students as research subjects in the research?

☒ Yes

\*required

**Rationale**

---

**Please provide a rationale for using your own students in the research:**

The research survey will be open to first year medical students across the United States which could include first year medical students at OUWB if they choose to participate in this study.

No

\*required

**INCLUSION OF POTENTIALLY VULNERABLE POPULATIONS**

---

**Does the research specifically target any of the following vulnerable populations:**

- **Decisionally Impaired Individuals, or**
- **Pregnant Women, Fetuses, and/or Neonates, or**
- **Prisoners (the research is about prisoners)?**

Yes

☒ No

## 8. Screening Questions

\*required

### MORE THAN MINIMAL RISK

---

**"Minimal risk"** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or in the performance of routine physical or psychological examinations or tests (per [45 CFR 46](#)).

**Based on the above definition, will any part of your research expose participants to *more than* minimal risk (as defined above)?**

Yes

✓ No

\*required

### UNAUTHORIZED DECEPTION OR INCOMPLETE DISCLOSURE

---

**If the research involves deception, will any part of the research involve unauthorized deception or incomplete disclosure of information to participants (in which participants are *NOT* aware of the deception/incomplete disclosure)?**

**"Deception"** means data collected when an investigator deliberately misleads participants during research by withholding information or providing false information. As a result, participants are not fully informed about the research when they consent to participate.

**"Unauthorized"** means researchers will not seek participants' prospective agreement to be unaware or misled regarding the nature or purposes of the research.

Yes

✓ No

\*required

## CONSTRUCTING AUDIO-VISUAL OR IMAGE RECORDING LIBRARY

---

If your research involve collection of recordings or images, will you be constructing a library of participants' voice, video, digital or image recordings that will be saved after the study is completed to be used in future research?

### Important Note:

- If the purpose of the recordings is one or more of the following: 1) Transcription of interviews/focus groups, 2) Observation of public behavior, or 3) Collection of information from an adult participating in a benign behavioral intervention, and the recordings will be deleted after the study is completed, your response should be **NO**.
- If the purpose of the recordings is to construct a library of recordings that will be saved after the study is completed to be used in future research, your response should be **YES**.

Yes

☒ No

\*required

## COLLECTION/RECORDING OF PROTECTED HEALTH INFORMATION (PHI)

---

If your research involves the use of medical records, will you be collecting/recording any of the following 18 Protected Health Information (PHI) as defined by the [HIPAA Privacy Rule](#) from the medical records of a HIPAA-covered entity?

The 18 HIPAA identifiers that make health information PHI are:

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)

- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

Yes

✓ No

\*required

## FDA REGULATIONS

---

**Is any part of your research regulated by the Food and Drug Administration (FDA) for a reason OTHER THAN testing and/or evaluating food taste and/or quality?**

Yes

✓ No

\*required

## MEDICAL INTERVENTIONS

---



**Will the research involve medical interventions or the use of drugs or medical devices?**

**Yes**

☒ **No**

\*required

## **BIOSPECIMEN COLLECTION**

---

**Will this research involve collecting blood or other biospecimens?**

**Yes**

☒ **No**

\*required

## **USE OF RADIATION**

---

**Will this research involve the use of radiation?**

**Yes**

☒ **No**

## 9. Exemption Categories

Per the Code of Federal Regulations ([45 CFR 46.104](#)), certain kinds of research activities may be exempted from the requirements of the policy on protection of human subjects. Exempt determinations are made by the IRB.

Please review the categories below, and check all the statements that apply to your research activities.

---

\*required

### EXEMPTION CATEGORIES

---

Select each category that applies to your research.

Exempt Category 1: Instructional Research in Educational Settings.

✓ Exempt Category 2: Surveys, Interviews, Standardized Educational Tests, Observation of Public Behavior

*Note: This exemption DOES NOT apply to research with children as subjects when:*

1. *The research procedures include interviews, surveys, or observation of public behavior when an investigator participates in the observed activities;*  
**or**
  2. *The information is possibly sensitive and recorded with direct or indirect identifiers.*
- 

*Note: Interaction includes communication or interpersonal contact between investigator and subject for the purpose of collecting data only.*

---

\*required

## Proposed Research

---

Will your research **ONLY** include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), and/or survey procedures, and/or interview procedures, and/or observation of public behavior (including visual or auditory recording)?

Yes

✓ No

**Your research does not qualify under Exempt Category 2.**

---

### **Exempt Category 3: Brief Benign Behavioral Interventions with Adults**

Per the Code of Federal Regulations ([45 CFR 46.104.d.3.ii](#)), "benign behavioral interventions" are activities (such as playing an online game, solving puzzles under various noise conditions, or deciding how to allocate a nominal amount of received cash between themselves and others) that are brief in duration (should occur on a single day and not exceed a few hours in its entirety), harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and which the investigator has no reason to think the subjects will find offensive or embarrassing. Data collection to test the intervention is limited to the one or more of the following: a) Verbal (oral) or written responses by the subject, b) data entry by the subject, or c) observation of the subject, including audiovisual recording.

*Note: This exemption DOES NOT apply to research with children or research involving any kind of medical intervention.*

***Interaction*** includes communication or interpersonal contact between investigator and subject for the purpose of collecting data only.

***Intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are preformed for research purposes.

---

### **Exempt Category 4: Secondary Research Uses of Identifiable Private Information or Biospecimens**

**This exemption only applies to secondary research for which consent is NOT required. (Note: if the research involves the use of educational records, consent may be required under FERPA.)**

### **Exempt Category 5: Federally Supported Public Benefit or Service programs and Demonstration Projects**

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 (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are **designed to study, evaluate, improve, or otherwise examine public benefit or service programs**, including (i) procedures for obtaining benefits or services under those programs, (ii) possible changes in or alternatives to those programs or procedures, or (iii) possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

#### **Exempt Category 6: Taste Testing and Food Quality Evaluation**

**None of the above**

\*required

### PROCESS(ES) FOR IDENTIFYING, RECRUITING AND SELECTING PARTICIPANTS

---

**Describe the process(es) for identifying, recruiting, and selecting participants for your research. Be sure to include all of the following:**

- **How you will identify participants;**
- **How, where, and by whom initial contact will be made with potential study participants;**
- **If applicable, any pre-screening procedures to verify that potential participants meet the inclusion criteria.**

- For our research study, we would like to survey first-year medical school students (ages 18 years or above) who graduated less than a year ago either from an undergraduate degree or from a post-bac program. We are also interested in first-year medical students who joined medical only after a one-year gap. We will be recruiting research participants through our professional networks consisting of faculty at other medical schools within the United States.

- We also plan to recruit participants via social media such as "X" and "Instagram". We will post flyers along with a description on social media. Flyer is attached in the recruitment material along with the social media post.

We will be first sending out the screener questions to our professional network which will then be shared with potential participants. Initial contact with our professional network will be made via an email from the PIs. This email will include the study description and instructions on sending out the 'recruitment email' to potential research participants. The 'recruitment email' sent out by the personal and professional networks of the research team will include a link to the screener. We have several screener questions to help us identify our potential research participants. We will then contact only those participants who meet our research inclusion criteria and send them the link to the online anonymous Qualtrics survey. The email will state that student participation will not impact their grades or their college enrollment. Any student who does not wish to complete the survey will be offered an opportunity to decline. We have linked the screener in the recruitment document attached below.

\*required

### RECRUITMENT MATERIALS (Advertisement, Flyer, Ad, Post, Email, etc.)

---

**Will your research use any materials for recruiting participants in the research?**  
**Recruitment materials include but are not limited to the following:**

- Advertisement
- Flyer
- Ad
- Internet or website posting
- Brochure
- Email message
- Announcement

✓ Yes

\*required

### Type(s) of Recruitment Materials Used

---

Indicate the type(s) of materials that your research will use to recruit participants. Select all that apply.

Note:

- All recruitment materials must (i) indicate that the project is research; and include (ii) the name of the investigator; (iii) the purpose; (iv) the inclusion/exclusion criteria; (v) the time commitment; (vi) incentives, if any; and (vii) the location. **A Recruitment Sample Template can be accessed and downloaded from [espace IRB Forms and Templates Library](#).**  
*Directions to access documents in espace are in the "0. General Instructions" section of this application. (Left side of the screen).*
- Any recruitment materials (flyers, posters, table tents, banners) that will be posted in buildings or common areas on the OU campus (except the Recreation Center) must be approved by the Center for Student Activities before posting.
- Any recruitment materials or information posted in the Recreation Center must be approved by a Recreation Center administrator before posting.
- Distribution of any recruitment materials, or announcements about recruitment or your research project in any course must be approved by the instructor(s) of that course before the distribution or announcement is made.
- The IRB Office does not oversee any of these approval procedures.
- Permission must be obtained prior to initiation of the research project and retained in the researcher's files.

✓ Advertisements (Print)

Advertisements (Radio and/or TV)

Brochures

✓ E-mail notices

✓ Flyers

Group announcements (e.g., during a class or other group meeting)

✓ Internet postings

Mass mailings

Oral script/outline

OU Psychology Pool ad (SONA)

Participant letters

Physician referrals

Telephone scripts

Other

\*required

**Copies**

---

**Attach copies of all types of recruitment materials indicated above:**

[Recruitment documents \(2\).pdf](#)

[Screener\\_Med student.pdf](#)

**No**

**Note:**

- ***Researchers should use the OU IRB templates for informed consent documents which can be accessed and downloaded from [espace IRB Forms and Templates Library](#). Directions to access documents in espace are in the "0. General Instructions" section of this application. (Left side of the screen).***
  - ***If personal data will be collected from citizens or residents of a European country, or from persons residing in or visiting an European country at the time of the research, contact the IRB staff to ensure compliance with consent procedures under the European Union General Data Protection Regulation.***
  - ***An information sheet or consent form should be used as a cover page or be embedded into the first section of all survey instruments.***
  - ***For electronic surveys, a copy of the information sheet or the consent form must be used as a cover page or introduction to the survey.***
  - ***For research involving children as research subjects, the OU Office of Legal Affairs and General Counsel requires obtaining parental permission before children are enrolled in the research project.***
  - ***All signed informed consent documents must be maintained for a period of at least three (3) years after the research has been completed in case of an audit.***
- 

\*required

### INFORMED CONSENT

---

**Note:**

- ***For exempt research, Oakland University IRB requires the use of an Information Sheet. Collection of participants' signatures is **not** a requirement for exempt research unless it is required by other laws such as FERPA.***
- ***For exempt research involving children, Oakland University IRB requires the use of a Child Assent and Parent Permission.***

**Will participants be consented to participate in the research?**



✓ Yes

\*required

## Consent Documents

---

Indicate the type(s) of consent document(s) that will be used to obtain consent from participants. Select all that apply.

### Information sheet(s):

These are required for exempt research (not involving FERPA) and when a waiver of consent documentation is requested for non-exempt research (expedited and full board).

✓

Please note that this sheet does not have signature lines.

### Informed consent form(s):

These forms include signature lines and they are required for expedited and full board research unless a waiver of consent documentation is requested.

### Child assent form(s)

These are required when the research involves interaction or intervention with children (less than 18 years of age).

### Parental permission form(s)

These are required when the research involves interaction or intervention with children (less than 18 years of age).

Script(s) for oral consent/assent/parental permission including the following:

- Short form; and
- Written summary.

Other documents to facilitate consent

\*required

## Copies

---

Attach copies of all consent documents by clicking on the ATTACH button below.

[Consent form \(3\).pdf](#)

\*required

## Consent Process

---

Describe research participants consent process, including how, where, and by whom consent will be obtained.

**If children are participants, describe the child assent and parental permission process.**

*Note: The consent process should include an opportunity for study participants to ask questions and have those questions answered, time for study participants to consider their participation, and an assessment of whether study participants understand the study.*

Participants will be presented with an information sheet before starting the survey. They will then have the option to participate in the online survey. This is the language found in the survey after the information sheet. “ By clicking the box below, you consent to participate in this research. Please print a copy of this consent form for your information. “ options: I consent. Or I do not consent. Those who do not consent will be directed to the end of the survey.

No

\*required

#### **INCLUSION OF PARTICIPANTS NOT FLUENT IN ENGLISH**

---

**Will your research involve recruitment of participants who cannot speak or read English fluently?**

Yes

✓ No

\*required

#### **WAIVER OF CONSENT OR WAIVER OF CONSENT DOCUMENTATION**

---

**Does your study involve the use of deception and/or require a waiver or alteration of a consent document or its documentation?**

"Deception" means data collected when an investigator deliberately misleads participants

during research by withholding information or providing false information. As a result, participants are not fully informed about the research when they consent to participate.

✓ No; the project is exempt. A waiver is not required.

No; the project is non-exempt (expedited or full board) and does not include deception or require waiver of consent or a waiver of consent documentation.

Yes; the project is non-exempt (expedited or full board) and a waiver is requested. This may include a project that is using deception in which the participants are not prospectively notified of the deception.

\*required

### RESEARCH PROCEDURES

---

**In detail and in chronological order, describe all the procedures used in the study AFTER the participants have been recruited and informed consent has been obtained.**

**Include all of the following:**

- Description of all of the procedures to be used in the study to collect data;
- Who will administer the procedures;
- The setting in which the research procedures will be conducted;
- Any screening procedures which occur after the participant gives consent;
- The interventions or interactions that will be performed;
- Any randomization/group assignment procedures;
- The data that will be collected;
- How the data will be collected (in person, via e-mail, U.S. mail, on the internet, etc.); and
- Any required follow-up with the participants.

After screening participants who fit the research study inclusion criteria will receive an email with the link for the survey and consent, which will be hosted online on qualtrics. The information sheet will be the first page of the survey. The information sheet will include a link to the survey. Participants who wish to participate will consent by clicking "continue" to the survey after reading the information sheet. Individuals will complete the consent and proceed to the survey. Information will be collected regarding demographics (race, ethnicity, household income, major, e.g.); study habits; perceptions regarding preparedness for medical school and thoughts on what is needed to be prepared; and participation in post-baccalaureate programs if any. The survey is an online survey/questionnaire that will take less than 30 mins to complete. Participants can take the survey at a time and location of their choosing to optimize privacy while completing the survey. Participants will continue on the survey if they agree to participate. Researchers will potentially reconnect with the participants at a later date. Any future data collection will be discussed in a future modification that may be filed.

\*required

### NON RESEARCH PURPOSES

---

Are any of the procedures described above being performed for non-research purposes (i.e., the procedures would occur regardless of the participants' engagement in the research)?

Yes

✓ No

\*required

## COMPLETION TIME

---

What is the estimated time required for participants to complete the research? Include the time required to complete each survey, procedure, intervention, etc., as well as the total time to complete the entire study.

***Note:** If the study procedures are spread out over multiple days, months, or years, the "total time" to complete the study should include the number of hours per data collection session, the total number of hours to complete the study, AND the number of days/months/years to complete the study. For example, if participants will complete five (5) one-hour sessions over three (3) consecutive months, the total time should be described as "five hours consisting of five one-hour sessions spread over three consecutive months."*

The online survey will take the participants about 30 minutes to complete.

\*required

## Secondary Research Involving Identifiable Private Information or Identifiable Biospecimens

---

Does the research study involve the secondary use of identifiable private information and/or identifiable biospecimens?

Yes

✓ No

\*required

## DATA COLLECTION TYPES

---

Check each means by which data will be collected from participants in the research. Check all that apply.

### Data collection tools

- ✓ Interviews, Questionnaires and/or Surveys

\*required

### Types of Questions and/or Surveys

---

Indicate the type(s) of questionnaires and/or surveys that will be employed in the project research. Check all that apply.

- ✓ Self-generated

\*required

Name

---

Provide the name(s) of the questionnaires and/or surveys to be used:

SDLR competency in M1 medical students - SURVEY

### Standardized measures

### Modification of standard measures

- ✓ Internet/online research

### Data collected by the use of deception

"Deception" means data collected when an investigator deliberately misleads participants during research by withholding information or providing false information. As a result, participants are not fully informed about the research when they consent to participate.

### Data collected by the use of Virtual Reality or Augmented Reality

### Medical records and/or databases that contain protected health information (PHI)

Student educational records (such as course grades, individual assignments, etc.) that can be linked back to students

### Other

\*required

## DATA COLLECTION INSTRUMENTS

---

**Attach copies of each type of data collection instrument checked above.**

[SDLR competency in M1 medical students - SURVEY.pdf](#)

[Incentive survey.pdf](#)

**Note:**

- Research conducted online via the internet must provide the same level of protection as any other research.
  - Any materials or information that will be transmitted by e-mail should be blind-copied (BCC) to participants.
- 

\*required

### RECRUITMENT

---

Will the proposed research involve recruitment via the internet?

✓ Yes

\*required

#### Recruitment Methods

---

Select the electronic recruitment method(s) that will be utilized. Check all that apply.

Website/internet advertising

✓ Social media sites (e.g., Facebook, Reddit, Twitter, etc.)

\*required

Site Name(s)

---

Provide the name(s) of the site(s) you will use to recruit participants:

X, Instagram

MTurk

✓ Listserv

\*required



## Listserv Name(s)

---

**Provide the name(s) of the listserv(s) you will use to recruit participants:**

ppb@lists.johnshopkins.edu, DR-ED@list.msu.edu

**E-mail solicitation**

**OU Psychology Pool (SONA)**

☒ **Other**

\*required

**Explanation**

---

**Please explain:**

We will also reach out to individuals within our professional networks (faculty at other medical schools) for participant recruitment.

No

\*required

**Publicly Available**

---

**Are all of the recruitment methods checked above publicly available?**

☒ **Yes**

No

\*required

**INFORMED CONSENT**

---

How will informed consent be obtained and documented for the research? Check all that apply.

The project is secondary research only; a consent is not required

✓ This is an exempt research and documentation of consent is not required. Information sheet(s) will be used.

Electronic consent form with "I agree" check box

Electronic consent form with typed name

A signed consent form sent from participant to PI by e-mail

In-person informed consent

Waiver of consent or documentation of consent

\*required

## AUTHENTICATION

---

Will measures be taken to authenticate the identity of participants?

### **Note:**

- *The need to verify the identity of participants should take into consideration the importance of the research, the sensitivity of the data being collected, the possibility of fraudulent behavior, or the involvement of children, especially those 13 years of age or younger. An example of an authentication measure is providing subjects with a personal identification number (PIN), either in person or via U.S. mail, to be used in data collection procedures for the study. The PIN used must not be one that could identify the participants by others (e.g., social security number, birth date, phone number, etc.).*
- *Minors may be screened out by checking for Internet monitoring software such as SafeSurf and RSACi rating or using Adult Check systems. This can be necessary if the study presents more than minimal risk to subjects or asks particularly sensitive questions.*

Yes

✓ No

\*required

**Click what applies:**

---

✓ This is an exempt research project

This is a minimal risk expedited project and no sensitive information will be collected.

Other:

\*required

## **DATA COLLECTION METHODS**

---

**What type(s) of collection methods will be used for the research? Check all that apply.**

Existing Data

✓ Surveys and/or questionnaires

E-mail correspondence

Listserv and/or bulletin board postings

Chatroom

Observation of online behavior

OU Moodle

Other

\*required

## **INTERNET SURVEY SERVICE**

---

**Does the research make use of an internet survey service (e.g., Qualtrics, SurveyMonkey, etc.)?**

**Note:**

- The use of **Qualtrics** for internet research is strongly recommended as the University Technology Services (UTS) currently maintains an agreement with Qualtrics.
- **Qualtrics is free for Oakland University researchers.** To use Qualtrics at OU, researchers need to do the following:
  - 1) Log into: [oakland.qualtrics.com](https://oakland.qualtrics.com)
  - 2) Login using your existing OU NETID and password
  - 3) Create surveys!
- Please review the information provided by University Technology Services (UTS) about the [usage and limitations of the survey services available at OU](#).
- Investigators should review any applicable Terms of Service, confidentiality measures and data security policies for the given online survey platform.

✓ Yes

\*required

**Provide the name(s) of the internet survey service(s) you will use in the project research:**

Qualtrics

\*required

**Explain how the survey instrument format allows participants to refuse to answer specific questions. For example, will the survey be formatted to allow for skipping questions? Or, will a "Decline to answer" or "Prefer Not to Answer" option be included after each question?**

---

**Please Explain:**

We have a "prefer not to answer" option for every question. Except for one question where the students need to provide the name of the medical school that you are currently attending. Since we are interested in recruiting first year medical students only we need this information to confirm our inclusion criteria and to provide the online survey link. Hence they need to answer.

---

**If using Qualtrics, please follow the steps listed below to provide a link to the survey**

1. Choose "Preview" from the Qualtrics Edits Page or Top Page (three dots)
2. Click "Share"
3. Select "Brand Internal Only"

4. Copy the link and paste it in the text box below.

"Instructions on Providing Link to Qualtrics Survey" screenshot document can be a [Templates Library](#)

Directions to access documents in espace are in the "0. General Instructions" section  
<https://oakland.az1.qualtrics.com/jfe/preview/previewId/0ec1a42d-8571-45d3-be13-88628370>

No

\*required

## PUBLIC WEBSITE DATA

---

**Will the research involve data obtained from a public website?**

*Note:*

- *Using data that are both existing and public is not considered human subject research. However, if accessing the data requires special permission (e.g., registration, login, payments, etc.) then that data are not considered public and IRB review is required. Researchers should consider whether the information that is collected is potentially identifiable through deductive disclosure.*
- *Researchers should consider if there exists an expectation of privacy and users of a particular public website would consider their posts to be private (e.g. sensitive information is shared with the intention that it be restricted to a particular group or professional norms would consider the information private).*

Yes

✓ No

\*required

## PRIVATE CONTENT

---

**Will private internet posts, messages, broadcasts (e.g., webcam, chat), social media, or other private internet content be collected for research purposes?**

**Note:** Researchers should be aware of the Terms of Service and Privacy Policy of

*any websites from which data is collected.*

*It is advised that the researcher keep a copy of these documents for future reference.*

Yes

✓ No

\*required

## DATA CONFIDENTIALITY AND SECURITY

---

### **Note:**

- Survey software should be used in accordance with [OU AP&P #860 - Information Security](#).
- The use of Qualtrics for internet research is strongly recommended by UTS. Qualtrics provides the following protections:
  - All Qualtrics accounts are password-protected
  - Data collected in the United States are stored in the United States
  - Data backups are performed nightly
  - Data are owned and controlled by the researcher

**Will the research involves the collection of any identifiable information e.g., IP addresses, SONA ID, MTurk Worker ID?**

---

✓ Yes

\*required

**Check all that apply:**

---

Collection of IP Addresses

Collection of SONA ID

MTurk Worker ID

✓ Others

\*required

### Specify:

---

As part of this research study, an honest broker will manage the process of incentive payments. The broker will keep all identifiable information separate from the researchers. The broker will distribute incentives to participants at study completion. Participants' personal identifying information (PII) will be kept strictly confidential during the incentive distribution process. This measure is designed to protect the privacy and anonymity of participants. Rest assured; the research team will not have access to any identifiable data during the incentive distribution process. We prioritize protecting participant information and will maintain the highest ethical standards throughout the research endeavor.

An Honest Broker will collect the following information to provide an incentive to participants:

- First and last names
- Email address
- Phone number
- Mailing address

Once participants finish the survey and are linked to the incentive survey, the following narrative will be at the top: "We'll use this information to give you a \$10 Amazon gift card as a thank-you for participating. An honest broker will manage your personal information so the researchers won't see it."

No

\*required

### Data Collection, Transmission, and Storage

---

**Describe confidentiality measures/security provisions that are in place to protect the identity of the participants during data collection, transmission and storage (e.g., data will be encrypted, secure socket layer (SSL) will be used, etc.). Include whether or not survey responses will be linked to any identifiers or online host specific ID:**

*Note:*

- *All identifiable or coded data transmitted or stored over the internet should be encrypted.*

- *The level of security should be appropriate to the risk. For most research, standard security measures like encryption and SSL will suffice.*

As part of this research study, an honest broker will manage the process of incentive payments. The broker will keep all identifiable information separate from the researchers. The broker will distribute incentives to participants at study completion. Participants' personal identifying information (PII) will be kept strictly confidential during the incentive distribution process. This measure is designed to protect the privacy and anonymity of participants. Rest assured; the research team will not have access to any identifiable data during the incentive distribution process. We prioritize protecting participant information and will maintain the highest ethical standards throughout the research endeavor.

An Honest Broker will collect the following information to provide an incentive to participants:

- First and last names
- Email address
- Phone number
- Mailing address

Once participants finish the survey and are linked to the incentive survey, the following narrative will be at the top: "We'll use this information to give you a \$10 Amazon gift card as a thank-you for participating. An honest broker will manage your personal information so the researchers won't see it."

\*required

## **SURVEY HOST**

---

**Will Qualtrics be the survey host?**

*Note: Researchers are advised to consult with the survey service or host's Terms of Service/End User License Agreement to assist in answering the following questions.*

☒ Yes

☐ No

\*required

## **RESEARCH INCENTIVE**

---

**If multiple surveys are being used and/or a research incentive/payment is offered, will there be additional measures to protect the survey from being hacked?**

- **Note: If the study is offering \$5 or more online payment to participants, please check the Guidance to Minimize the Hacking of Online Surveys document available in the [\*espace IRB Forms and Templates Library\*](#) for**



suggested language to include in the recruitment and consent documents to help deter hackers.

Not Applicable, multiple surveys and/or a research incentive/payment are not being used.

No

✓ Yes, Qualtrics "HTTP referrer verification" will be used.

*Note: Qualtrics recommends that whenever a survey is created with a second, incentive survey, researchers should add "[HTTP referrer verification](#)" to the second survey to avoid having respondents take the second survey who have not taken the first. This will require people to complete the first survey before they can access the payment page.*

---

Yes, a method other than the Qualtrics "HTTP referrer verification" will be used.

## 14. Research Locations

\*required

Provide the name of each research location (or a description of it, if it does not have a formal name) where OU research work on your project will be conducted, together with the city, state, and country corresponding to each site.

### **Notes:**

- *For internet research, describe the site as "online."*
- *If you are collecting data at times and places that are convenient for the participants (such as interviews, etc.), describe the site as "TBD based on convenience of the participants."*
- *Permission to conduct research at a given site must be obtained from all research locations listed in the IRB submission before the project is initiated. You must keep copies of all such permission letters for your files. Based on the project, the IRB may ask researchers to provide copies of the permission letters before an approval is issued.*
- *It is the responsibility of each researcher to follow all applicable policies and procedures of any outside institution where the research will be conducted.*
- *For research conducted on Oakland University's campus, you must secure permission, in writing, from an appropriate administrative official (director of the Oakland Center, library administrator, director of student housing, etc.), to carry out recruitment of participants or data collection with participants in any OU building or classroom to which the researcher does not ordinarily have access before the project is initiated. You must keep copies of all such permission letters in your research files for this project. OU student researchers must contact the appropriate administrator at each research site to determine whether a Research Credentials Badge is needed to conduct research at that site. If needed, the Research Credentials Badge must be worn at all times when recruiting participants or collecting data for the project in OU buildings to which the student researcher does not ordinarily have access, or in common areas of the OU campus. Research Credentials Badges are only available from the IRB Office, and will only be provided after an appropriate permission letter has been submitted.*

---

**List Research Location(s):**

Online

## Research Location Permission

---

If the IRB requires you to provide a copy of the research site permission letter or email, please attach it by clicking on the ATTACH button below.

\*required

### INTERNATIONAL RESEARCH

---

Will any portion of your project research be conducted outside the United States?

Yes

☒ No

\*required

### IRB OF RECORD

---

Will one or more outside institutions rely on OU's IRB as the IRB of Record?

Yes

☒ No

## 15. Incentives and Payments

**"Payment"** means that participants will receive monetary payments or compensation (including gift cards, vouchers, etc., that carry a monetary value) for participating in the research.

**"Incentive"** means that participants will receive non-monetary payments or compensation (including course credit) for participating in the research.

**"Research expenses"** means any expenses the participants may incur as a result of participating in the research. Additional research-related expenses include, but are not necessarily limited to, travel costs, additional clinic visits, research-related procedures, extra tests related to the research, shipping costs, etc. Compensation for research expenses is not considered to be a payment or an incentive.

### Important IRB Notes:

- Information regarding payment or other incentives must be detailed in the information sheet or consent document.
- If the research involves the administration of an online survey, make sure to set the survey limit to the number of participants you are proposing to enroll in the study and provide with research incentive.
- If research incentive is a course credit, the researcher needs to provide an alternative activity for students to obtain the same credit if they choose not to participate in this research.
- Payment should be prorated for the time of participation in the study rather than delayed until study completion, because the latter could unduly influence a subject's decision to exercise his or her right to withdraw from the research at any time.
- The IRB will not allow payment or incentive that may cause undue influence. Payment or incentive may constitute undue influence when there is an (1) excessive offer of something valuable or desirable that leads to (2) poor judgment or a compromised decision-making process, which in turn leads to (3) a decision to engage in harmful activity that seriously contravenes the decision-maker's interests or obligations.

### Notes from the Accounts Payable Office:

- Disbursement of cash, gift cards, and/or tangible gifts \$75 or greater per participant must be reported to the Accounts Payable Office. If the research incentive meets

or exceeds \$75, include the following statement in the consent, "Because the research incentive meets or exceeds \$75, your name and social security number will be shared with the Oakland University Accounts Payable Office."

- Small amounts of cash can be used for participant incentives in face-to-face research, however, please note that the Oakland University Accounts Payable Office **cannot approve cash payment via mail**. If you are planning on using cash, please contact the Accounts Payable Office to get approval for disbursement of cash.
  - Participants will be required to complete a W-9 Form for aggregate payments of \$600 or more per calendar year. Accounts Payable will issue an IRS Form 1099 for aggregate payments of \$600 or more per calendar year. Researchers should contact the Accounts Payable Office for assistance with procedures on the research payment process and required documentation.
  - Since receipt of payments that meet the above thresholds must be reported to Accounts Payable and/or to the IRS, subjects must be informed during the consent process and in the informed consent document.
  - The IRB does not oversee the process of reporting research payments to Account Payable and/or IRS.
  - If the study is offering \$5 or more online payment to participants, please check the **Guidance to Minimize the Hacking of Online Surveys** document available in the [espace IRB Forms and Templates Library](#) for suggested language to include in the recruitment and consent documents to help deter hackers.
- 

\*required

## PAYMENTS OR INCENTIVES

---

**Will your study offer payments and/or incentives to research participants to participate in the study, or will there be any additional research-related expenses to participants not covered by the research study, as described above?**

✓ Yes

\*required

**Types of payments and/or incentives**

---

Indicate the type(s) of payment or incentives that participants will receive to participate in the research (e.g., cash, gift card, class credit, etc.). Check all that apply.

Monetary

☒ Non-monetary

\*required

**Description and Monetary Equivalent**

---

**Describe the non-monetary payment(s) and/or incentive(s) that participants will receive, and also the monetary equivalent of the compensation received by each participant at the time of study initiation.**

Gift cards. Participants will receive a \$10 gift card if you fit the study inclusion criteria and upon completing the anonymous online survey.

\*required

**Milestones**

---

**Describe the milestones for each payment or incentive.**

☒ Per session

At the end of the study

Pro-rated

Other

No

\*required

**ADDITIONAL RESEARCH RELATED EXPENSES**

---

**Will the participants incur any other research-related expenses (as described above) not covered by the research study?**

Yes

✓ No

## 16. Privacy of Research Participants

**"Privacy"** relates to the methods of gathering information from research participants and is defined as having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Privacy is about the people, and not the data.

---

\*required

### PROCESSES FOR PRIVACY PROTECTION

---

Describe how you will protect the privacy of research participants during ALL stages of the research, including during recruitment, when obtaining consent, and during data collection. Examples include conducting the consent process, interviews, and/or data collection in a private location.

Participants will complete the online survey at a time and place of their choosing, thus ensuring their own privacy.

\*required

### INTERNET OR EMAIL RECRUITMENT

---

Will your project research involve recruitment of participants via the internet or through mass e-mails?

✓ Yes

\*required

#### Protection of Personally Identifying Information

---

Describe how you will protect personally identifying information during recruitment of participants via the internet or through mass e-mails. For example, in mass e-mails, the e-mails should be sent to potential participants as blind copies.



We will request our professional networks to send out the recruitment via mass email via the bcc function.

**No**

**"Confidentiality"** pertains to the treatment of information that an individual discloses in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission. This section pertains to research data only.

**"Identifiable"** pertains to private information and/or biospecimens for which the identity of the subject is, or may readily be, ascertained by the investigator or associated with the private information and/or biospecimens.

**"De-identified data"** are data from which all personal identifiers have been permanently removed, and for which no master list is available with a code or key that would enable a researcher to link the data back to the individual.

**"Coded data"** are data where identifying information has been replaced by a number, letter, or symbol, and for which a master list has been created to link the data back to the research participants' identifiable information (name, Social Security number, etc.). Coded data are considered identifiable. If data are coded, the master list must be stored in a separate location from the data itself.

### **Secure Data Storage:**

For secure storage of data, researcher should do the following:

1. Use institutional resources for data storage, such as secure department server, institution-approved cloud/server, locked campus office.
  2. Use only approved portable devices for temporary storage. Data should be moved to more secure location as soon as possible and deleted from the portable device.
  3. The level of security required for storage is guided by the level of sensitivity of the information:
    - If protected health information (PHI) is collected, storage location must be compliant with the Health Insurance Portability and Accountability Act (HIPAA).
    - Sensitive/identifiable information should be stored separately from remainder of the data.
    - Use encrypted files or clean/cold room servers when necessary.
-

\*required

## **INFORMATION TYPE**

---

**As part of your research, will you be recording/collecting any identifiable information from records or participants?**

**No:**

- The information will be recorded/collected by the investigators **WITHOUT** personal identifiers that can be linked to participants directly or indirectly through a combination of indirect identifiers (i.e. ethnicity, age, gender, etc.);
- The re-identification of participants through deductive disclosure is not possible; and
- None of the researchers on this project can readily ascertain the identity of the participants nor will try to re-identify the participants.

**Yes:**

- ✓ • The information will be recorded/collected by the investigators **WITH** personal identifiers (e.g. name, address, social security number, voice and/or video recordings, etc.) that can be linked to participants directly or through a deductive disclosure
- Researchers on this project can readily ascertain the identity of the participants or may try to re-identify the participants.

\*required

## **AUDIOVISUAL RECORDINGS**

---

**Will any portion of your research involve collection of audio and/or visual recordings?**

**Yes**

✓ **No**

\*required

## **DATA COLLECTION FORMAT**

---

## In what format(s) will data be collected and stored (e.g., paper, electronic, audio/video)?

Electronic survey data

\*required

### DATA ACCESS

---

Enter the names of all research personnel, including the PI, who will have access to research data using the FIND PEOPLE function below.

#### **Notes:**

- *If you cannot find the name(s) in the finder, please contact the Research Office to have that person (if an OU personnel) added to Cayuse.*
- *If the personnel do not have an OU email account, please add their name(s) in the text box below.*
- *The name(s) that are added in this section should also be listed in Section 3, Key Personnel.*

Name: Kyeorda Kemp

Organization: Foundational Medical Studies

Address: 403 O'Dowd Hall , Rochester, MI 48309-4482

Phone:

Email: kyeordakemp@oakland.edu

Name: Deidre Hurse

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive O'Dowd Hall, Rochester, MI 48309-4482

Phone:

Email: dhurse@oakland.edu

Name: Cameron Davidson

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive 400 O'Dowd Hall, Rochester, MI 48309-4482

Phone:

Email: cjdavidson@oakland.edu

Name: Akshata Naik

Organization: Foundational Medical Studies

Address: 586 Pioneer Drive O'Dowd Hall Room 408, Rochester, MI 48309-4482

Phone: 248-370-3887

Email: anaik@oakland.edu

Names of non-OU personnel who will have access to research data:

---

\*required

## DATA TRANSMISSION

---

Will research data be transmitted between or among research personnel working on the project?

✓ Yes

\*required

### Description

---

**Describe how data will be transmitted between or among research personnel on the project:**

Once information is downloaded from the secure online platform it will be stored on a private google drive and shared only with the researchers.

No

\*required

## DATA PROTECTION DURING THE STUDY

---

**How will identifiable data be protected DURING the study, to prevent access by individuals outside the research team (e.g., stored on a password-protected and/or encrypted computer or file, locked filing cabinet, locked office, data will be de-identified by the investigators, data will be coded and a master list will be created that links the codes to identifiable information, etc.)**

*Note: If coding data, the master list must be stored in a location that is separate from the coded data.*

Data will be stored in shared drive which is password protected that only researchers will have access to. Researchers use password protected laptops to store of all their research data.

\*required

## POTENTIAL FOR DEDUCTIVE DISCLOSURE

---

Is it likely that participants could be identified by deductive disclosure (i.e., identifying participants from a combination of indirect identifiers)?

✓ Yes

\*required

### Discussion

---

**Discuss the potential for deductive disclosure, and the means you will take to prevent it:**

Participants are providing their email addresses as part of survey data so we are collecting their identities. Researchers will not publish any direct identifying information but if there is a small group of individuals that are potentially deductible they will not be reported or their data will be aggregated with other data.

No

\*required

## DATA DISPOSITION

---

What will happen to identifiable information when the study is CLOSED? (Check all that apply)

✓ Data will be de-identified (identifiers will be permanently removed and destroyed)

Identifiable coded data with a separate master list that can link data to participants will be retained, and the master list will be retained and stored in a separate location

Coded data will be retained, but the master list linking data back to participants will be destroyed

Identifiable data will be indefinitely retained

\*required

## **PROTECTION OF PERSONALLY IDENTIFYING INFORMATION IN RESEARCH PUBLICATION(S)**

---

**Please describe the way(s) in which you will protect the personally identifying information you collected and/or analyzed in your project research in any public presentation or publication of your research findings.**

Researchers will not publish anyone's personally identifiable information.

### POTENTIAL RESEARCH RELATED RISKS

Risks can be physical, psychological, social, financial, and/or legal. Risks may include, but are not limited to possible stress, physical or psychological discomfort, invasion of privacy, and breach of confidentiality.

---

\*required

---

**Is your research Exempt (does your research fit under the exemption categories)?**

☒ **Yes; my research is exempt**

\*required

**Describe all reasonably foreseeable risks participants may experience as a result of participating in this research and how these risk will be minimized. Include only those risks that are a direct result of participating in the research.**

**Do not include those risks the participant would be exposed to even if the research were not being conducted.**

---

Research studies may involve different kinds and levels of risks or discomforts. These could be physical, emotional, social, economic or legal risks. For this study, the potential risks and discomforts that we know about are risks such as a breach of confidentiality and possibly invasion of privacy. All measures will be made to keep information secure; however, we ask that individuals complete surveys on a secure Wi-Fi network to help reduce the risk. Additionally, once information is downloaded from the secure online platform it will be stored on a private google drive and shared only with the researchers.

**No; my research is not Exempt (does not fit under the exemption categories)**

\*required

### POTENTIAL BENEFITS



---

Describe the potential benefits of participation in the research to the participants, to others, and/or to society as a whole.

If the research benefits only others or society as a whole, please indicate that there are no direct benefits to the participants.

**Note:** Research incentive or payment is *NOT* a benefit.

There are no direct benefits to the participants.

\*required

## RISK REASONABILITY

---

Choose one of the following:

☒ Click here if conducting exempt research; skip to the next question.

Click here for non-exempt research (expedited or full board), please explain how the potential risks are reasonable in relation to the anticipated benefits to participants, to others, and/or to society as a whole.

\*required

## ALTERNATIVE TO PARTICIPATION IN RESEARCH

---

Are participants provided with an alternative to participating in the research?

Yes

☒ No

## 19. Additional Regulations

\*required

### CLINICAL TRIALS, FDA REGULATED ARTICLES, BIOSAFETY, RADIATION SAFETY

---

Does the research project involve any of the following:

- Clinical Trial, or
- Registration in Clinicaltrials.Gov, or
- FDA Regulated Article(s), or
- Radioisotopes or Radiation Emitting Devices, or
- Biohazardous Materials?

Yes

✓ No

\*required

### DATA AND SAFETY REQUIREMENT

---

Is your research any of the following:

- One that poses more than minimal risk to participants; or
- A clinical trial; or
- Funded by the National Institutes of Health; or
- Funded by a sponsor other than NIH that requires data and safety monitoring

Yes

✓ No

To certify/route/complete the submission, make sure to do both of the following:

- Click on "Routing- Complete Submission" that appears underneath Section 20 in left column, and
- Click on the blue "Certify" button that appears on the up right corner of the next screen.

After you certify an Initial submission, please note the following:

- The submission will automatically be routed to your Co-PI and/or Faculty Advisor, if applicable, to certify.
- Subsequently, the Initial submission will automatically be routed to the department chair or dean of the school (Org Approver) of the faculty PI (or the Faculty Advisor, when applicable) and of the Co-PI to certify before the submission is routed to the IRB.

### IMPORTANT NOTES:

- If "Routing - Complete Submission" does not appear, please check all the sections on the left column to make sure that the green check marks are in place. If one of your sections doesn't have a green check mark, search the section for any required questions (with red \*) you may have missed. When all the green check marks are in place, the "Routing - Complete Submission" should appear and you will be able to certify the submission.
- After clicking on "Routing - Complete Submission," you must click on the "Certify" button that appear on the upper right corner of the following screen in order for the submission to be routed to the next step in the system.
- Cayuse email messages are sent at every stage of the submission/review of the study to all researchers who are added through the People Finder option. If you are not receiving Cayuse messages, please check your email Spam folder.

- Upon IRB review, if you are asked to make changes, you would need to re-certify in order to resubmit the study to the IRB. To re-certify, click on "Routing - Complete Submission," then on the "Certify" button on the following screen. Re-certification can be done by the PI or Co-PI (Faculty Sponsor) or PC.
-