Attachment 11:
Consent & Assent Forms

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For Participation In A Research Study Focus Group

Parent/Caregiver/Adult Consent Form (CCHMC)

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

STUDY NUMBER: N/A

FUNDING ORGANIZATION: Agency for Healthcare Research and Quality (AHRQ)

Maria Britto, MD

Name of Principal Investigator

(513) 636-8583

Telephone Number

Introduction

We are asking you to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

Why Are We Doing This Research?

In this research study we use focus groups to learn more about parents/caregivers' previous experiences and perceived needs with transitioning your child and/or young adult with sickle cell disease (SCD) between healthcare sites and from pediatric to adult care, to identify barriers and facilitators to high quality care during these transitions, and understand your current use of technology and how it could be used to improve transitional care.

We are asking you and other parents/caregivers to be in the research, because you are a parent/caregiver of a child or young adult with a positive diagnosis of sickle cell disease (SCD).

Who Is In Charge Of The Research?

Dr. Britto is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

CCHMC is being paid by The Lewin Group through funds awarded to AHRQ to do this study.

Who Should Not Be In The Study?

You can not be in this study if you:

- Do not have a child/young adult with SCD or are not the primary caregiver of a child/young adult with SCD
- Do not speak/read English

What Will Happen In The Study?

If you agree to participate, you will complete a brief questionnaire at the beginning of the focus group. You will complete the following measures:

Demographics form: On this form we will ask you basic demographic questions (e.g., gender, age, occupation, etc.). This will take approximately 5-10 minutes to complete.

Afterwards, the focus group moderator will ask you questions about your experiences with care transitions for a child/young adult with sickle cell disease and technology use. There will be 6-10 participants in the focus group. The session will be audiotaped, as well as recorded in written notes by the research staff. Your first name will not be recorded. The recording is required to participate for the purposes of identifying each speaker. If at any time you feel uncomfortable you may ask to stop the recording. The research assistant will restart the recording when you indicate you are ready to continue.

What Are The Good Things That Can Happen From This Research?

Being in this study may not help you right now. Potential benefits for you may include learning from other participants through the sharing of experiences and insights during the focus group.

The information learned from this research study may benefit other patients with sickle cell disease in the future.

What Are The Bad Things That Can Happen From This Research?

The risks for participation in this study are minimal. The two possible risks for this study are: (1) you may feel some discomfort when discussing your experiences of caring for a child/young adult with SCD; and (2) loss of confidentiality. If you become uncomfortable with the discussion during the focus group, you will be free to leave at any time during the discussion. Please let a member of the research team know if this is the case. We will discuss this with you and help you get any follow up services you may want or need.

There may be other risks that we do not know about yet.

What Other Choices Are There?

Instead of being in this study, you can choose not to be in it. Even if you do not participate in this study, your child/young adult will continue to receive routine care.

How Will Information About You Be Kept Private?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will take the following precautionary measures:

- At the start of the focus group, all participants will be asked to keep all comments made in the group confidential.
- The audiotapes from the focus group will be stored in computer data files that are password-protected, and it will not contain any information that can personally identify you or your child/young adult.
- Each participant will be assigned an anonymous study code number and this will be used in the group transcript (written document of everything said in the group).

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

What If We Learn New Information During The Research?

The study doctor will tell you if they find out about new information from this or other studies that may affect your/your child's health, safety or willingness to stay in this study.

Will It Cost You Anything Extra To Be In The Research Study?

There are not costs for participating in this research study. You will be responsible for the usual costs of your medical care, but you will not be charged any additional costs for participation in this study.

Will You Be Paid To Be In This Research Study?

You will be reimbursed for your time, effort and travel while you are in this research study.

You will be paid $50 cash as reimbursement for your time, effort, and travel.

Who Do You Call If You Have Questions Or Problems?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

Authorization For Use/Disclosure Of Health Information For Research

To be in this research study you must also give your permission (or authorization) to use and

disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Your CCHMC medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?

By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment ***not*** related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

Signatures

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____

Printed Name of Research Participant

_____ _____

Signature of Research Participant Indicating Consent Date

_____ _____

Signature of Legally Authorized Representative* Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____

Signature of Individual Obtaining Consent Date

Children's National Medical Center

Department of Hematology
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Parent/Caregiver/Adult Consent Form (CNMC)

TITLE OF STUDY: Improving Sickle Cell Transitions of Care through Health Information Technology

PRINCIPAL INVESTIGATOR: Emily R. Meier, MD, Division of Hematology

You refers to "You" and/or "Your Child" throughout this document

Introduction:

We would like you and your child to be part of a research study at Children's Hospital. Before you decide, we want you to know why we are doing the study and if it will help your child. We also want you to know about any risks (what might go wrong) and what you and your child will have to do in the study.

This form gives you information about the study. Your doctor will talk to you about the study and answer any questions you have. We will ask you to sign this form to show that you understand the study. If your child is twelve years old or older, we will talk to your child about the study and ask your child to sign a form like this one. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and drop out of the study any time you want
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

A. Purpose of Study

You are being asked to participate in this study because you visit the Sickle Cell Disease (SCD) clinic as a patient or because you are related to a child with SCD.

The Sickle Cell Program at Children's National Medical Center (CNMC) is working with the Agency for Healthcare Research and Quality (AHRQ) to learn more about how an electronic medical tool or app can help people with sickle cell disease (SCD) when they change doctors or are seen in different parts of the hospital [like the emergency room (ER) or outpatient clinic]. We call these changes between doctors and medical settings health care transitions. We want this app to help organize your personal medical information so that health care transitions are as safe as possible.

In this study, we are trying to understand what SCD patients, their caregivers, and their doctors need to know about what complications (if any) a SCD patient has had in the past and how an app can help them remember and organize this information.

B. Procedure

Doctors and nurses who take care of SCD patients, parents of children with SCD and children with SCD are being asked to participate in this study. As a participant in this study, you will be asked to participate in a focus group. The focus group will last approximately 2 hours and will meet only once. The focus groups will be divided into groups separated by age, parent or guardian, and health care provider (doctors and nurses). The focus group leader will ask you to discuss topics related to your understanding of SCD, your experience in the hospital setting, and your use of technology. There will be a maximum of 9 other people in the group with you.

We want to make sure that we remember all of the things that you said about you and your child's experience with SCD, so with your permission we will audio record the focus group and take some notes during the meeting. During the recording, we will call you by your first name only. You may also ask us to turn off the audio recorder at any point in the conversation. You can still participate in the study if you ask us not to record the conversation. We will destroy the recordings at the end of the study.

You may decide to withdraw from the study at any time and for any reason. If you withdraw, no more information will be collected from you, and your prior records will be destroyed.

_____ YES, I give permission to have my study interview audio recorded as part of this research study

_____ NO, I do not give my permission to have my study interview audio recorded as part of this research study

C. Potential Risks/Discomfort

Your participation could result in a possible breach of confidentiality. Participating in this study about your experience with SCD and use of technology could cause embarrassment or a feeling of invasion of privacy. You do not have to answer any questions you are uncomfortable with and we will do everything we can to ensure you are comfortable during the focus group, as well as take all precautions to ensure your private information is protected.

D. Potential Benefits

There will be no direct benefit to you for participation in this research study. However, your participation in this study may help in our understanding of how people manage their SCD and lead to the development of an app that will help people with SCD.

E. Alternatives to Participation

You have the alternative to choose not to participate in this research study. You can still participate in the study if you ask us not to record your interview.

F. Questions – Who to Call

We want you to ask questions about any part of this study or consent form either now or at any time in the future. If you have research or medical questions about this study, call the Principal Investigator, Emily R. Meier, MD at (202)476-2800. If you believe you have been injured as a result of being in this study, you should call the Principal Investigator, Emily R. Meier, MD at (202)476-2800. If you have any questions or concerns about your rights in this research study at any time, please call Children's Hospital's Manager of Customer Relations, at (202) 476-5000 or call the Chief Academic Officer of the Children's National Medical Center at (202) 476-5000.

G. Confidentiality

We will keep the records of this study confidential. We will not tell anyone you are in the study. Only the people working on the study will know your name. They will keep this information in case we have to find you later for medical reasons. The federal government can review the study records and medical records to make sure we are following the law and protecting the children in the study and to make sure our results are correct. Your child's medical record is confidential, but just like any medical record; there are some exceptions under state and federal law.

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

H. Compensation

Each participant will be given a $50 gift card for their participation in this study.

We cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that something bad happened because your child was in the study, please call the Chief Academic Officer of the Children's National Medical Center at (202) 476-5000. We do not promise to pay you anything or give your child free medical care if something bad happens, but we will look at each case carefully. We will give your child any emergency treatment needed. You do not give up any legal rights by signing this form and you are not releasing us from any responsibility if we do anything wrong.

Consent:

By signing this form, you agree that you have talked to your child's doctor about the study and understand it, and want your child to be in the study. You agree that we have talked to you about the risks and benefits of the study, and about other choices. You may take your child out of the study at any time and no one will mind and nothing will change about your child's medical care other than not being in the study. Copies of this form will be:

1. kept in the study file by the Principal Investigator;
2. put in your child's medical record; and
3. given to you to keep.

Please call the Principal Investigator, Emily R. Meier, MD at (202)476-2800 if you have any questions.

Printed Name of Participant: _____

Medical Record Number: _____

Printed Name of Parent(s)/Guardian(s): _____

Signature of Participant: _____Date:_____
(Participant must be 18 years of age or older)

Signature of Parent(s)/Guardian(s): _____Date:_____
[Note: signature of both parents required if more than minimal risk and no direct benefit, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child]

Witness (to signatures): _____Date:_____
(may be investigator)

Translator's Signature (if, applicable): _____

Language: _____

INVESTIGATOR'S AFFIDAVIT: I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Consent: _____

Title: _____ Signature: _____ Date: _____

Affidavit Of Person Obtaining Assent For Children 7-11 Years Old:

I have explained all aspects of the research study to the participant to the best of his or her ability to understand.

I have answered all the questions of the participant relating to this research.

I believe the participant's decision to enroll is voluntary.

The study doctors and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of the research.

Printed Name of Individual Obtaining Assent: _____

Title: _____ Signature: _____ Date: _____

For Participation In A Research Study Focus Group

Parent/Caregiver/Adult Consent Form (Nemours)

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

STUDY NUMBER: N/A

FUNDING ORGANIZATION: Agency for Healthcare Research and Quality (AHRQ)

Paul A. Pitel, MD

Name of Principal Investigator

(904) 697-3789

Telephone Number

Introduction

We are asking you to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

Why Are We Doing This Research?

In this research study we use focus groups to learn more about parents/caregivers' previous experiences and perceived needs with transitioning your child and/or young adult with sickle cell disease (SCD) between healthcare sites and from pediatric to adult care, to identify barriers and facilitators to high quality care during these transitions, and understand your current use of technology and how it could be used to improve transitional care.

We are asking you and other parents/caregivers to be in the research, because you are a parent/caregiver of a child or young adult with a positive diagnosis of sickle cell disease (SCD).

Who Is In Charge Of The Research?

Dr. Pitel is the researcher at Nemours Children's Clinic - Jacksonville (NCC-J) that is in charge of this study.

NCC-J is being paid by The Lewin Group through funds awarded to AHRQ to do this study.

Who Should Not Be In The Study

You can not be in this study if you:

- Do not have a child/young adult with SCD or are not the primary caregiver of a child/young adult with SCD
- Do not speak/read English

What Will Happen In The Study?

If you agree to participate, you will complete a brief questionnaire at the beginning of the focus group. You will complete the following measures:

Demographics form: On this form we will ask you basic demographic questions (e.g., gender, age, occupation, etc.). This will take approximately 5-10 minutes to complete.

Afterwards, the focus group moderator will ask you questions about your experiences with care transitions for a child/young adult with sickle cell disease and technology use. There will be 6-10 participants in the focus group. The session will be audiotaped, as well as recorded in written notes by the research staff. Your first name will not be recorded. The recording is required to participate for the purposes of identifying each speaker. If at any time you feel uncomfortable you may ask to stop the recording. The research assistant will restart the recording when you indicate you are ready to continue.

What Are The Good Things That Can Happen From This Research?

Being in this study may not help you right now. Potential benefits for you may include learning from other participants through the sharing of experiences and insights during the focus group.

The information learned from this research study may benefit other patients with sickle cell disease in the future.

What Are The Bad Things That Can Happen From This Research?

The risks for participation in this study are minimal. The two possible risks for this study are: (1) you may feel some discomfort when discussing your experiences of caring for a child/young adult with SCD; and (2) loss of confidentiality. If you become uncomfortable with the discussion during the focus group, you will be free to leave at any time during the discussion. Please let a member of the research team know if this is the case. We will discuss this with you and help you get any follow up services you may want or need.

There may be other risks that we do not know about yet.

What Other Choices Are There?

Instead of being in this study, you can choose not to be in it. Even if you do not participate in this study, your child/young adult will continue to receive routine care.

How Will Information About You Be Kept Private?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will take the following precautionary measures:

- At the start of the focus group, all participants will be asked to keep all comments made in the group confidential.
- The audiotapes from the focus group will be stored in computer data files that are password-protected, and it will not contain any information that can personally identify you or your child/young adult.
- Each participant will be assigned an anonymous study code number and this will be used in the group transcript (written document of everything said in the group).

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

What If We Learn New Information During The Research?

The study doctor will tell you if they find out about new information from this or other studies that may affect your/your child's health, safety or willingness to stay in this study.

Will It Cost You Anything Extra To Be In The Research Study?

There are not costs for participating in this research study. You will be responsible for the usual costs of your medical care, but you will not be charged any additional costs for participation in this study.

Will You Be Paid To Be In This Research Study?

You will be reimbursed for your time, effort and travel while you are in this research study.

You will be paid $50 cash as reimbursement for your time, effort, and travel.

Who Do You Call If You Have Questions Or Problems?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the NCC-J Institutional Review Board at 904-697-3600.

Authorization For Use/Disclosure Of Health Information For Research

To be in this research study you must also give your permission (or authorization) to use and

disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

NCC-J will need to use and share your PHI as part of this study. This PHI will come from:

- Your NCC-J medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including NCC-J)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the NCC-J Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or

maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?

By signing this document you are agree to participate in this research study and give permission to NCC-J to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment ***not*** related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

Signatures

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____

Printed Name of Research Participant

_____ _____

Signature of Research Participant Indicating Consent Date

_____ _____

Signature of Legally Authorized Representative* Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____

Signature of Individual Obtaining Consent Date

For Participation In A Research Study Focus Group

Provider Informed Consent Form (CCHMC)

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

STUDY NUMBER: N/A

FUNDING ORGANIZATION: Agency for Healthcare Research and Quality (AHRQ)

Maria Britto, MD

Name of Principal Investigator

(513) 636-8583

Telephone Number

Introduction

We are asking you to be in a research study so that we can learn new information that may help others. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

Why Are We Doing This Research?

In this research study we will use focus groups to help us understand providers' experiences with transitioning sickle cell disease (SCD) patients: (1) between and among care sites, and (2) from pediatric to adult care; and to identify barriers and facilitators to providing high quality care during these transitions.

We are asking you and other providers who treat patients with SCD to be in the research, because you are:

- Pediatric or Adult Hematologist, NP, Nurse, SW, Health Educator caring for SCD patients
- Pediatric or Adult Primary Care Physicians, NP, Nurse, PA caring for SCD patients
- Practice physician/provider in the greater Cincinnati region

Who Is In Charge Of The Research?

Maria Britto is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

CCHMC is being paid by The Lewin Group through funds awarded by AHRQ to do this study.

Who Should Not Be In The Study

You cannot be in this study if you are:

- A practice physician/provider not caring for patients with SCD
- A practice physician/provider caring for adolescents and young adults with SCD years who do not have a practice in the greater Cincinnati region
- Non-English speaking

What Will Happen In The Study?

If you agree to be in this study, you will be in the study for approximately two hours. Once all data is collected, your involvement in the study will be concluded.

You will complete a brief questionnaire at the beginning of the focus group. You will complete the following measure:

Demographics Form. This questionnaire will ask some basic information such as your profession, number of years you have been caring for SCD patients, number of patients with SCD in your setting and basic demographics (e.g., gender, age, etc.).

Afterwards, the focus group moderator will ask you questions about your experiences with transitioning sickle cell disease (SCD) patients and to identify barriers and facilitators to providing high quality care during these transitions. There will be 6-10 participants in the focus group. The session will be audiotaped, as well as recorded in written notes by the research staff. First names will not be recorded. The recording is required to participate for the purposes of identifying each speaker. If at any time you feel uncomfortable you may ask that the recording be stopped. The research assistant will restart the recording when you indicate you are ready to continue.

What Are The Good Things That Can Happen From This Research?

If you agree to take part in this research study, you may not *receive* a direct benefit. Potential benefits for you may include learning from other participants through the sharing of experiences and insights during the focus group.

The information learned from this research study may benefit patients with sickle cells disease in the future.

What Are The Bad Things That Can Happen From This Research?

The risks for participation in this study are minimal. The two possible risks for this study are: (1) participants may feel some discomfort when discussing their preferences; (2) loss of confidentiality. If you become uncomfortable with the discussion during the focus group, you will be free to leave at any time during the discussion. Please let a member of the research team know if this is the case. We will discuss this with you and help you get any follow up services you may want or need.

There may be other risks that we do not know about yet.

What Other Choices Are There?

Instead of being in this study, you can choose not to be in it. This will not change CCHMC's relationship (e.g., referrals, etc.) with you as a provider.

How Will Information About You Be Kept Private?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will take the following precautionary measures to protect your privacy and confidentiality of research and/or medical records:

- At the start of the focus group, all participants will be asked to keep all comments made in the group confidential.
- The audiotapes from the focus group will be stored in computer data files that are password-protected, and it will not contain any information that can personally identify you or your patients.
- Each participant will be assigned an anonymous study code number and this will be used in the group transcript (written documentation of everything said in the group).

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

What If We Learn New Information During The Research?

The study doctor will tell you about new information from this or other studies that may affect your willingness to stay in this study.

Will It Cost You Anything Extra To Be In The Research Study?

There are not costs for participating in this research study.

Will You Be Paid To Be In This Research Study?

You will be reimbursed for your time, effort and travel while you are in this research study.

Each focus group participant will received $50 cash for their time, participation, and travel.

Who Do You Call If You Have Questions Or Problems?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

Signatures

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____

Printed Name of Research Participant

_____ _____

Signature of Research Participant Indicating Consent Date

_____ _____

Signature of Legally Authorized Representative* Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____

Signature of Individual Obtaining Consent Date

Children's National Medical Center

Department of Hematology
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Consent to Participate in a Clinical Research Study Focus Group Provider Informed Consent Form (CNMC)

TITLE OF STUDY: Improving Sickle Cell Transitions of Care through Health Information Technology

PRINCIPAL INVESTIGATOR: Emily R. Meier, MD, Division of Hematology

Introduction:

We would like you to be part of a research study at Children's Hospital. Before you decide, we want you to know why we are doing the study. We also want you to know about any risks (what might go wrong) and what you will have to do in the study.

This form gives you information about the study. We will ask you to sign this form to show that you understand the study. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and drop out of the study any time you want
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

A. Purpose of Study

You are being asked to participate in this study because you are a health care provider for SCD patients.

The Sickle Cell Program at Children's National Medical Center (CNMC) is working with the Agency for Healthcare Research and Quality (AHRQ) to learn more about how an electronic medical tool or app can help people with sickle cell disease (SCD) when they change doctors or are seen in different parts of the hospital [like the emergency room (ER) or outpatient clinic]. We call these changes between doctors and medical settings health care transitions. We want this app to help organize personal medical information of people with SCD so that health care transitions are as safe as possible.

In this study, we are trying to understand what SCD patients, their caregivers, and their healthcare providers need to know about what complications (if any) a SCD patient has had in the past and how an app can help them remember and organize this information.

B. Procedure

SCD providers, parents of children with SCD and children with SCD are being asked to participate in this study. As a participant in this study, you will be asked to participate in a focus group. The focus group will last approximately 2 hours and will meet only once. The focus groups will be divided into groups separated by age, parent or guardian, and health care provider. The focus group leader will ask you to discuss topics related to your understanding of SCD, your experience in the hospital setting, and your use of technology. There will be a maximum of 9 other people in the group with you.

We want to make sure that we remember all of the things that you said about you and your child's experience with SCD, so with your permission we will audio record the focus group and take some notes during the meeting. During the recording, we will call you by your first name only. You may also ask us to turn off the audio recorder at any point in the conversation. You can still participate in the study if you ask us not to record the conversation. We will destroy the recordings at the end of the study.

You may decide to withdraw from the study at any time and for any reason. If you withdraw, no more information will be collected from you, and your prior records will be destroyed.

_____ YES, I give permission to have my study interview audio recorded as part of this research study

_____ NO, I do not give my permission to have my study interview audio recorded as part of this research study

C. Potential Risks/Discomfort

Your participation could result in a possible breach of confidentiality. Participating in this study about your experience with SCD and use of technology could cause embarrassment or a feeling of invasion of privacy. You do not have to answer any questions you are uncomfortable with and we will do everything we can to ensure you are comfortable during the focus group, as well as take all precautions to ensure your private information is protected.

D. Potential Benefits

There will be no direct benefit to you for participation in this research study. However, your participation in this study may help in our understanding of how people manage their SCD and lead to the development of an app that will help people with SCD.

E. Alternatives to Participation

You have the alternative to choose not to participate in this research study. You can still participate in the study if you ask us not to record your interview.

F. Questions – Who to Call

We want you to ask questions about any part of this study or consent form either now or at any time in the future. If you have research or medical questions about this study, call the Principal Investigator, Emily R. Meier, MD at (202)476-2800. If you believe you have been injured as a result of being in this study, you should call the Principal Investigator, Emily R. Meier, MD at (202)476-2800. If you have any questions or concerns about your rights in this research study at any time, please call Children's Hospital's Manager of Customer Relations, at (202) 476-5000 or call the Chief Academic Officer of the Children's National Medical Center at (202) 476-5000.

G. Confidentiality

We will keep the records of this study confidential. We will not tell anyone you are in the study. Only the people working on the study will know your name. They will keep this information in case we have to find you later for medical reasons. The federal government can review the study records and medical records to make sure we are following the law and protecting the children in the study and to make sure our results are correct. Your child's medical record is confidential, but just like any medical record; there are some exceptions under state and federal law.

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

H. Compensation

Each participant will be given a $50 gift card for their participation in this study.

We cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that something bad happened because your child was in the study, please call the Chief Academic Officer of the Children's National Medical Center at (202) 476-5000. We do not promise to pay you anything or give your child free medical care if something bad happens, but we will look at each case carefully. We will give your child any emergency treatment needed. You do not give up any legal rights by signing this form and you are not releasing us from any responsibility if we do anything wrong.

Consent:

By signing this form, you agree that you have talked to your child's doctor about the study and understand it, and want your child to be in the study. You agree that we have talked to you about the risks and benefits of the study, and about other choices. You may take your child out of the study at any time and no one will mind and nothing will change about your child's medical care other than not being in the study. Copies of this form will be:

1. kept in the study file by the Principal Investigator;
2. put in your child's medical record; and
3. given to you to keep.

Please call the Principal Investigator, Emily R. Meier, MD at (202)476-2800 if you have any questions.

Printed Name of Participant: _____

Medical Record Number: _____

Printed Name of Parent(s)/Guardian(s): _____

Signature of Participant: _____Date:_____

(Participant must be 18 years of age or older)

Signature of Parent(s)/Guardian(s): _____Date:_____

[Note: signature of both parents required if more than minimal risk and no direct benefit, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child]

Witness (to signatures): _____Date:_____

(may be investigator)

Translator's Signature (if, applicable): _____

Language: _____

INVESTIGATOR'S AFFIDAVIT: I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Consent: _____

Title: _____ Signature: _____ Date: _____

Affidavit of Person Obtaining Assent for Children 7-11 Years Old:

I have explained all aspects of the research study to the participant to the best of his or her ability to understand.

I have answered all the questions of the participant relating to this research.

I believe the participant's decision to enroll is voluntary.

The study doctors and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of the research.

Printed Name of Individual Obtaining Assent: _____

Title: _____ Signature: _____ Date: ____

National Initiative for Children's Healthcare Quality

IT Developer Informed Consent Form (NICHQ)

Title of Study: ACTION – Improving Sickle Cell Transitions of Care through Health Information Technology

Research Activity: Focus Group for IT Developers

Principal Investigator: Charles Homer

Co-Investigators: Anjali Jain, Marianne McPherson, Suzette Oyeku, Elissa Faro

Consent To Participate In Research

Introduction & Study Purpose

You are being asked to participate in a research study regarding developing an electronic transition tool or app for individuals with Sickle Cell Disease to help organize medical information to improve the safety of health care transitions. The National Initiative for Children's Healthcare Quality and the Lewin Group are conducting this study. The project is sponsored by the Agency for Healthcare Research and Quality.

Please read the following information carefully. You should ask the focus group moderator to explain any sections that are unclear to you and to answer any questions that you have. You should not sign this form unless you understand what is written in this form and have had your questions answered to your satisfaction. If, after deciding to participate in this study, you find you have more questions, you should contact Charles Homer, MD, MPH, at the number given at the end of this form.

If you decide to participate in this study, please keep a copy of this consent form for your records as it contains important information, including names and telephone numbers that you may wish to have in the future.

Purpose of Study

The objective of this research is to develop an electronic transition tool or app for individuals with Sickle Cell Disease to help organize medical information to improve the safety of health care transitions. This focus group is one of three components (environmental scan, focus groups, summary report) of a larger project that has as its goal to understand whether and how a patient-centered, technology-based tool can improve the health of individuals with SCD during care transitions.

In this focus group for Information Technology Developers, we will discuss the following:

1. Identification of key functional specifications, including considerations in the development of information architecture
2. Identification of factors promoting patient/parent/physician digital interactivity

3. Identification of key factors relevant to a positive user experience and interface design
4. Criteria for selecting an appropriate software development platform and design elements that considers integration with clinical workflows
5. Criteria for selecting an appropriate software development platform and design elements that considers integration with existing HIT tools, including electronic health records, patient registries, pharmaceutical databases, and other health IT systems
6. Analysis of potential challenges relating to compatibility with existing electronic health record and other HIT systems, including Health Information Exchanges, pharmaceutical databases and claims information
7. Development of technical specifications for an SCD care transitions tool
8. Issues relating to security of a SCD care transitions too

Specific goals of this focus group include: 1) To understand how to translate the needs of tool users (patients, caregivers, providers) into tool specifications and user experience cases so that technical implementation of the actual tool is effective; and 2) To understand the questions that need to be posed to patients, parents and providers participating in focus groups in the broader study.

Procedures to be Followed

You are being asked to participate in a 4 hour focus group with 8 or 9 other health information technology developers.

Risks of Participation

We expect the risk or discomforts of participating in this study to be extremely minimal. We do not foresee any psychological, social or legal risks to your participation.

Benefits of Participation

While we do not expect you to experience any direct benefit from participation in this focus group, the knowledge and experience you impart will provide a valuable and unique contribution to the development of a technology tool to aid individuals with SCD as they experience care transitions.

Withdrawal

You may decide at any time not to participate in the study, and that this decision will not result in the loss of any benefits to which you would otherwise be entitled. You may also withdraw from a study at any time (including once it has begun) without losing any of the benefits or services to which you would otherwise be entitled.

Costs

Beyond travel costs to the NICHQ office, which we regret that we are not able to reimburse, there are no costs you will incur for participating in this study.

Stipend/Remuneration

You will receive a $50 stipend for your participation in the focus group.

Compensation for Research-Related Injury

If physical injury resulting from participation in this research should occur, although NICHQ's policy is not to provide compensation, medical treatment will be available including first aid, emergency treatment and follow-up care as needed, and your insurance carrier may be billed for the cost of such treatment. In making such medical treatment available, or providing it, the persons conducting this research project are not admitting that your injury was their fault.

Privacy and Confidentiality

As an expert in Health Information Technology, your input into the development of the tool is incredibly valuable. We may wish to share that you were a contributor to this effort via your participation in the focus group. We would like to ask your permission to note your name as a participant. However, all data we report will be in aggregate and not identified. Any identifiable data will be destroyed at the conclusion of the Action SCD project.

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

Contact Numbers

1. For answers to questions about the research or to voice concern or complaint about the research, or to report a study-related problem or injury:

   Charles J. Homer, MD, MPH (Principal Investigator)
   Chief Executive Officer, National Initiative for Children's Healthcare Quality (NICHQ)
   30 Winter Street, 6th Floor, Boston, MA 02108-4720
   617-391-2700, chomer@nichq.org

   Anjali Jain, MD
   The Lewin Group
   703-269-5537, anjali.jain@lewin.com

2. For questions, problems, concerns or complaints about the study, or for information about your rights as a research participant:

   Carolyn M. Connelly, PhD, Director, Office of Research Subject Protection,
   Harvard Medical and Dental Schools, 617 432 0651

Participant Statement

I have read this consent form. I have discussed with Dr. Homer, Dr. Jain, or their research team, the information in this consent form. I have been given the opportunity to ask questions and my questions were answered to my satisfaction.

I understand that I may refuse to participate in this study and that if I refuse to participate, this will not result in the loss of any benefits or services to which I am otherwise entitled. I agree to participate in this study. I also understand that if, for any reason, I wish to stop participating, I will be free to do so, and this will have no effect on my future care or services. I have been given a copy of this consent form for my records.

_____ _____

Date Participant

Please check one of the statements below to indicate whether or not we may note that you were an expert who participated in this project:

- *I do grant permission for the study team to use my name to indicate that I was an HIT expert who participated in focus group research.*
- *I DO NOT grant permission for the study team to use my name to indicate that I was an HIT expert who participated in focus group research.*

I have fully explained to _____ the purpose, procedures and risks that are involved in the above-described study. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator

Adolescent Assent Form (CCHMC)

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

SPONSOR STUDY NUMBER: N/A

SPONSOR NAME: Agency for Healthcare Quality and Research (AHRQ)

Maria Britto, MD
Principal Investigator Name

(513) 636-8583
Telephone Number

What is Research?

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Being in research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

Why Are We Doing This Research?

In this research study we want to learn more about how children and adolescents live with and think about sickle cell disease (SCD), your experiences moving between health care systems (for example, going from the emergency room to the inpatient unit or from a pediatric facility to adult facility), and your current use of technology things like: cell phones, computers, and tablets.

We are asking you and other children with SCD to be in the research, because:

- You are between the ages of 9.00-13.99
- You are a patient at CCHMC
- You speak and read English

What Will Happen In The Research?

You will participate in one discussion group for about two hours. At the beginning of the discussion group you will complete a brief questionnaire. You will complete the following measure:

- *Demographics form*: On this form we will ask your basic questions about yourself (e.g., gender, age, grade in school, etc.). This will take approximately 5-10 minutes to complete.

Afterwards, the leader of the group will ask you questions about your experiences with sickle cell disease and technology use. There will be 6-10 participants in the discussion group. The session will be audio taped, as well as recorded in written notes by the research staff. Your first name will not be recorded. The recording is required for the purpose of identifying each speaker. If at any time you feel uncomfortable you may ask to stop the recording. The research assistant will restart the recording when you tell us you are ready to continue.

What Are The Good Things That Can Happen From This Research?

Being in this research may not help you directly. As part of this research you may learn from other participants through the sharing of experiences during the discussion group.

The information learned from this research study may benefit other patients with sickle cell disease in the future.

What Are The Bad Things That Can Happen From This Research?

The risks for participating in this study are minimal. The two possible risks for being in this study are: (1) you may feel some worry when discussing your experiences with SCD; and (2) loss of confidentiality. If you become uncomfortable with the discussion during the group, you will be free to leave at any time during the discussion. Please let a member of the research team know if this happens. We will talk with you and get you any help you may need.

There may be other risks that we do not know about yet.

What Else Should You Know About The Research?

Being in the research is your choice. You can say Yes or No. It is OK to say No. No matter what you decide, we will still take good care of you.

If you say Yes now and change your mind later that is also OK. You can stop being in the research at any time.

If you want to stop being in the research, all you have to do is tell one of the doctors or nurses here at the hospital.

Take all the time you need to make your choice. Ask us any questions you have.

It is also okay to ask more questions after you decide to be in the research. You can ask questions at any time.

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

Child's Assent

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research.

If you want to be in this research you should sign or write your name below.

_____	_____
Child's Assent	Date
_____	_____
Signature of Person Obtaining Assent	Date

CHILDREN'S NATIONAL MEDICAL CENTER

Department of Hematology
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Adolescent Assent (Ages 12 To 17) Form (CNMC) to Participate in a Clinical Research Study Focus Group

Title of Study: Improving Sickle Cell Transitions of Care through Health Information Technology

Principal Investigator: Emily R. Meier, M.D., Division of Hematology

INTRODUCTION:

We would like to invite you to be part of a research study at Children's National Medical Center. Before you decide if you would like to participate, we want you to know why we are doing the study. We also want you to know about any risks (anything unexpected that might happen) and what you will be expected to do in the study. You can only be in the study if your parent(s) agree(s).

This form gives you information about the study. Your doctor or a research staff member will talk to you about the study and answer any questions you have. We encourage you to discuss this study with your family before making your decision. We will ask you to sign this form to show that you understand the study. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and stop being in the study any time you want and no one will mind. In some cases however, stopping the study medication early may cause harm to you. Your doctor will discuss this with you;
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

A. What Is The Reason For The Study?

You are being asked to participate in this study because you visit the Sickle Cell Disease (SCD) clinic as a patient.

We are trying to learn more about how an electronic medical tool or app can help kids with sickle cell disease (SCD) when they change doctors or are seen in different parts of the hospital [like the emergency room (ER) or outpatient clinic]. We call these changes between doctors and medical settings health care transitions. We want this app to help organize your personal medical information so that health care transitions are as safe as possible.

In this study, we are trying to understand what you know about what problems your SCD has caused (if any) in the past and how an app can help you remember and organize this information.

B. What Will Happen In The Study?

We are asking other kids with SCD, their parents and doctors and nurses to be in this study. You and some other kids around your age with SCD (no more than 9 other kids) will meet with an adult who will ask you some questions about SCD and how you use technology like cell phones or the internet. You will only meet with the group one time. The meeting will last 2 hours.

We want to make sure that we remember all of the things that you said, so with your permission we will audio record the focus group and take some notes during the meeting. During the recording, we will call you by your first name only. You may also ask us to turn off the audio recorder at any time. You can still participate in the study if you ask us not to record what you say. We will destroy the recordings at the end of the study.

You may decide to withdraw from the study at any time and for any reason. If you withdraw, no more information will be collected from you, and your prior records will be destroyed.

_____ YES, I give permission to have my study interview audio recorded as part of this research study

_____ NO, I do not give my permission to have my study interview audio recorded as part of this research study

C. What Possible Unexpected Things Could Happen?

You might feel embarrassed when you talk to other kids about your SCD. You do not have to answer any questions you are uncomfortable with and we will do everything we can to ensure you are comfortable during the group meeting.

D. What Possible Good Things Could Happen?

The things you tell us about kids remember things about their SCD might help us develop an app that will help a lot of people with SCD.

E. What Other Choices Do You Have If You Do Not Want To Be In The Study?

Your do not have to participate in this research study. You can still participate in the study if you ask us not to record your interview.

F. How Will We Keep Your Records Private?

We will keep the records of this study confidential. Only the people working on the study will know your name. They will keep this information in case we have to find you later to let you know of any new information that may affect your health.

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

Assent

By signing this form, you agree that you have talked to your doctor about the study and understand it, and want to be in the study. You also agree that you have been told about the risks (unexpected things) and benefits (good things) of the study, and about other choices. You may stop being in the study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Please call the Principal Investigator, Emily R. Meier, MD at 202-476-2800 if you have any questions.

Printed Name of Participant: _____

Medical Record Number: _____

Signature of Participant: _____

Witness (to signature): _____Date:_____
(may be investigator)

Translator's Signature (if, applicable): _____Date:_____

Language: _____

Affidavit of Person Obtaining Assent:

I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Consent: _____

___

Title: _____ Signature: _____ ___ Date: _____

Adolescent Assent Form (Nemours)

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

SPONSOR STUDY NUMBER: N/A

SPONSOR NAME: Agency for Healthcare Quality and Research (AHRQ)

Paul A. Pitel, MD ___
Principal Investigator Name

(904)-697-3789
Telephone Number

What Is Research?

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Being in research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

Why Are We Doing This Research?

In this research study we want to learn more about how children and adolescents live with and think about sickle cell disease (SCD), your experiences moving between health care systems (for example, going from the emergency room to the inpatient unit or from a pediatric facility to adult facility), and your current use of technology things like: cell phones, computers, and tablets.

We are asking you and other children with SCD to be in the research, because:

- You are between the ages of 14-17.99
- You are a patient at NCC-J
- You speak and read English

What Will Happen In The Research?

You will participate in one discussion group for about two hours. At the beginning of the discussion group you will complete a brief questionnaire. You will complete the following measure:

- *Demographics form*: On this form we will ask your basic questions about yourself (e.g., gender, age, grade in school, etc.). This will take approximately 5-10 minutes to complete.

Afterwards, the leader of the group will ask you questions about your experiences with sickle cell disease and technology use. There will be 6-10 participants in the discussion group. The session will be audio taped, as well as recorded in written notes by the research staff. Your first name will not be recorded. The recording is required for the purpose of identifying each speaker. If at any time you feel uncomfortable you may ask to stop the recording. The research assistant will restart the recording when you tell us you are ready to continue.

What Are The Good Things That Can Happen From This Research?

Being in this research may not help you directly. As part of this research you may learn from other participants through the sharing of experiences during the discussion group.

The information learned from this research study may benefit other patients with sickle cell disease in the future.

What Are The Bad Things That Can Happen From This Research?

The risks for participating in this study are minimal. The two possible risks for being in this study are: (1) you may feel some worry when discussing your experiences with SCD; and (2) loss of confidentiality. If you become uncomfortable with the discussion during the group, you will be free to leave at any time during the discussion. Please let a member of the research team know if this happens. We will talk with you and get you any help you may need.

There may be other risks that we do not know about yet.

What Else Should You Know About The Research?

Being in the research is your choice. You can say Yes or No. It is OK to say No. No matter what you decide, we will still take good care of you.

If you say Yes now and change your mind later that is also OK. You can stop being in the research at any time.

If you want to stop being in the research, all you have to do is tell one of the doctors or nurses here at the hospital.

Take all the time you need to make your choice. Ask us any questions you have.

It is also okay to ask more questions after you decide to be in the research. You can ask questions at any time.

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

Child's Assent

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research.

If you want to be in this research you should sign or write your name below.

_____	_____
Child's Assent	Date
_____	_____
Signature of Person Obtaining Assent	Date

PARENTAL PERMISSION AND ADOLESCENT ASSENT FORM (CCHMC) FOR PARTICIPATION IN A RESEARCH STUDY PATIENT FOCUS GROUP

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

STUDY NUMBER: N/A

FUNDING ORGANIZATION: Agency for Healthcare Research and Quality (AHRQ)

Maria Britto, MD

Name of Principal Investigator

(513) 636-9910

Telephone Number

Introduction

We are asking for your permission for your child to be in a research study so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow your child to be in the study. You can ask questions at any time.

Why Are We Doing This Research?

In this research study we will use focus groups to help us understand how young adolescents think about and live with sickle cell disease (SCD), define experiences around care transitions (e.g., being admitted to a hospital and then taking care of your sickle cell at home, or switching

from seeing a doctor for kids to a doctor for adults), and how they currently use technology and understand how they think technology could help with health care transitions.

We are asking your child and other children with sickle cell disease to be in the research, because:

- Your child has sickle cell disease (SCD)
- Is between the ages of 9.00-13.99
- Is a patient at CCHMC
- Speaks/reads English

Who Is In Charge Of The Research?

Maria Britto is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

CCHMC is being paid by The Lewin Group through funds awarded by AHRQ to do this study.

Who Should Not Be In The Study?

Your child cannot be in this study if he/she has any of the following:

- Is younger than 9 or older than 13
- Has significant health complications that would interfere with completion of the focus group
- Has significant cognitive or developmental disabilities (by parent or physician report)
- Is not a patient at CCHMC
- Does not speak/read English

What Will Happen In The Study?

If you agree to allow your child to participate and he/she qualifies for this study, your child will complete a brief questionnaire at the beginning of the focus group. Your child will complete the following measure:

- *Demographics form*: On this form we will ask your child basic demographic questions (e.g., gender, age, grade in school, etc.). This will take approximately 5-10 minutes to complete.

Afterwards, the focus group moderator will ask your child questions about his/her experiences with sickle cell disease and technology use. There will be 6-10 participants in the focus group. The session will be audiotaped, as well as recorded in written notes by the research staff. Your child's first name will not be recorded. The recording is required to participate for the purposes of identifying each speaker. If at any time your child feels uncomfortable he/she may ask to stop the recording. The research assistant will restart the recording when your child indicates he/she is

ready to continue.

What Are The Good Things That Can Happen From This Research?

Being in this research may not help your child directly. As part of this research your child may learn from other participants through the sharing of experiences and insights during the focus group.

The information learned from this research study may benefit other patients with sickle cell disease in the future.

What Are The Bad Things That Can Happen From This Research?

The risks for participating in this study are minimal. The two possible risks for being in this study are: (1) your child may feel some discomfort when discussing his/her experiences with SCD; and (2) loss of confidentiality. If your child becomes uncomfortable with the discussion during the focus group, he/she will be free to leave at any time during the discussion.

There may be other risks that we do not know about yet.

What Other Choices Are There?

Instead of being in this study, you can choose not to have your child be in it. Even if your child does not participate in this study, he/she will continue to receive routine care.

How Will Information About Your Child Be Kept Private?

Making sure that information about your child remains private is important to us. To protect your child's privacy in this research study we will take the following precautionary measures to protect the privacy and confidentiality of his/her research and/or medical records:

- All participants will be asked to keep all comments made in the group confidential
- The audiotapes from the focus group will be stored in computer data files that are password-protected, and it will not contain any information that can personally identify you or your child.
- Your child will be assigned an anonymous study code number and this will be used in the group transcript (written document of everything said in the group)

Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

What If We Learn New Information During The Research?

The study doctor will tell you about new information from this or other studies that may affect

your child's health, welfare, or willingness to stay in this study.

Will It Cost You Anything Extra For Your Child To Be In The Research Study?

There are no costs for participating in this research study. You will be responsible for the usual costs of your medical care, but you will not be charged any additional costs for participation in this study.

Will You/Your Child Be Paid To Be In This Research Study?

Your child will be reimbursed for your time, effort and travel while you are in this research study.

At the end of the focus group, your child will be paid $50 cash as reimbursement for his/her time and effort.

Who Do You Call If You Have Questions Or Problems?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

Authorization For Use/Disclosure Of Health Information For Research

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

What Protected Health Information Will Be Used And Shared During This Study?

CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's CCHMC medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who Will Share, Receive And/Or Use Your Child's Protected Health Information In This Study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your child's PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?

By signing this document you agree for child to participate in this research study and give permission to CCHMC to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment <u>not</u> related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

Signatures

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____

Printed Name of Research Participant

_____ _____

Signature of Research Participant Indicating Consent Date

_____ _____

Signature of Legally Authorized Representative* Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____

Signature of Individual Obtaining Consent Date

Parental Permission and Adolescent Assent Form (Nemours) for Participation in a Research Study Focus Group

STUDY TITLE: Improving Sickle Cell Transitions of Care through Health Information Technology: Phase 1

STUDY NUMBER: N/A

FUNDING ORGANIZATION: Agency for Healthcare Research and Quality (AHRQ)

Paul A. Pitel, MD

Name of Principal Investigator

(904) 697-3789

Telephone Number

Introduction

We are asking for your permission for your child to be in a research study so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow your child to be in the study. You can ask questions at any time.

Why Are We Doing This Research?

In this research study we will use focus groups to help us understand how young adolescents think about and live with sickle cell disease (SCD), define experiences around care transitions (e.g., being admitted to a hospital and then taking care of your sickle cell at home, or switching from seeing a doctor for kids to a doctor for adults), and how they currently use technology and understand how they think technology could help with health care transitions.

We are asking your child and other children with sickle cell disease to be in the research, because:

- Your child has sickle cell disease (SCD)
- Is between the ages of 14.00-17.99
- Is a patient at NCC-J
- Speaks/reads English

Who Is In Charge Of The Research?

Dr. Pitel is the researcher at Nemours Children's Clinic – Jacksonville (NCC-J) that is in charge of this study.

NCC-J is being paid by The Lewin Group through funds awarded by AHRQ to do this study.

Who Should Not Be In The Study?

Your child cannot be in this study if he/she has any of the following:

- Is younger than 14 or older than 17
- Has significant health complications that would interfere with completion of the focus group
- Has significant cognitive or developmental disabilities (by parent or physician report)
- Is not a patient at NCC-J
- Does not speak/read English

What Will Happen In The Study?

If you agree to allow your child to participate and he/she qualifies for this study, your child will complete a brief questionnaire at the beginning of the focus group. Your child will complete the following measure:

Demographics form: On this form we will ask your child basic demographic questions (e.g., gender, age, grade in school, etc.). This will take approximately 5-10 minutes to complete.

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The information learned from this research study may benefit other patients with sickle cell disease in the future.

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What protected health information will be used and shared during this study?

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- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the NCC-J Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

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Signature of Legally Authorized Representative* Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided

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Signature of Individual Obtaining Consent Date