Title: Peer Mentoring to Improve Self-Management in Youth with IBD

NCT Number: NCT03827109

Included consent forms:

- Mentoring/Educational Activity Programs
  -Document date: 4/26/2019
- Mentors<18 Years, Mentoring Program Phase
  -Document Date: 4/26/2019
- Mentors <18 Years, Application Phase
  -Document Date: 4/26/2019
- Mentors>18 Years
  -Document Date: 4/26/2019

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
Mentoring/Educational Activity Programs

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

PRINCIPAL INVESTIGATOR: Laura Mackner, PhD

CONTACT TELEPHONE NUMBER: 614-722-4744

STUDY SPONSOR: National Institutes of Health (NIH)

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study
The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to is to find out if a mentoring program helps youth live well with IBD.

Study participation:
Separately, parents and children will complete a set of questionnaires. Children will provide a stool sample for information about disease severity. Next, you will be put into the Mentoring Program or an IBD Educational Activity Program.

- The Educational Activity Program is 3 group educational activities over 1 year.
- The Mentoring Program is 3 group educational activities, 3 group recreational activities, a parent group, and a 1:1 mentor over 1 year.

After completing the program, you will complete questionnaires and provide a stool sample again. Then 6 months later, you will complete a brief, online survey.

Study visits:
The study visits before and after the programs will last 1 – 1.5 hours, and the online survey will last about 20 minutes. See a more detailed discussion later in this form.

The main risks of the study are loss of confidentiality (privacy), since participants will be engaging in group activities with other participants and potentially sharing personal information. In the Mentoring Program, there is a risk of emotional or physical harm for mentees. Other risks are listed later in this form.

The benefit(s) of the study are:
You might learn new things about IBD and how to manage it, and you might meet other supportive

1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree to be in this study. If you do not want to be in this study, all regular and standard medical care will still be available to you at Nationwide Children's Hospital or at another institution. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent and the assent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

IBD affects life in many ways. This study is to find out if a mentoring program helps youth live well with IBD.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at several sites, including Nationwide Children's Hospital. Overall, we hope to enroll 100 mentors, 100 mentees, and 100 children in a comparison group.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

Visit 1: Separately, parents and children will be asked to complete a set of questionnaires with a research assistant at Nationwide Children's Hospital or in their home at a time that is convenient for them. The questionnaires will take 1 – 1.5 hours to complete. The questionnaires will ask about behaviors, feelings, typical life activities, coping, and how IBD affects your life. You will also provide a stool sample for information about disease severity. We will send you a collection kit in the mail before the visit.

Randomization: Next, you will be put into the mentoring program or the educational activity program. This study is randomized. Randomized means that each person will be picked by chance, like tossing a coin or drawing straws, to participate in the mentoring program or the education activity program. Each subject has a 50/50 (e.g., 1 in 2) chance of participating in the mentoring program and a 50/50 chance of participating in the education activity program. This lets us compare the subjects in the mentoring program to those who are not, to see if it is helpful.

Educational Activity Program:

(1) 3 educational group activities.

- IBD Nutrition
- Taking IBD to School
- Behind the Scenes at the GI Center

(2) A private website with information about living well with IBD. Information from the group activities will be posted here too. You will also be able to post questions that will be answered by project staff.

(3) Monthly "check-in" phone call from the program coordinator. We will call you once a month to encourage you to "live well with IBD" by doing something fun with a friend.

Mentoring Program: The mentoring program includes the educational activities plus:

(1) A one-on-one relationship between a mentee and mentor.
Mentors will be at least 16 years old, have had IBD for at least one year, and will be extensively screened and trained. They will be matched to mentees based on gender, age, ethnicity, where they live, and interests if possible. Mentors will check in with mentees every week (e.g., texting, phone call) and will have 6 in-person visits.

(2) 3 fun activities
Children and mentors nominate and vote on the activities to participate in. Previous activities include bowling, putt-putt golf, canoeing, laser tag, and ice skating.

(3) A separate parent group.
The parent group will occur during the youth group activities. The parent group will engage in formal self-management education during the mentor/mentee group activities and informal support. A separate, monitored online community will also be available for the parents for additional support.

(4) The monthly "check-in" phone call for the mentoring group will focus on satisfaction and any concerns with the mentoring relationship and the mentoring program.

Visit 2: This is the same as Visit 1, and it will occur after your child has completed the program. We will also ask your permission to get attendance information from your school. The school will not be told what the study is about. A stool sample will be collected from you at this visit as well.

Visit 3: 6 months after completing the program, we will send you a brief, online survey about the effect of IBD on your life and how you manage it. This will take about 20 minutes.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

There is also a risk of loss of confidentiality (privacy), since participants will be engaging in group activities with other participants, sharing information with mentors and potentially sharing information through social media. Other people attending the group activities will know that you have IBD, and social media may not be private. Confidentiality will be emphasized in mentor training and supervision, and during the mentee orientation. We will also remind everyone about confidentiality at each group activity.

There is a risk that the web-based components of the study could be "hacked." This risk is low due to all of the security precautions used by NCH.

There may be other risks of being in this research study that are not known at this time.

Mentoring Program
There is a risk of emotional or physical harm for mentees in the mentoring program. Big Brothers Big Sisters (BBBS) states they get reports about this happening for less than 1% of children in their program per year.

We have worked with BBBS and are taking every precaution to minimize this risk. We are following their recommendations and expanding them in several ways. We rigorously screen mentors with a written application based on the one used by BBBS, background checks, an interview, and references. Mentors are extensively trained with BBBS and other mentoring training materials. Mentors are closely supervised, and all group activities are supervised by project staff. Finally, mentees and parents are contacted monthly to identify any concerns, and they may contact project staff at any time. The amount of supervision we are requiring for mentors in this program is more than BBBS requires in its programs.

If participants feel uncomfortable at any time, they can call the mentoring program Urgent Response number, 614-722-4745, and/or leave the activity.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

You might learn new things about IBD and how to manage it, and you might meet other supportive people. Also, we might learn something that could help others.

7) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE?

Your participation is this study is voluntary. It is not necessary to be in this study to get care for this condition. Other treatments such as usual IBD care and psychotherapy are available. If you decide not to be in this study, the Principal Investigator will talk to you about other treatments or refer you to your regular doctor for care.

8) WHAT ARE THE COSTS AND REIMBURSEMENTS?

For your time and inconvenience, you will receive $50 at the end of Study Visits 1 and 2, and you will receive $25 after you complete Study Visit 3—up to a total of $125. You will be issued a debit card specially designed for clinical research. When a study visit is completed, funds will be approved and automatically loaded onto your card.

If you receive $600 or more in a calendar year from participating in research studies, you will be issued a 1099 IRS Form to file with your income taxes.

All costs related to the research parts of this study will be covered by the research team. There will be addition costs related to participating in the mentoring program. You will be responsible for costs of activities you participate in with your mentor. We have some funds to help pay costs for the group activities, and we will provide lists of free and inexpensive activity ideas. However, if you participate in the mentoring program, you may incur some cost.

9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

If you/your child is hurt by the procedures that are part of the Study, you should seek medical treatment for the injuries and call the study team as soon as possible at the number on the first page of this form. If it is an emergency, call 911 or go to the nearest emergency department.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

10) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, call the study team at the number on page 1 of this form. If you stop being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study team will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected problems come up, the Principal Investigator or the Sponsor, (NIH), may decide to stop your participation in the study.

11) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is being paid by NIH for the time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

Some people have asked us to text them study-related reminders rather than calling them. Information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages. Would you like us to text you or to call you?

Initial:

____ I authorize study staff to contact me via text message. I understand that information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages.

____ I do not authorize study staff to contact me via text message. I prefer to be called.

12) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and disclose your PHI for this research study and for future research purposes (including purposes that are currently unknown) unless otherwise allowed by applicable laws. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to mood and behavior.

PHI that may be used or disclosed: Names; Address; Telephone Numbers; Birth Date; E-mail Addresses/URLs; Medical Record Numbers.

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:
PI and study staff
The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
Nationwide Children's Hospital internal auditors
The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: For mentoring program matching, supervision and other communication; to ensure appropriate and complete data collection

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at 700 Children's Drive, Columbus, Ohio 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your entire medical records.

The results from this study may be published but your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

Future Research Use:

With your permission, we would like to store your PHI for future research purposes, and as part of such future research purposes, your PHI may be disclosed to people or entities not listed above, such as

researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research. This future research may or may not be related to your medical problem. This future research may include sensitive information. Any future research projects will be reviewed and approved by an Institutional Review Board which protects the rights, welfare, and safety of human research subjects. If your PHI is used or disclosed in future research studies, absolute confidentiality cannot be guaranteed. Information shared for future research may be shared further with others and no longer be protected by federal privacy rules.

If you decide at any time that you do not want your PHI stored for future research, you must make this request in writing to the Principal Investigator at 700 Children's Drive, Columbus OH 43205. Once we receive your written request, we will destroy your PHI. However, if we have already shared your PHI with another individual or entity, we will not be able to destroy any of the PHI that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage and destroy the PHI at any time without sending notice to you or obtaining your consent.

You do not have to agree to use of your PHI for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my PHI to be stored and used for future research as described above: (initial)

____ YES ____ NO

13) FUTURE USE OF SAMPLES

Your study samples collected as part of this study, even if the identifiers are removed, will not be used or distributed for future research purposes.

With your permission, we would like to store unused stool samples and information related to such samples (diagnosis, age at diagnosis, etc.) for research that may be performed in the future. Any unused samples will be stored for an indefinite amount of time. Information related to the samples may or may not include personal identifiers, such as your name, address, etc. There could be widespread sharing of these samples and associated information, but an Institutional Review Board, which protects the rights, welfare, and safety of human research subjects, will review and approve each new project.

Use of your samples for future research may help researchers learn more about how to prevent, find, and treat various diseases and conditions, even diseases and conditions that are different from yours. Genetic material (such as DNA and RNA) may be removed from the stored samples and used for genetic testing.

Some of your specimens and genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

Using your samples for future research will probably not help you. You will not be told the results of any future research. Your doctor will also not be told the results of any future research.

Your samples and information will be used only for research and will not be sold. There is a possibility that future research may lead to development of products that will be sold to the public. If this happens, there is no plan to share any financial gain with you.

The results from this future research may be published but your identity will not be revealed.

If you decide at any time that you do not want your samples or related information stored for future research, you must make this request in writing to the Principal Investigator at 700 Children's Drive, Columbus, OH 43203. Once we receive your written request, we will destroy your samples and related information. However, once your samples and related information have been de-identified, we will not be able to destroy them because we will not be able to link your samples or information back to you. Also, if we have already shared your samples or information with another individual or entity, we will not be able to destroy any of the samples or information that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage of the samples or related information at any time and destroy the samples or information without sending notice to you or obtaining your consent.

You do not have to agree to use of your samples or related information for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my samples and related information to be stored and used for future research as described above: (initial your choice)

___ YES _____ NO

NOTE: If identifiers are removed from your samples that are collected during this research, those samples could be used for future research studies or distributed to other investigators for future research studies without your additional informed consent.

14) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, or complaints about anything while on this study or you have been injured by the research, you have 24 hour access to talk to study staff via the Urgent Response Line at 614-722-4745. You can contact Dr. Laura Mackner at 614-722-4700 Monday – Friday between 9:00am – 5:00pm.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else - please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

Your signature documents your permission for the named child to take part in this research.

_____
Printed name of child

_____ _____
Signature of parent or individual legally authorized to consent *Date & Time* *AM/PM*

_____
Printed name of parent or individual legally authorized to consent

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact Legal Services if any questions arise.

If signature of second parent not obtained, indicate why: (select one)

- ✓ **Not required by IRB**
- ❑ **Second parent is deceased**
- ❑ **Second parent is unknown**
- ❑ **Second parent is incompetent**
- ❑ **Second parent is not reasonably available**
- ❑ **Only one parent has legal responsibility for the care and custody of the child**

_____ _____
Signature of person obtaining consent *Date & Time* *AM/PM*

_____
Printed name of person obtaining consent

Assent

_____ _____
Signature of subject *Date & Time* *AM/PM*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____
Signature of witness to consent process *Date & Time* *AM/PM*

_____
Printed name of person witnessing consent process

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
Mentors <18 years, Mentoring Program Phase

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

PRINCIPAL INVESTIGATOR: Laura Mackner, PhD

CONTACT TELEPHONE NUMBER: 614-722-4744

STUDY SPONSOR: National Institutes of Health (NIH)

SUBJECT'S NAME: _____ **DATE OF BIRTH:** _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study
The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to is to find out if a mentoring program helps youth live well with IBD.

Study participation:
You will participate in the mentoring program as a mentor for one year, and you will complete questionnaires to evaluate it. You will have a 1:1 relationship with a mentee, which will include weekly contact (e.g., phone, text, videochat) and in person contact 1 – 2 times per month. There are also group activities for mentors and mentees, and you will check in with the Program Coordinator on a regular basis.

Study visits:
You will complete 3 online questionnaires to see if the mentoring program is helpful 12 months after you meet your mentee. The questionnaires will take about 15 minutes to complete. See a more detailed discussion later in this form.

The main risk of the study is loss of confidentiality (privacy), since participants will be engaging in group activities with other participants and potentially sharing personal information. Other risks are listed later in this form.

The benefit(s) of the study are: You might learn new things about IBD and how to manage it, and you might meet other supportive people. You might help someone else learn how to better manage the impact of IBD.

If you are interested in learning more about this study, please continue reading below.

1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree to be in

this study. If you do not want to be in this study, all regular and standard medical care will still be available to you at Nationwide Children's Hospital or at another institution. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent form and assent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

IBD affects life in many ways. This study is to find out if a mentoring program helps youth live well with IBD.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at several sites, including Nationwide Children's Hospital. Overall, we hope to enroll 100 mentors, 100 mentees, and 100 children in a comparison group.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

You will participate in the mentoring program as a mentor for one year, and you will complete questionnaires to evaluate it.

Mentoring Program: The mentoring program has 4 parts:

(1) A one-on-one relationship between a mentee and mentor.
Mentors will be at least 16 years old, have IBD for at least one year, and will be extensively screened and trained. They will be matched to mentees based on gender, age, ethnicity, where they live, and interests if possible. Mentors and mentees are expected to have weekly contact (e.g., phone, text, videochat), and to meet in person 1 – 2 times per month for 1 year.

(2) Group activities that occur every other month.
Some group activities are educational activities and others are solely "fun" activities.

(3) A private program website.
This website has educational materials. You will be given log-in information for it. Private, secure messages can be sent to program staff if you have questions about the information.

(4) A separate parent group.
The parent group will meet during the mentor/mentee group activities for education and support.

Mentor Orientation and Supervision: You will complete our 3.5 hour mentor orientation before being matched with a mentee, and you will participate in regular "check-in" phone calls with program staff to talk about your experiences with your mentee. You will participate in weekly phone check-ins for the first month, then twice monthly check-ins. We think that each phone call will last 10-15 minutes. Mentors can always contact program staff for help or advice at any time.

Questionnaires: You will complete 3 online questionnaires to see if the mentoring program is helpful 12 months after you meet your mentee. The questionnaires will ask about your satisfaction with the program, the effect of your IBD on your life and how you manage it. The questionnaires will take about 15 minutes to complete.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

There is also a risk of loss of confidentiality (privacy), since participants will be engaging in group activities with other participants, sharing information with mentors and potentially sharing information through social media. Other people attending the group activities will know that you have IBD, and social media may not be private. Confidentiality will be emphasized in mentor training and supervision, and during the mentee orientation. We will also remind everyone about confidentiality at each group activity.

If participants feel uncomfortable at any time, they can call the mentoring program Urgent Response number, 614-722-4745, and/or leave the activity.

There is a risk that the web-based components of the study could be "hacked." This risk is low due to all of the security precautions used by NCH.

There may be other risks of being in this research study that are not known at this time.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

You might learn new things about IBD and how to manage it, and you might meet other supportive people. You might help someone else learn how to better manage the impact of IBD. Also, we might learn something that could help others.

7) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE?

Your participation is this study is voluntary. It is not necessary to be in this study to get care for this condition. If you would like to be a mentor but are not interested in this study, you can apply to be a mentor with other organizations.

8) WHAT ARE THE COSTS AND REIMBURSEMENTS?

For your time and inconvenience, you will receive $20 after you complete the online questionnaires.

If you receive more than $600 compensation from research in a calendar year, you will be issued a 1099 tax form to file with your income taxes.

All costs related to the research parts of this study will be covered by the research team. There will be addition costs related to participating in the mentoring program. You will be responsible for costs of activities you participate in with your mentee. We have some funds to help pay costs for the group activities, and we will provide lists of free and inexpensive activity ideas. However, if you participate in the mentoring program, you may incur some cost.

9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

If you or your child are hurt by the procedures that are part of the Study, you should seek medical treatment for the injuries and tell the Study Doctor as soon as possible at the number on the first page of this form. If it is an emergency, call 911 or go to the nearest emergency department.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

10) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, call the study team at the number on page 1 of this form. If you stop being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study team will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected problems come up, the Principal Investigator or the Sponsor, (NIH), may decide to stop your participation in the study. Please see the Crohn's and Colitis Connect Mentoring Program Procedures Manual for procedures for stopping your participation in the study.

11) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is being paid by NIH for the time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

Some people have asked us to text them study-related reminders rather than calling them. Information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages. Would you like us to text you or to call you?

Initial:

____ I authorize study staff to contact me via text message. I understand that information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages.

____ I do not authorize study staff to contact me via text message. I prefer to be called.

12) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and disclose your PHI for this research study. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to mood and behavior.

PHI that may be used or disclosed: Names; Address; Telephone Numbers; Birth Date; E-mail Addresses/URLs; Medical Record Numbers.

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:
PI and study staff
The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
Nationwide Children's Hospital internal auditors
The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: For mentoring program matching, supervision and other communication; to ensure appropriate and complete data collection

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at 700 Children's Drive, Columbus, Ohio 43205. If you

withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your entire medical records.

The results from this study may be published but your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

Future Research Use:

With your permission, we would like to store your PHI for future research purposes, and as part of such future research purposes, your PHI may be disclosed to people or entities not listed above, such as researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research. This future research may or may not be related to your medical problem. This future research may include sensitive information. Any future research projects will be reviewed and approved by an Institutional Review Board which protects the rights, welfare, and safety of human research subjects. If your PHI is used or disclosed in future research studies, absolute confidentiality cannot be guaranteed. Information shared for future research may be shared further with others and no longer be protected by federal privacy rules.

If you decide at any time that you do not want your PHI stored for future research, you must make this request in writing to the Principal Investigator at 700 Children's Drive, Columbus OH 43205. Once we receive your written request, we will destroy your PHI. However, if we have already shared your PHI with another individual or entity, we will not be able to destroy any of the PHI that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage and destroy the PHI at any time without sending notice to you or obtaining your consent.

You do not have to agree to use of your PHI for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my PHI to be stored and used for future research as described above: (initial)

____ YES ____ NO

12) <u>WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?</u>

If you have questions, concerns, or complaints about anything while on this study or you have been injured by the research, you have 24 hour access to talk to study staff via the Urgent Response Line at 614-722-4745. You can contact Dr. Laura Mackner at 614-722-4700 Monday – Friday between 9:00am – 5:00pm.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else - please call (614) 722-2708, Nationwide Children's Hospital Institutional Review

Board, (IRB, the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

Your signature documents your permission for the named child to take part in this research.

_____

Printed name of child

_____ _____

Signature of parent or individual legally authorized to consent *Date & Time* *AM/PM*

_____

Printed name of parent or individual legally authorized to consent

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact Legal Services if any questions arise.

If signature of second parent not obtained, indicate why: (select one)

- ✓ **Not required by IRB**
- ❑ **Second parent is deceased**
- ❑ **Second parent is unknown**
- ❑ **Second parent is incompetent**
- ❑ **Second parent is not reasonably available**
- ❑ **Only one parent has legal responsibility for the care and custody of the child**

_____ _____

Signature of person obtaining consent *Date & Time* *AM/PM*

_____

Printed name of person obtaining consent

Assent

_____ _____

Signature of subject *Date & Time* *AM/PM*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____

Signature of witness to consent process *Date & Time* *AM/PM*

_____

Printed name of person witnessing consent process

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
Mentors <18 years, Application Phase

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

PRINCIPAL INVESTIGATOR: Laura Mackner, PhD

CONTACT TELEPHONE NUMBER: 614-722-4744

STUDY SPONSOR: National Institutes of Health (NIH)

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study

The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to is to find out if a mentoring program helps youth live well with IBD. We invite you to apply to be a mentor in this study.

Study participation:
For mentors, there are two parts of the study, the application phase and the mentoring phase. This is the application phase. You will complete an online application and 3 questionnaires. You will also give us 3 references, and you'll participate in an interview. Completing the application and questionnaires will take about 30 minutes, and the interview will be 30 minutes. Next, you'll complete our 3.5 hour orientation about the program. If you pass the screening, then you will be invited to participate in the mentoring program as a mentor.
See a more detailed discussion later in this form.

The main risks of this part of the study are: You could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions a little boring.

The benefit(s) of the study are: For this application phase of the study, we might learn something that

If you are interested in learning more about this study, please continue reading below.

1) INTRODUCTION

We invite you to apply to be a mentor in this study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree

to be in this study. If you do not want to be in this study, all regular and standard medical care will still be available to you here or at another institution. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

IBD affects life in many ways. This study is to find out if a mentoring program helps youth live well with IBD.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at several sites, including Nationwide Children's Hospital. Overall, we hope to enroll 100 mentors, 100 mentees, and 100 children in a comparison group.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

For mentors, there are two parts of the study, the application phase and the mentoring phase. This is the application phase.

If you agree to be in the study, we will give you a website address where you will complete an online application and 3 questionnaires about the impact IBD has on your life. You will also give us 3 references for us to talk to, and you'll participate in an interview. Completing the application and questionnaires will take about 30 minutes, and the interview will be 30 minutes.

Next, you'll complete our 3.5 hour orientation about the program. If you pass the screening, then you will be invited to participate in the mentoring program as a mentor. You will sign another consent form if you agree to be a mentor

Mentoring Phase (second phase)

Mentoring Program: The Mentoring Program has 4 parts:

1. A one-on-one relationship between a mentee and mentor.
   Mentors will be at least 16 years old, have IBD for at least one year, and will be extensively screened and trained. They will be matched to mentees based on gender, age, ethnicity, where they live, and interests if possible. Mentors and mentees are expected to have weekly contact (e.g., phone, text, videochat), and to meet in person 1 – 2 times per month for 1 year.

2. Group activities that occur every month.
   Some group activities are educational activities and others are solely "fun" activities.

3. A private program website.
   This website has educational materials and activity ideas for in-person get-togethers. You will be given log-in information for it. Private, secure messages can be sent to program staff if you have questions about the information.

4. A separate parent group.
   The parent group will meet during the mentor/mentee group activities for education and support.

Mentor Orientation and Supervision: You will complete our 3.5 hour mentor orientation before being matched with a mentee, and you will participate in regular "check-in phone calls with program staff to talk about your experiences with your mentee. You will participate in twice monthly phone check-ins for the first 2 months, then monthly. We think that each phone call will last 10-15 minutes. Mentors can always contact program staff for help or advice at any time.

Questionnaires: You will complete questionnaires to see if the mentoring program is helpful 12 months after you meet your mentee. The questionnaires will ask about your satisfaction with the program and the effect of your IBD on your life and how you manage it. The questionnaires will take about 15 minutes to complete.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

For this application phase of the study, we might learn something that could help others.

7) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE?

Your participation is this study is voluntary. It is not necessary to be in this study to get care for this condition. If you would like to be a mentor but are not interested in this study, you can apply to be a mentor with other organizations.

8) WHAT ARE THE COSTS AND REIMBURSEMENTS?

There are no costs or reimbursements associated with this application phase of the study.

9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

If you or your child are hurt by the procedures that are part of the Study, you should seek medical treatment for the injuries and tell the Study Doctor as soon as possible at the number on the first page of this form. If it is an emergency, call 911 or go to the nearest emergency department.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

10) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, call the study team at the number on page 1 of this form. If you stop being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled. You can participate in this application phase and then say no to the mentoring phase.

If at any time the Principal Investigator believes that this study is not good for you, the study team will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected problems come up, the Principal Investigator or the Sponsor, (NIH), may decide to stop your participation in the study.

11) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is being paid by NIH for the time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

Some people have asked us to text them study-related reminders rather than calling them. Information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages. Would you like us to text you or to call you?

Initial:

____ I authorize study staff to contact me via text message. I understand that information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages.

____ I do not authorize study staff to contact me via text message. I prefer to be called.

12) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and disclose your PHI for this research study. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to mood and behavior.

PHI that may be used or disclosed: Names; Address; Telephone Numbers; Birth Date; E-mail Addresses/URLs; Medical Record Numbers.

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

PI and study staff
The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
Nationwide Children's Hospital internal auditors
The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: For mentoring program matching, supervision and other communication; to ensure appropriate and complete data collection

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at 700 Children's Drive, Columbus, Ohio 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your entire medical records.

The results from this study may be published but your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

13) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, or complaints about anything while on this study or you have been injured by the research, you have 24 hour access to talk to one of the investigators at 614-722-4744.

If you have questions, concerns, or complaints about the research, questions about your rights as a research volunteer, cannot reach the Principal Investigator, or if you want to call someone else, please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, the committee that reviews all research in humans at Nationwide Children's Hospital).

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

Your signature documents your permission for the named child to take part in this research.

_____
Printed name of child

_____ _____
Signature of parent or individual legally authorized to consent *Date & Time* *AM/PM*

_____
Printed name of parent or individual legally authorized to consent

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact Legal Services if any questions arise.

If signature of second parent not obtained, indicate why: (select one)

- ✓ **Not required by IRB**
- ❑ **Second parent is deceased**
- ❑ **Second parent is unknown**
- ❑ **Second parent is incompetent**
- ❑ **Second parent is not reasonably available**
- ❑ **Only one parent has legal responsibility for the care and custody of the child**

_____ _____
Signature of person obtaining consent *Date & Time* *AM/PM*

_____
Printed name of person obtaining consent

Assent

_____ _____
Signature of subject *Date & Time* *AM/PM*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____
Signature of witness to consent process *Date & Time* *AM/PM*

_____
Printed name of person witnessing consent process

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
Mentors ≥ 18 years

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

PRINCIPAL INVESTIGATOR: Laura Mackner, PhD

CONTACT TELEPHONE NUMBER: 614-722-4744

STUDY SPONSOR: National Institutes of Health (NIH)

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study

The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to see if a mentoring program helps youth live well with IBD.

Study participation:
You will participate in the mentoring program as a mentor for one year, and you will complete questionnaires to evaluate it. You will have a 1:1 relationship with a mentee, which will include weekly contact (e.g., phone, text, videochat) and in person contact 1 – 2 times per month. There are also group activities for mentors and mentees, and you will check in with the Program Coordinator on a regular basis.

Study visits:
You will complete 3 online questionnaires to see if the mentoring program is helpful 12 months after you meet your mentee. The questionnaires will take about 15 minutes to complete. See a more detailed discussion later in this form.

The main risk of the study is loss of confidentiality (privacy), since participants will be engaging in group activities with other participants and potentially sharing personal information. Other risks are listed later in this form.

The benefit(s) of the study are: You might learn new things about IBD and how to manage it, and you might meet other supportive people. You might help someone else learn how to better manage the impact of IBD.

If you are interested in learning more about this study, please continue reading below.

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree to be in this study. If you do not want to be in this study, all regular and standard medical care will still be available to you at Nationwide Children's Hospital or at another institution. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent form.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

IBD affects life in many ways. This study is to find out if a mentoring program helps youth live well with IBD.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at several sites, including Nationwide Children's Hospital. Overall, we hope to enroll 100 mentors, 100 mentees, and 100 children in a comparison group.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

You will participate in the mentoring program as a mentor for one year, and you will complete questionnaires to evaluate it.

Mentoring Program: The mentoring program has 4 parts:

(1) A one-on-one relationship between a mentee and mentor.
Mentors will be at least 16 years old, have IBD for at least one year, and will be extensively screened and trained. They will be matched to mentees based on gender, age, ethnicity, where they live, and interests if possible. Mentors and mentees are expected to have weekly contact (e.g., phone, text, videochat), and to meet in person 1 – 2 times per month for 1 year.

(2) Group activities that occur every other month.
Some group activities are educational activities and others are solely "fun" activities.

(3) A private program website.
This website has educational materials and activity ideas for in-person get-togethers. You will be given log-in information for it. Private, secure messages can be sent to program staff if you have questions about the information.

(4) A separate parent group.
The parent group will meet during the mentor/mentee group activities for education and support.

Mentor Orientation and Supervision: You will complete our 3.5 hour mentor orientation before being matched with a mentee, and you will participate in regular "check-in" phone calls with program staff to

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

talk about your experiences with your mentee. You will participate in weekly phone check-ins for the first month, then twice monthly check-ins. We think that each phone call will last 10-15 minutes. Mentors can always contact program staff for help or advice at any time.

Questionnaires: You will complete 3 online questionnaires to see if the mentoring program is helpful 12 months after you meet your mentee. The questionnaires will ask about your satisfaction with the program, the effect of your IBD on your life and how you manage it. The questionnaires will take about 15 minutes to complete.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

There is also a risk of loss of confidentiality (privacy), since participants will be engaging in group activities with other participants, sharing information with mentors and potentially sharing information through social media. Other people attending the group activities will know that you have IBD, and social media may not be private. Confidentiality will be emphasized in mentor training and supervision, and during the mentee orientation. We will also remind everyone about confidentiality at each group activity.

If participants feel uncomfortable at any time, they can call the mentoring program Urgent Response number, 614-722-4745, and/or leave the activity.

There is a risk that the web-based components of the study could be "hacked." This risk is low due to all of the security precautions used by NCH.

There may be other risks of being in this research study that are not known at this time.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

You might learn new things about IBD and how to manage it, and you might meet other supportive people. You might help someone else learn how to better manage the impact of IBD. Also, we might learn something that could help others.

7) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE?

Your participation is this study is voluntary. It is not necessary to be in this study to get care for this condition. If you would like to be a mentor but are not interested in this study, you can apply to be a mentor with other organizations.

8) WHAT ARE THE COSTS AND REIMBURSEMENTS?

For your time and inconvenience, you will receive $50 at the end of Study Visits 1 and 2, and you will receive $25 after you complete Study Visit 3—up to a total of $125. You will be issued a debit card

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

specially designed for clinical research. When a study visit is completed, funds will be approved and automatically loaded onto your card.

If you receive $600 or more in a calendar year from participating in research studies, you will be issued a 1099 IRS Form to file with your income taxes.

All costs related to the research parts of this study will be covered by the research team. There will be addition costs related to participating in the mentoring program. You will be responsible for costs of activities you participate in with your mentee. We have some funds to help pay costs for the group activities, and we will provide lists of free and inexpensive activity ideas. However, if you participate in the mentoring program, you may incur some cost.

9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

If you are hurt by the procedures that are part of the study, you should seek medical treatment for the injuries and call the study team as soon as possible at the number on page 1 of this form. If it is an emergency, call 911 or go to the nearest emergency department.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

10) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, call the study team at the number on page 1 of this form. If you stop being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study team will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected problems come up, the Principal Investigator or the Sponsor, (NIH), may decide to stop your participation in the study. Please see the Crohn's and Colitis Connect Mentoring Program Procedures Manual for procedures for stopping your participation in the study.

11) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is being paid by NIH for the time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

Some people have asked us to text them study-related reminders rather than calling them. Information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages. Would you like us to text you or to call you?

Initial:

____ I authorize study staff to contact me via text message. I understand that information sent and received via text message may not be private and individuals unrelated to this study could obtain the information in the messages.

____ I do not authorize study staff to contact me via text message. I prefer to be called.

12) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and disclose your PHI for this research study. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to mood and behavior.

PHI that may be used or disclosed: Names; Address; Telephone Numbers; Birth Date; E-mail Addresses/URLs; Medical Record Numbers.

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:
PI and study staff
The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
Nationwide Children's Hospital internal auditors
The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: For mentoring program matching, supervision and other communication; to ensure appropriate and complete data collection

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at 700 Children's Drive, Columbus, Ohio 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your entire medical records.

The results from this study may be published but your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

Certificate of Confidentiality

To help us protect your privacy, the National Institutes of Health has issued a Certificate of Confidentiality for this study. This Certificate will be used to resist attempts to force us to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The Certificate cannot be used to resist a demand for information that is used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will release the information even though we have the Certificate of Confidentiality.

The Certificate of Confidentiality also does not prevent us from disclosing voluntarily, without your consent, information that would identify you as a participant in the research if required by state and/or federal law. In Ohio, if we have reasonable knowledge that a felony has been or is being committed we are required to notify state officials.

The Certificate does not protect study information that is placed into your medical records.

Future Research Use:

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

With your permission, we would like to store your PHI for future research purposes, and as part of such future research purposes, your PHI may be disclosed to people or entities not listed above, such as researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research. This future research may or may not be related to your medical problem. This future research may include sensitive information. Any future research projects will be reviewed and approved by an Institutional Review Board which protects the rights, welfare, and safety of human research subjects. If your PHI is used or disclosed in future research studies, absolute confidentiality cannot be guaranteed. Information shared for future research may be shared further with others and no longer be protected by federal privacy rules.

If you decide at any time that you do not want your PHI stored for future research, you must make this request in writing to the Principal Investigator at 700 Children's Drive, Columbus OH 43205. Once we receive your written request, we will destroy your PHI. However, if we have already shared your PHI with another individual or entity, we will not be able to destroy any of the PHI that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage and destroy the PHI at any time without sending notice to you or obtaining your consent.

You do not have to agree to use of your PHI for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my PHI to be stored and used for future research as described above: (initial)

____ YES ____ NO

13) <u>WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?</u>

If you have questions, concerns, or complaints about anything while on this study or you have been injured by the research, you have 24 hour access to talk to study staff via the Urgent Response Line at 614-722-4745. You can contact Dr. Laura Mackner at 614-722-4700 Monday – Friday between 9:00am – 5:00pm.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else, call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

STUDY TITLE: Peer Mentoring to Improve Self-Management in Youth with IBD

Your signature documents your permission to take part in this research.

_____ _____

Signature of subject Date & Time AM/PM

_____

Printed name of subject

_____ _____

Signature of person obtaining consent Date & Time AM/PM

_____

Printed name of person obtaining consent