Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Self-Management for Families and Youth Living with Sickle Cell Disease – SMYLS

Consent for Parents/Caregivers and Children/Adolescents

A. PURPOSE OF THE RESEARCH

You and your child are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study nurse or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this study is to find out whether a web-based intervention using a mobile device over a 12-week period is helpful in managing symptoms of Sickle Cell Disease, such as pain and fatigue and quality of life. The study will take place in your home, but you will be asked to meet with the research staff by phone or in person four times over the six-month study period to complete questionnaires and provide information. You and your child/adolescent are being asked to participate in this study because your child has Sickle Cell Disease, and you are his/her parent or primary caregiver. The investigator in charge of this study is Shannon Phillips PhD, RN. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Shannon Phillips' and her research team's salaries will be paid by this grant. The study is being done at the Medical University of South Carolina (MUSC). Approximately 60 people (30 child/adolescent/caregiver pairs) will take part in this part of this study, all at MUSC.

B. PROCEDURES

Data collection for this study consists of four visits over a six-month period: Visit One (Baseline) which will take place at MUSC Sickle Cell Clinic, and Visit Two (week 6), Visit Three (week 12) and Visit Four (3-month-follow up) which will take place by phone.

<u>During Visit One, also called your Baseline visit:</u>

1. If you agree to be in this study, the following will happen:
2. You and your child will be asked a series of questions about your demographic information and their Sickle Cell Disease diagnosis. You and your child will also be asked to complete a set of questionnaires about your daily levels of pain, tiredness, anxiety and depression, and general quality of life while living with Sickle Cell Disease.
3. You and your child will have a web-based application (app) downloaded onto your smartphones or tablets. If you or your child do not have a mobile device (such as a phone or tablet) one will be provided for study use. You will be asked to return these devices at the end of the study. The app is designed to help parents/caregivers and children with sickle cell disease. You and your child will be taught how to use the app, work the device,

and will also be given written instructions and a phone number to contact if you should have any problems.

4. You and your child will receive weekly phone calls for the next 12 weeks from one of the researchers to see how you are both doing. Your child will also get a daily automated text sent to your mobile device to remind you to record their levels of pain or activities on that day.

Visit Two and Three:

Visit Two will occur six weeks after study enrollment and Visit Three at 12 weeks after enrollment. At both these visits, you and your child will meet with a member of the research staff by phone or in person to discuss both of your progress in the study. You will also be asked to complete all of the same questionnaires from Visit One, as well as an app satisfaction and a provider communication survey.

Visit Four:

Visit Four will occur 6 months after enrollment. At this visit, you will meet with the Investigator by phone if you used your own device, or in person if you borrowed a device. You will discuss your and your child's experience in the study and turn in any borrowed mobile device at that time. You will also be asked to complete all of the same questionnaires from Visit One again.

At the end of this visit, you and your child, as well as all the other caregivers and their children taking part in this study will be asked to participate in a post-study interview with the Investigator. Should you like to take part in the interview, both you and your child will have to agree to do so. However, only 15 pairs of caregiver/child will be chosen for this part of the study. Participants will be selected randomly by computer. You will have a 50-50 chance (like a coin-toss) of being selected. At this interview, you both will be asked about your thoughts and experiences with using the app. The interview should last about one hour and will be audio recorded and transcribed by an outside agency so that the investigator can review the information.

C. DURATION

This study consists of four visits over a six-month period: Visit 1 (Baseline), Visit 2 (week-6), Visit 3 (week-12) and Visit 4 (3-month follow-up). Participation in the first visit will take about two hours. The other visits should take about one hour each.

D. RISKS AND DISCOMFORTS

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. To help protect against this risk, your name will not be stored with your study data.

There is a risk you or your child could become tired or fatigued during the visits. Breaks will be offered, but if you or your child becomes exhausted, the visit may be rescheduled.

Financial risks include lost time from work to participate in interviews. To prevent this risk, the interviews will be carefully scheduled.

E. BENEFITS

There will be no direct benefit to you or your child from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with sickle cell disease.

F. COSTS

There will be no cost to you or your child as a result of participation in this study.

G. PAYMENT TO PARTICIPANTS

In return for your and your child's time and effort, you will be paid $50.00 in the form of a gift card for each study visit completed. You could be paid a total of $200.00. The participants completing the post-study interviews will receive an additional $40.00 gift card as compensation. All gift cards will be given to the adult caregiver.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES

Your and your child's alternative is to not participate in this study.

I. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

J. DATA SHARING

The results of all surveys and tests that you or your child complete will be shared by the MUSC researchers with the National Institutes of Nursing Research (NINR) and stored electronically on a password protected secure server. The purpose of sharing this information is to build a large repository of data for future research purposes among the general scientific community and for public health benefit. Only de-identified data (that is data which do not include anything that might directly identify you or your child) will be shared.

K. ADDITIONAL INFORMATION

Results of this research will be used for the purposes described in this study. This information may be published, but you and your child will not be identified. Information that is obtained concerning this research that can be identified with you or your child will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you or your child is injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you or your child are in a research study. They will call your or your child's study doctor who will make arrangements for treatment. If the study sponsor does not pay for your or your child's treatment, the Medical University Hospital and the physicians who render treatment to you or your child will bill your insurance company. If your or your child's insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you or your child.

Your and your child's participation in this study is voluntary. You both may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your or your child's decision not to take part in the study will not affect your or your child's current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your or your child's participation in this study at any time if they decide it is in your best interests. They may also do this if you or your child do not follow the investigator's instructions.

Volunteers Statement

We have been given a chance to ask questions about this research study. These questions have been answered our satisfaction. If we have any more questions about our participation in this study or study related injury, we may contact Shannon Phillips at (843/792-9379). We may contact the Medical University of SC Hospital Medical Director (843/792-9537) concerning medical treatment.

If we have any questions, problems, or concerns, desire further information or wish to offer input about our rights as a research subject in this study, we may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my or my child's rights as a research subject in this study.

We agree to participate in this study. We have been given a copy of this form for my own records.

If you and your child wish to participate, you should sign below.

Signature of Person Obtaining Consent	Date	*Name of Participant	Date

Signature of Parent/Legal Guardian	Date

Child Assent
*12-17 years of age:
"My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____

Age:_____ Date of Birth: _____

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

A Family-Centered Self-Management Program for Young Children with Sickle Cell Disease: Phase II

Consent for Parents/Caregivers and Children

A. PURPOSE OF THE RESEARCH

You and your child are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study nurse or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this study is to find out whether a web-based intervention using a mobile device over a 12-week period is helpful in managing symptoms of Sickle Cell Disease, such as pain and fatigue and quality of life. The study will take place in your home, but you will be asked to meet with the research staff by phone or in person four times over the six-month study period to complete questionnaires and provide information. You and your child are being asked to participate in this study because your child has Sickle Cell Disease, and you are his/her parent or primary caregiver. The investigator in charge of this study is Shannon Phillips PhD, RN. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Shannon Phillips' and her research team's salaries will be paid by this grant. The study is being done at one site. Approximately 60 people (30 child/caregiver pairs) will take part in this part of this study, all at MUSC.

If you/your child agree to be in this study, the following will happen:

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Data collection for this study consists of four visits over a six-month period: Visit One (Baseline) which will take place at MUSC Sickle Cell Clinic, and Visit Two (week 6), Visit Three (week 12) and Visit Four (3-month-follow up) which will take place by phone.

<u>During Visit One, also called your Baseline visit:</u>

1. You will be asked a series of questions about your demographic information and your child's Sickle Cell Disease diagnosis. You, and your child if aged 5-7 years old, will also be asked to complete a set of questionnaires about your child's daily level of pain, tiredness, anxiety and depression, and general quality of life while living with Sickle Cell Disease.
2. You will have a web-based application (app) downloaded onto your smartphone or tablet. If you do not have a mobile device (such as a phone or tablet) one will be provided for study use. You will be asked to return this device at the end of the study. The app is designed to help parents/caregivers and children with sickle cell disease. You and your

child will be taught how to use the app, work the device, and will also be given written instructions and a phone number to contact if you/your child should have any problems.

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At the end of this visit, you, as well as all the other caregivers taking part in this study will be asked whether to participate in a post-study interview with the Investigator. However, only 15 caregivers will be chosen for this part of the study. Participants will be selected randomly by computer. You will have a 50-50 chance (like a coin-toss) of being selected. At this interview, you will be asked about your thoughts and experiences with using the app. The interview should last about one hour and will be audio recorded and transcribed by an outside agency so that the investigator can review the information.

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F. COSTS

There will be no cost to you/your child as a result of participation in this study.

G. PAYMENT TO PARTICIPANTS

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K. ADDITIONAL INFORMATION

Results of this research will be used for the purposes described in this study. This information may be published, but you/your child will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you/your child are injured as a result of participation in this study, you/your child should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you/your child are in a research study. They will call you/your child's study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your/your child's treatment, the Medical University Hospital and the physicians who render treatment to you/your child will bill your/your child's insurance company. If your/your child's insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you/your child.

Your/your child's participation in this study is voluntary. You/your child may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you/your child decide to do this. Your/your child's decision not to take part in the study will not affect your current or future medical care or any benefits to which you/your child are entitled.

The investigators and/or the sponsor may stop your/your child's participation in this study at any time if they decide it is in your/your child's best interest. They may also do this if you/your child do not follow the investigator's instructions.

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If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you and your child wish to participate, you should sign below.

_____	_____	_____	_____
Signature of Person Obtaining Consent	Date	Signature of Parent/Legal Guardian	Date
		_____	_____
		Printed Name of Minor Participant	Date