**Stepped Care Intervention (Phase 1)**
Consent Information Sheet

**Study Title:** SUPPORT Study

**Site Principal Investigator:** Rebecca Rossom, MD, MS
952-883-5466

We are inviting you to take part in services offered as part of a research study called SUPPORT. The goal of research studies is different from the goal of medical care. The goal of medical care is to help each individual person. The goal of research is to learn more so we can help people in the future.

This information sheet will help you decide if you want to be part of the services offered in this study. Before deciding, you will have the chance to ask questions on the phone. You will not be asked to say yes to the study services (give your consent) until you have had the chance to ask questions.

**Who is doing this study?**

This study will include adolescents and researchers from four health care systems: Kaiser Permanente (KP) Northwest, KP Washington, KP Georgia, and HealthPartners in Minnesota. This study also includes researchers at Georgia State University and University of California, Los Angeles. The study is funded by the Patient-Centered Outcomes Research Institute (PCORI), in Washington, DC.

**What is this study about?**

In this study, we want to learn more about how to keep adolescents from harming themselves. We are asking you to take part in the services offered by this study based on the results of a computer program that searches health records to find people who may be at risk for self-harm. As researchers, we are allowed to search health records to find people who might be helped by a study and invite them to join the study.

**What will I be asked to do?**

If you decide to use the services offered, you will still get your regular care from HealthPartners/Park Nicollet. But you will also get services from our study, such as phone or video calls. Plus, you may get email, U.S. mail, or text messages. You may also be asked to join online group therapy sessions. The services we offer you will be based on the results of the computer program mentioned above. While the services in this study are not new, we are testing new ways of combining these services.

On the phone or video calls, our study staff may discuss your mental health, ask about your risk of self-harm, and work with you to develop a safety plan. They may review your regular care services with you (like visits to a therapist).

The group sessions will teach you skills that help to change behaviors, thoughts, and emotions that cause distress. Research has shown that it is helpful to involve caregivers, like parents or guardians, in these groups



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when possible. If you are offered this study service, we will encourage you to invite a caregiver to participate in group sessions with you.

We will record all calls and group sessions to monitor the quality of these services and train study staff.

The services we provide as part of this study are in addition to your regular care. They are not meant to replace any care or services you already get.

Some people will be invited to complete a phone interview about what it was like to be in the study. The phone interview is optional. If you do the interview, it will last up to an hour. If you do not want to do the interview, you can say no.

**How long will I be in this study?**

If you choose to use the study services, they will last for 6-8 months. The exact length of time will depend on the services you are getting. Here is some information on how long your services could last.

Phone and video calls: Every 1-4 weeks over six months. Calls will last 30 minutes to an hour.
Group sessions: Some people will be asked to join the online group. If you decide to join, there will be 18 weekly sessions over 4-6-months. Each session will last up to an hour and a half.

**Are there any risks to being in the study?**

There are some possible risks.

1. You may have negative thoughts or feelings that make you uncomfortable. We may ask you questions or bring up things that upset you. You can tell us if you do not want to answer any questions. A study care manager can also help you manage bad feelings.

2. There is a small risk that your private information will be seen by people who should not see it.
   - We may contact you by phone, video calls, email, U.S. mail, and text. Any information sent through the Internet has a small risk of being read by someone other than the person it was sent to. We cannot protect against all computer or human errors. But we will work hard to keep your information from being seen by someone who is not on the research team.
   - If we think you are in danger or unsafe, we will report this right away to a licensed member of our study team. A study team member may ask about your mood, thoughts, self-harm urges, and safety. They may also speak with a parent or another adult who can monitor your risk of danger or request emergency services. The study team member might suggest that you seek emergency services right away, such as going to the nearest emergency room, contacting a local emergency response team, or requesting supervision and monitoring. As a result of some of these situations, there is a small chance you could be admitted to a psychiatric hospital as a safety precaution.
   - There are times when, to follow the law, we cannot keep your information private. The law requires us to report a medical emergency, child abuse, elder abuse, or serious threats of harm to you or others.

3. There is a small chance that taking part in study services may have unexpected risks that we do not know about. If we learn new information about risks that might affect your willingness to use study services, we will let you know.


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**Are there any benefits to being in the study?**

You may or may not be helped by being in this study. The study services may improve your well-being, but we cannot guarantee that. What we learn in this study may help other people in the future.

**Will I be paid?**

You will not be paid for taking part in the phone/video calls or the group sessions. If you are invited to do the optional interview and you do it, we will give you a $40 gift card. You will not be charged for any study services you chose to participate in.

**Do I have to join?**

No, you do not have to accept the services offered as part of the research study. If you do use the services, you can decide to stop at any time. Taking part in the study services is completely up to you. Your decision to use study services or not will not affect your regular medical care or health care benefits in any way. If you choose to not use study services, the alternative is to continue to receive your regular medical care.

**What happens if a child participant turns 18 during the course of the study?**

The prior parent permission is no longer effective, but because parent or guardian participation is required, study staff will ask the teen to verbally confirm their participation.

**Privacy and Your Health Information**

HealthPartners has made a commitment to protect your health information. State and federal laws also protect your privacy.

By agreeing to take part in study services, you are giving HealthPartners permission to collect, use, and share information about you with other researchers. They have also agreed to keep this information private:

- Your use of study services, such as phone or video calls, text messages and group sessions
- Personal information from your medical record such as age, sex, race, ethnicity, sexual orientation, and gender identity
- Any mental health or medical diagnosis you may have or receive, which includes information from your medical record
- Health care you receive, such as outpatient, emergency, or hospital services recorded in your medical record that are not part of the study
- Your answers to surveys on depression, anxiety, suicidal ideation, and substance use

To protect your privacy, all study records, audio and video recordings, and information about your participation will be carefully protected. Your information will be stored on password-protected computers from HealthPartners on a secure study website or tracking system, or in locked file cabinets.



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The health information we may use or share includes:

1. We may add information to your medical record, like the safety plan created with our study staff, so it is available to your regular healthcare team.

2. A member of the research team might share information with your regular medical provider, mental health provider(s), nurses, and other healthcare professionals to provide you with the best care. We might share or ask about your risk of harm and your medications, therapy, or hospitalizations.

3. Audio or video recorded calls and group sessions shared with research team members at another study location to monitor quality and train others. These recordings may include personal health information (for example, this could be names used in a conversation or personal stories). Any personal health information included in a recording will not be used as study data.

Your medical record and information about your study services will be stored on secure servers at HealthPartners to help answer study research questions. Interview transcripts will be stored on secure servers at Georgia State University.

People and organizations who oversee or monitor this study may also see or receive your information. These may include the Institutional Review Board (a group that protects the rights of people in research studies), the organization funding the study, other researchers, and the FDA or Office of Human Research Protection.

**Whether or not you accept the services offered by the study, our research team will use information from your medical records to see if the whole group of people offered this program are less likely to harm themselves. If you have any questions or concerns about this part of the study, please contact the Site Principal Investigator Rebecca Rossom by phone at 952-883-5466, or by email at Rebecca.C.Rossom@HealthPartners.com.**

We may publish the results of this research. However, we will not publish your name or any other information that could identify you as someone in this study.

Information that identifies you might be removed from data or specimens collected in this research and the de-identified information may be used for future research or distributed to another investigator for future research without your consent.

**HIPAA Authorization**

By agreeing to take part in the services offered as part of this study, you give permission to researchers at HealthPartners to use and share your health information for the research described above. Once your information has been given to others, it may no longer be protected by state or federal privacy laws. It will still be protected by other rules and agreements with our research partners. However, there is still a risk that a person or organization could share your information without your permission. We would like your permission to keep your contact and study information for 5 years after you join the study. At that time, we will destroy any study records that could identify you.

If you decide you want to stop sharing your health information for this study, you will need to tell us in writing. You can tell us by writing to:

Rebecca Rossom, MD, MS
Site Principal Investigator
HealthPartners Institute
8170 33rd Ave S, MS 21112R
Bloomington, MN 55425
Rebecca.C.Rossom@HealthPartners.com

When we get your request, we will stop using and sharing your health information related to research study services. We may continue to use information we collected before we got your request. If we have already shared your information with someone else, we will probably not be able to get it back.

You do not have to allow the use and sharing of your health information to receive the services offered as part of this study. But, if you do not, you cannot receive study services. If you choose not to use the services offered, or if you decide to stop using the study services at any time, that will not affect your ability to receive health care at HealthPartners/Park Nicollet or your insurance coverage.

**What if I have questions?**

If you have any questions about this study, or if you feel you have been harmed by the study procedures, please contact Rebecca Rossom by phone at 952-883-5466, or by email at Rebecca.C.Rossom@HealthPartners.com. If you have questions about your rights as someone in a research study, you can contact the Institutional Review Board (IRB) at HealthPartners, 8170 33rd Ave S, MS 21112R, Bloomington, MN, 55425; Tel: 952-967-5025. The Institutional Review Board (IRB) is a group of scientists, non-scientists, and community members who review research studies to protect the rights and welfare of people in studies.

**ASSENT/CONSENT FOR TAKING PART IN STUDY SERVICES**

**Youth Assent**

By taking part in study services, you are confirming that:

- You have read the consent information sheet, or it has been read to you.
- You have had a chance to ask questions.
- You have received a copy of the consent information sheet (either by postal mail, email, or downloaded from the study website).

Accepting the services offered as part of this research study means:

- You have freely agreed to use the study services.
- You have agreed to let us use and share study information as described above.

You do not have to agree to these terms. However, if you do not agree, we cannot offer you the study services described above.



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**Parent/Guardian Consent**

By allowing your child to take part in study services, you are confirming that:

- You have read the consent information sheet, or it has been read to you.
- You have had a chance to ask questions.
- You have received a copy of the consent information sheet (either by postal mail, email, or downloaded from the study website).

Accepting the services offered as part of this research study means:

- You have freely agreed to let your child use the study services.
- You have agreed to let us use and share your child's study information as described above.

You do not have to agree to these terms. However, if you do not agree, we cannot offer your child the study services described above.



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