UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: MYHealth Summer Launch Research Training Program

Company or agency sponsoring the study:
National Institute of General Medical Sciences and National Institutes of Health
Science Education Partnership Award

Names, degrees, and affiliations of the principal investigator and study coordinator:
Principal Investigator: Melissa DeJonckheere, PhD, Department of Family Medicine, University of Michigan
Project Manager: Sam Chuisano, MPH, Department of Family Medicine, University of Michigan

1.1 Key Study Information

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child.' This form contains important information that will help you decide whether you want to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or others about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

Research studies hope to make discoveries and learn new information that can improve current educational, medical, or practices. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of improving your life, education, or health personally. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects information to understand how adolescents and young adults experience a research training program. The goal of the research training program is to introduce health services research and research career opportunities to high school students in Southeast Michigan. Participants in this research will:

- Learn about research, research ethics, and research design
- Apply their learning to a sample research project
- Complete activities in small groups with other participants and instructors
- Complete surveys and interviews that will help us evaluate the research training program.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feeling some discomfort or embarrassment when learning about research and participating in sample research activities. More detailed information will be provided later in this document.

This study may offer some benefit to you now by learning about research, research ethics, and scientific concepts. This study may also benefit others in the future by helping us to improve our research training program for future participants. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately three weeks.

You can decide not to be in this study. Your participation in this study will not affect your ability to participate in other academic programs at the University of Michigan or with our partners (for example, Wolverine Pathways, Adolescent Health Initiative, Doctors of Tomorrow, Michigan Health Sciences Pre-College Exposure Academy, Washtenaw Intermediate School District).

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Michigan Youth Health (MYHealth) is a research training program designed to introduce high school students in Southeast Michigan to health services research. The goal of the program is to increase interest in research and research careers.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Current and recent high school students who self-identify as a member of an underrepresented group in health and science, living in Southeast Michigan may participate in this study. You must be in 9th, 10th, 11th, or 12th grade or have graduated high school in the last 6 months and be at least 14 years old.

All study activities will be completed remotely. You must be able to access the internet to participate.

Study participants will receive a computer to use for study activities, which will be returned upon completion of their participation in the study.

3.2 How many people are expected to take part in this study?
Up to 70 people are expected to participate in the MYHealth Summer Launch each year. In the entire study, up to 280 people are expected to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

First, you will talk with a member of the research team to make sure you are **eligible to participate**. This will involve answering some questions about you, your grade level, and your ability to join our study sessions using video conferencing platforms and online tools. If you are eligible and want to participate, you will **sign a consent or assent form**.

At the start of the program, we will ask you to complete a **brief online survey**. The survey will ask you questions about your experiences with and feelings about science and research and your feelings about future science and research careers.

Next, you will meet with program faculty and other participants every day for approximately 10 days in both large and small groups to complete the MYHealth Summer Launch program. Small groups will be made up of anywhere from 3-20 participants of mixed grades and ages. All sessions will take place using a virtual video conferencing platform (e.g., Zoom) and other online tools. In this program, you will learn about research, research ethics, research careers, and related topics. You may apply what you learn by completing research activities (like developing a research question, collecting data, analyzing data, and sharing your findings with others). Most of these activities will take place with your small groups, but some activities you will complete independently.

All online sessions will be audio-video recorded for the purposes of the study. Participants will have the option to keep their cameras off, but recording will be necessary for participation in the study.

After the program, you will be asked to complete a brief survey. The **brief survey** will ask about your feelings related to science, research, and future science and research careers. In the interview, we will ask you what it was like to participate in the program. We will ask what activities you enjoyed, what may have been challenging, and other questions about your experience that will help us to improve the program. You may be asked to have **1 follow-up meeting** with a member of the research team to complete an audio-video recorded interview about your experience during the Summer Launch. Interviews will include questions surrounding thoughts and feelings about research careers and the MYHealth Summer Launch curriculum and last for approximately 45 minutes.

4.2 How much of my time will be needed to take part in this study?

After agreeing to participate in this research, we will ask you to complete a brief online survey. We expect it will take about **30 minutes** to complete this survey.

The MYHealth Summer Launch Research Training program will last approximately 10 days. Each participant will meet virtually with our research team in a small group (including other participants), **for approximately 4 hours** per day for approximately **10 days**. In addition to the sessions where we meet as a group, you may also be asked to complete activities that take another **1 hour per day** to complete. This should not exceed **5 total hours per day**.

After the 10-day program, you will be asked to complete another brief survey online. The survey should take about 15 minutes. Some participants will be invited to have **1 follow-up meeting** with members of the research team to complete an interview. The interview will last about **one hour.**

4.3 When will my participation in the study be over?
Your participation in this research will last about **3 weeks**. There will be about 10 days weeks of program activities (learning about research, participating in activities with the MYHealth group). After the 10 days of program activities, you may be asked to complete a brief survey and interview about your experience during the program. The entire study is expected to last about **4 years**.

If you turn 18 years old during the study period (~3 weeks), you will be asked to provide written consent to continue participating in the study.

There may be an opportunity for you to enroll in future parts of this study with the MYHealth team. We will share information about these studies when the opportunities become available using the email address you provide.

4.4 What will happen with my information used in this study?
Your collected information may be shared with the National Institutes of Health and National Institute of General Medical Sciences.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
We anticipate that this research only poses minimal risks, including:

- Experiencing confusion, discomfort, or embarrassment when answering survey questions about your feelings related to science and research.
- Experiencing confusion, discomfort or embarrassment when talking about your experiences in the study.

The researchers will try to minimize these risks by:

- Reminding you that you may skip any questions that make you feel uncomfortable, or you do not want to answer.
- Conducting the interview in private so that other study participants will not be able to see or hear what you say.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
This study involves learning about research, research ethics, research careers, and applying your learning to a sample research project. We do not expect the study to cause you to get hurt, become sick, or have any other problems.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
This study may offer some benefit to you now by learning about research, research ethics, and scientific concepts. This study may also benefit others in the future by helping us to improve our research training program for future participants. More information will be provided later in this document.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation in this study is voluntary. If you decide not to participate, it will not affect your relationship with the University of Michigan or any of our recruitment partners who may have shared information about this study with you.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no risk to you for leaving the study before it is finished. Please let one of our team members know. We may ask if you are willing to complete an exit interview to tell us the reasons why you are leaving the study and no longer wish to participate.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- You become ineligible for the study (e.g., you do not have internet access anymore).
- You do not follow instructions from the researchers or participate in study activities.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Yes. In total, you can receive up to $565 for completing all study activities. You will be compensated up to $10 per hour for attending all study sessions ($500 maximum). In addition, you will receive $20 each for completing surveys at the start and end of the program ($40 maximum) and $25 for participating in the optional interview at the end of the study period. If you decide to withdraw from the study, you will still receive the incentives for the sessions that were completed.

Participants will receive a reloadable gift card to receive incentive payments which they should retain until all study activities have been completed. Incentive payments will be distributed at the end of the Summer Launch program and upon completion of the optional interview.

Once you have consented to participate in the study, you will be asked to complete an Equipment Loan/Lease agreement for a computer that will be mailed to your address. The computer should be used only for the purposes of completing study activities. Once the study is complete and/or your participation ends (whichever occurs first), we will ask that the computer and all accessories are returned in the original packaging. The study team will provide a return shipping label.

You will also receive small gifts from the study team (stickers, backpack, reusable water bottle). These gifts are yours to keep.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your research information and any audio-video recordings obtained as part of the study will be stored in a locked cabinet in a locked office and/or uploaded to the University of Michigan's secure online storage platforms. Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.

Because the study will take place in a group format, other participants will have access to information you publicly share with the group. Participants will work together to develop Participation Guidelines for respectful communication, fostering a safe space for sharing ideas and personal information, and

protection of privacy/confidentiality for group members. MYHealth Participation Guidelines will be developed collaboratively by participants and reviewed throughout the program. Participants who do not comply with the MYHealth Participation Guidelines may be removed from the program for the safety and respect of others.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or commuhnicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of General Medical Sciences which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local of child abuse and neglect or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Michigan law requires the reporting of actual or suspected child abuse or neglect. If you tell us or we learn something that makes us believe that you or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies.

Legal name, mailing address, and social security number (SSN) will be collected by the Program Manager over the phone or via a Qualtrics survey during the consent process and stored securely in the University of Michigan DropBox such that only the PI and Program Manager have access. The University of Michigan Human Subjects Incentive Program (HSIP) requires the sharing of name, address, SSN, and payment amounts and dates for the distribution of incentive payments. Reloadable gift cards will be used in this study so that sensitive information is only shared with HSIP at one time and proxy IDs can be used for subsequent payments.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article or presented at a scientific meeting, but would not include any information that would let others know who you are. If your name and pictures will be used in any publications or presentations, the researchers will ask for your separate written permission.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Melissa DeJonckheere, PhD
Mailing Address: 2800 Plymouth Road, Building 14, Room G-232, Ann Arbor, MI 48109
Telephone: 734-232-4501

Project Manager: Sam Chuisano, MPH
Mailing Address: 2800 Plymouth Road, Building 14, Room G-232, Ann Arbor, MI 48109
Telephone: 734-936-1927

Email: my.health@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. SIGNATURES

Date of birth (mm/dd/yy): _____

Participant ID number: _____

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits,

and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent to video/audio recording/photography solely for purposes of this research
This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, **I agree** to let the study team keep my data for future research.

_____ **No, I do not agree** to let the study team keep my data for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-E

Parent Permission

Subject Name: _____

Parent:

Printed Legal Name: _____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-F

Participation to Contact for Future Study Opportunities

There may be an opportunity for you to enroll in future parts of this study with the MYHealth team. We will share information about these studies when the opportunities become available using the email address you provide.

_____ (Initial here) **I DO AGREE** to be contacted by the MYHealth team with future study opportunities.
_____ (Initial here) **I DO NOT AGREE** to be contacted by the MYHealth team with future study opportunities.

Printed Legal Name: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____