

Parent Permission Form for Student Participation in Flipside Study

Title of Research Study: *Using a Mentoring Afterschool Program to Improve Adolescent and Young Adult Mental Health: Phase 2, Pilot Study*

Investigator Team Contact Information: Katie Hendel

For questions about research appointments, the research study, research results, or other concerns, contact the study team at:

Investigator Name: Katie Hendel

Investigator Departmental Affiliation: Division of Epidemiology & Community Health

Phone Number: 612-625-6616

Email Address: khendel@umn.edu

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Key Information You Should Know Before Agreeing to Participate

The information below will help you learn about this research study and decide if you want to join. Make sure to read the whole consent form or have someone read it with you. If you have any questions or don't understand something, ask the researcher or study team before you sign the consent form.

What is this study about?

Coming out of the COVID-19 pandemic many teenagers are struggling with their mental and physical health. St. Paul's Flipside afterschool program has partnered with the University of Minnesota to have more caring young adults (college students) to mentor and participate in afterschool programming with middle school students. Through this partnership, one semester of Flipside this year for your student will be a version of Flipside with the college student mentors and one semester of Flipside will be the typical Flipside program without college mentors. This research study will help us understand whether the version of Flipside with college students is liked better by students and if it helps them improve their mental, emotional, and social wellbeing more than the typical Flipside program. More information about the study can be found on page #3.

Why am I being asked to take part in this research study?

We are asking your student to take part in this research study because they are enrolled in Flipside afterschool during the 2024-2025 academic year.

What are the risks I should know about?

- It is unlikely that being a part of this study would be bad for your child.
- As is the case with any study, there is some risk of data breach involving information we would have about your child.
- We will ask questions on surveys about how your child feels mentally and emotionally. Should your child indicate on these questions that they are at elevated risk, we will alert school staff who will then follow the schools procedures, including notifying you, to provide timely support for your child.

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Will this study benefit me or others?

We cannot promise that you or others will benefit from this study. However, one possible benefit includes early detection and provision of support were your child to be found to be at elevated mental health risk.

What is research?

- The goal of research is to learn new things to help people in the future.
- Researchers follow the same plan with many participants and usually don't change that plan for one research participant.
- By volunteering for a research study, your child might or might not be helped personally.

Voluntary Participation and Right to Stop at Any Time

- You and your child get to decide whether your child participates or not.
- You or your child can decide not to participate.
- You and your child can say yes at first and then change your mind at any time.

How long will the research last?

We expect that your child's participation in this research study will last about 9 months (the 2024-2025 academic school year). The time they will spend actively doing study activities over the academic year is estimated to be no more than 9.5 hours. For more information about these activities, please see page #.

What will I need to do to participate?

Your student will be asked to do three types of activities. Immediately after completing each activity they will receive a Target Gift Card (see section "Will I be compensated for my participation?"). All activities will occur at your child's school.

1. Complete a survey at the beginning and end of each semester (3 total). This survey will include questions that screen for mental health concerns like depression and anxiety. The survey will also ask questions about peer relationships and how connected they feel to their school.
2. Each Flipside class will be visited by research staff 4 times over the course of the year. On these days, students in the study will be given the chance to wear an activity monitor (a watch similar to a Fitbit).
3. Participate in a focus group with peers in their Flipside class to give feedback on the program at the end of each semester (2 total).

As part of the survey taken at the beginning and end of each semester (#1 above), we will ask questions about how your child feels mentally and emotionally. Should your child indicate on these questions that they are at elevated risk, we will alert school staff who will then follow the schools procedures, including notifying you, to provide timely support for your child.

We are also providing a list of resources to your child in case you or they would like to talk to someone and get help. If you are thinking about hurting yourself or someone else, please tell someone who can help immediately. Call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you.

For more information about these activities, please see page #3.

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What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study. If you and your child decide not to participate in the research, your child will participate in Flipside as they normally would.

Will it cost me anything to participate in this study?

It will not cost you or your child any money to participate in this study.

More Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 200 students to participate in this research study.

What happens if I say “Yes, I want to be in this research”?

All study activities will occur at your child’s school.

1. When you give your permission for your child to participate, the research team will explain the study to your child during Flipside and give your child the choice of whether they want to participate.
2. During the first couple weeks of Flipside in October your child will take a survey including questions about their mental health. They will take the survey either on paper or on the iPad provided to them by the school. They will receive a \$10 gift card after taking the survey. The survey is estimated to take about 20-30 minutes.
3. Throughout the semester (October -January), researchers will visit each Flipside class two times on a random schedule. When your child’s class is visited, they will be asked to wear an activity monitor (specifically an Actigraph GT9X). This activity monitor is similar to a FitBit or Apple Watch in that it is a watch that tracks movement so we can learn how physically active someone is during Flipside. Students will be asked to wear it just while they are at Flipside that day. We anticipate students will wear it for about 1.5 hours each time. If students are absent the day their class is visited, they will forgo that opportunity to wear the activity monitor that day. At the end of Flipside that day, students will return the watch and receive a \$5 gift card for wearing it.
4. In the last two weeks of the semester (January) students will be asked to take an almost identical survey as they took at the beginning of the semester including the questions about mental health. This survey will also include questions about their satisfaction with Flipside that semester. Just like at the beginning of the semester, they will take the survey either on paper or on the iPad provided to them by the school. They will receive a \$10 gift card after taking the survey. The survey is estimated to take about 20-30 minutes.
5. Also in the last two weeks of the semester (January), students will be given the opportunity to participate in a feedback focus group with peers in their class. These groups will be led by a researcher who will ask questions like “What were your least favorite parts of Flipside this semester? How could we improve Flipside?” These group conversations will be audio recorded. We will transcribe the recording into a transcript. Once we check the transcripts for accuracy and remove any identifying information from them, we will delete the audio recording. The focus group is expected to last no more than an hour. Students will receive a \$15 gift card immediately after participating.

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6. The activities described in #3, #4, and #5 will occur for a second time during the second semester (January – May). Specifically, your child will once again have two more opportunities to wear an activity monitor between January and May (as described in #3), one more opportunity to take the survey (as described in #4, at the end of the semester in May), and one more opportunity to participate in a focus group (as described in #5, at the end of the semester in May).

What are my responsibilities if I take part in this research?

If your child takes part in this research, they will be responsible for returning the activity monitor to research staff before leaving the program anytime they wear it.

What happens if I say “Yes”, but I change my mind later?

Your child can leave the research study at any time and no one will be upset by their decision. Your choice for your child to not to be in this study will not negatively affect your child’s ability to participate in Flipside or their academic standing as a student.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

The study team may break confidentiality in an effort to keep your child safe, which will include informing parents, school authorities, and/or health care professionals.

If your child tells us that they are thinking about hurting themselves or others, the research staff may ask more questions. Depending on how intense their thoughts are or how much they feel like hurting themselves or others, the research staff will tell school staff at Flipside who will follow school policies to support your child. We will work with you and them on a plan that might include getting to a medical facility for safety if needed.

We may publish the results of this research or share the resulting data. However, all results will be reported in aggregate and we will keep your name and other identifying information confidential. For example, we will share the overall group results of the study in a report to the school district at the end of the study. This report will not contain any student names or other identifying information.

Based on requirements from the study sponsor, the National Institutes of Health, de-identified data from this study will be included in the Data Repository for the University of Minnesota (DRUM) <http://hdl.handle.net/11299/166578>. This University Libraries’ hosted institutional data repository allows researchers affiliated with the University of Minnesota to share, publish, and preserve their data for long term access and future use.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

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The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children or vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will I receive research test results?

No. The data collected are only for research and have no clear meaning for health care. The one exception to this is if your child were to screen for elevated mental health risk, we will tell the school staff and work with them to contact you and follow school mental health procedures to support your child.

Whom do I contact if I have questions, concerns or feedback about my experience?

If you have questions later regarding the study or your participation, you are encouraged to contact the research team. Please see the “Investigator Contact Information” section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB which is part of the Human Research Protections Program (HRPP). If there is an issue you would like to discuss with someone who is *not* on the research team you are encouraged to call the HRPP Research Participants’ Advocate Line at [612-625-1650](tel:612-625-1650) (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. For example:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to provide feedback about this research to someone who is not on the study team.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the “Investigator Contact Information” of this form for study team contact information and “Whom do I contact if I have questions, concerns or feedback about my experience?” of this form for HRPP contact information.

Will I be compensated for my participation?

Your child will be compensated for their time and effort completing each study activity:

- Each time they complete a survey (3 total over the academic year) they will receive a \$10 Target Gift Card.
- Each time they wear an activity monitor during program (4 total over the academic year) they will receive a \$5 Target Gift Card

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- Each time they participate in a focus group (2 total over the academic year), they will receive a \$15 Target Gift Card.

In total, the maximum compensation for participating in the study is \$80.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your child's name and contact information) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

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Return this study permission form to Flipside.

Printed name of the child participant

Check one:

☐

I **give my permission** for the named child to take part in this research

☐

I **do not** give my permission for the named child to take part in this research

Parent or Legal Guardian Name

Date

Email of parent or legal guardian

Phone number of parent or legal guardian