Date: Sunday, December 2, 2018 5:19:02 PM

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Study Identification (#: IRB18-00556)

Attention Investigators: if your research involves the NCH IRB review and oversight of research conducted at Ohio State University and/or other Relying Institutions please refer to the OVERALL PRINCIPAL INVESTIGATOR/LEAD STUDY TEAM GUIDANCE AND CHECKLIST.

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

1.1 **Short Title (to be used by study staff):**
Peer Mentoring R01

2.0 * **Description:**
This study is a multi-site R01 based on a previously approved pilot study (IRB12-00030). This study differs from the pilot study in 3 ways: (1) it adds 3 relying sites, all of which participate in the NIH SMART IRB master agreement, (2) it adds the biomarker of fecal calprotectin, which is collected at baseline and post-intervention, and (3) the timing of the study visits has changed. A post-intervention follow-up has been added 6 months after the end of the intervention, and an interim study visit that had occurred midway between the start and end of the intervention no longer occurs. The PI requests the use of a single IRB review of the study for sites listed under Other Sites/Institutions. After the IRB protocol is approved at NCH, reliance agreements will be executed and the IRB application will be amended to include approved relying institutions to the study before study activities can begin at each site.

Optimal self-management of a chronic illness includes managing its effects on life as well as medical self-management. Yet self-management interventions typically focus only on medical management. This is a problem because up to 35% of youth with IBD experience clinically significant difficulty in other areas of self-management, particularly in managing the overall impact of the disease on life (e.g., quality of life), even when the disease is inactive. The objective of this study is to address areas of impairment that persist even during remission with a multifaceted peer mentoring program. Mentoring programs are common in the general population and are well-known to improve a plethora of outcomes, including social, emotional and academic outcomes, all of which are necessary for successfully managing life with IBD. Peer mentoring programs in particular offer innovative advantages over other forms of intervention for youth with IBD: 1) A peer mentor is a role model who normalizes and de-stigmatizes the disease in a way that a professional cannot, and 2) With a peer mentor, self-management activities take place within the community, promoting generalization and independence in ways that traditional interventions do not. Our mentoring program was developed via focus groups, an NIH-funded pilot study, national mentoring resources, and the PI's 10 years of experience with Big Brothers Big Sisters. It consists of year-long, 1:1 mentee-mentor relationships with group self-management activities, a private program website, and a parent support component. Our pilot study demonstrated feasibility, satisfaction, and improvement in the areas of quality of life (QOL), functioning in typical life activities, IBD self-efficacy, and rates of remission. In the proposed study, 200 youth and their parents, and 100 mentors will be enrolled in this multisite, randomized controlled clinical trial comparing those in the Mentoring Program to an Educational Activity comparison group in the areas of QOL, functioning in typical life activities, and disease outcomes (e.g., biomarker and standardized indices). Mechanisms that contribute to outcomes, including perceived stigma, disease-related self-efficacy, coping and disease uncertainty will be examined as well.

3.0 **Proposed Project Start Date:**
7/2/2018

4.0
Proposed Project End Date:

Indefinite: ☑

5.0 * **Nationwide Childrens (NCH) Principal Investigator:**
Laura Mackner **CV:**Mackner CV 4-17-18 - highlighted.pdf(0.01)
This list will only show those users who currently have the Principal Investigator role. Contact RIS Help Desk if you do not find the user you are looking for.

6.0 Study Coordinator (Reliance Point of Contact):
Laura Mackner **CV:**Mackner CV 4-17-18 - highlighted.pdf(0.01)

7.0 Sub/Co-Investigators:

Study Staff	CHI Department/Section	CCRI Center	Employer	CV
Wallace Crandall	Gastroenterology/Nutrition	Hospital	Gastroenterology/Nutrition	CV(0.10)
Joseph Rausch		Center for Biobehavioral Health	Center for Biobehavioral Health	Joseph Rausch - CV, 04222016.docx(0.01)
Kathryn Vannatta	Psychology	Center for Biobehavioral Health	Center for Biobehavioral Health	Vannatta CV NCH format final.pdf(0.15)

8.0 Other NCH Study Staff (those engaged through intervention or interaction with subjects or obtaining individually identifiable information for research purposes.):

Name	Role On Study	CV
Elisabeth Balistreri	Research assistant	CV(0.01)
Megan Puritz	Research Assistant	Megan Puritz CV(0.01)
Kayce Reed	Mentoring program coordinator	Kayce Reed Resume.docx(0.01)

9.0 NCH administrative Staff (those not actively engaged.) or External (not agents of NCH) Study Staff with eIRB access:

Study Staff	CHI Department/Section	CCRI Center	Employer	CV

There are no items to display

10.0 Could this study qualify for NCH/OSU Reciprocity (i.e.: Study is being done at both sites)? If yes, check here:No

(Note: here for historical purposes only)

11.0 State the Children's site where research is being done:
Main campus; participants' homes

12.0 * Will Children's Hospital be engaged with any external (Non-Children's Hospital) sites in the conduct of this research?
Yes

Funding Source

1.0 * Is this an investigator initiated study? (created by NCH investigator, not outside sponsor or institution)
(●) **Yes** ( ) No

2.0 * Is this study funded by an external grant or contract?
Yes

3.0 * Is this study funded by internal funds?
No

If Question 2.0 and 3.0 answers are NO, the system will automatically set Question 3.0 to YES and Dept. /Division Funds will be selected for Question 3.1

3.1 If yes to 3.0, select all that apply:
There are no items to display
If Other, please specify:

4.0 If this study is not funded, does this study include any activities (medications, x-rays, labs, etc. that are not part of the standard of care)?
( ) Yes ( ) No

4.1 If you answer "Yes" to question 4.0, please describe the activities:

1.0 * **Requested Review Type:**

Name
○ Compassionate Use Request
○ Exempt
○ Expedited
◉ **Full IRB Review (including HUD)**
○ Reliant Review [DO NOT USE]

1.1 * **Please discuss your rationale for the classification you have chosen above in Question 1.0:**
The mentoring program may have greater than minimal risk.

2.0 **Required Department/Section/Center Approval**

Department/Section Name
Center for Biobehavioral Health

3.0 **Ancillary Reviews:**
(If an ancillary is not listed, please call IRB @722-2708.)

Name
☐ Anatomic Pathology
☐ Anesthesiology
☐ Biopathology Center
☐ Biosafety - IBCSC
☐ Cardiology
☐ Clinical Laboratory **Check if the study will require the use of laboratory services (ChildLab)*
☐ CTICU
☐ Dietetics
☐ Emergency Department
☐ NICU
☐ NICU - Nursing Required
☐ Nursing/Patient Care Services
☐ Occupational & Physical Therapy
☑ Office of Technology Commercialization - Material/Data Use Agreements **Check if sending/receiving specimens/data to/from external sites.*
☐ Pharmacy - Ancillary
☐ Psychology/Behavioral Health
☐ Radiation Safety
☐ Radiation Therapy - OSU
☐ Radiology
☑ Research Information Solutions and Innovation (RISI) **Check if the study will require the purchase and/or installation of computer hardware or software, data storage, equipment that may require IT support or any other IT solution.* **Check if sending/receiving data to/from external sites.*
☐ Respiratory Therapy

4.0 If you intend to use hospital medical records, please review the Medical Records Information form.

5.0 If you selected "Biosafety - IBCSC" as a required reviewer, please enter IBCSC Number:

Other Sites/Institutions

1.0 * Please identify the primary site or approved relying institution(s) (following the execution of a reliance agreement):

Reviewing IRB Institution	Contact Person/Lead PI (First, Last)	Contact Tel Number	IRB Approval Status	Description	Primary Site
Children's Hospital of Wisconsin	Rachel Greenley	847-578-8751	Approval Pending		no
Cincinnati Children's Hospital Medical Center	Kevin Hommel	513-803-0415	Approval Pending		no
Nationwide Children's Hospital	Laura Mackner	614-722-4716	Approval Pending		yes
Rosalind Franklin University Medical School	Rachel Greenley	847-578-8751	Approval Pending		no

1.1 If other sites are participating, briefly describe the setting of the site. In addition, if requesting the NCH IRB to serve as the reviewing IRB for relying sites, please list potential relying sites here.
Cincinnati Children's Hospital Medical Center (CCHMC) - relying site
Children's Hospital of Wisconsin (CHW) - relying site
Rosalind Franklin University Medical School (RFUMS) - relying site
Please note: Site PI Rachel Greenley is located at RFUMS and recruits patients from CHW. There are no patients at RFUMS.

1.2 * Does the inclusion/exclusion criteria impose fair and equitable burdens and benefits? (You are not unfairly including or excluding certain populations.)
(●) **Yes** ( ) No

2.0 If you are the primary site, describe the management of information obtained in this multi-site research that might be relevant to the protection of subjects, such as unanticipated events involving risks to subjects or others, protocol modifications (amendments), or interim results. If NCH is the Reviewing IRB of Record for potential relying sites, please upload the sIRB Communication Plan under Supporting Documents.
Please see sIRB Communication Plan

Study Summary

Make Sure You Click the Save Link (Above) Frequently While Entering Your Information.

1.0 * Describe the background and rationale for this project. Reference to peer reviewed literature is desirable:
Inflammatory bowel disease (IBD; Crohn's disease and ulcerative colitis) affects over 1 million people in the US.1 Unpredictable symptoms of abdominal pain, frequent diarrhea and fatigue can present significant challenges to living well with this chronic disease. Symptoms can be embarrassing and can result in spending a great deal of time in the bathroom. Youth with IBD can be reluctant to talk about their symptoms with peers, embarrassed by their frequent visits to the bathroom, and fearful of becoming the target of the "bathroom humor" popular among youth.2 In

fact, 84% of individuals with IBD report feeling disease-related stigma.3

IBD results in significantly impaired QOL and functioning in typical life activities. Our early work found that youth with IBD had significantly worse social functioning than healthy children, reaching clinical significance in over a third.4 A meta-analysis provided further support for significant social difficulty, as well as impaired QOL.5 We also found that youth with IBD had significantly more school absences than healthy children.6

The impaired QOL and life functioning occur with mild and remitted disease, highlighting the importance of targeting management of these nonmedical areas. In our studies investigating social functioning and school absences, 94% of the children with IBD had mild symptoms or were in remission,4,6 suggesting difficulties persist even when the disease is not particularly active. In the school absence study, psychosocial factors were significant predictors of absences, but disease factors were not,6 suggesting that interventions focusing on medical management may be of limited utility in promoting functional abilities.

These impairments may continue to adulthood. Childhood functioning is a significant predictor of successful adult functioning,7 and adults with IBD are more likely to be unemployed or absent from work than those without IBD.8 In fact, $5.5 billion in indirect costs of work force nonparticipation are lost per year.9 Similar to our findings with school absences, relationships between disease factors and work-related disability are not always found,8 highlighting again the importance of addressing non-medical areas of self-management.

Few interventions have attempted to address the impact of IBD on life. Research on IBD camps and a support group suggests that structured activities with similar peers result in improved QOL immediately after the intervention.10-12 While they may be helpful, support groups for youth suffer from negative perceptions and often disband.13 Camp takes place in a setting that does not reflect typical life and occurs only one week per year.

Mentoring programs are especially well-suited for improving QOL and functioning in typical life activities. A peer mentor is a role model that can normalize the experience of IBD, reducing both disease-related stigma and stigma related to seeing a professional for help with self-management. Youth may be more receptive to learning strategies when provided by a peer rather than a parent or professional. A peer mentoring relationship is a natural source of social support that also provides opportunities for the mentee to engage in both positive social interactions and typical life activities with a similar peer who has learned to successfully manage the disease. The activities take place within the community, promoting generalization and guided independence in ways that traditional interventions do not. Mentoring programs can also include group activities that provide opportunities for generalization to group social settings and even more peer support.

However, peer mentoring has received little attention in youth with chronic illness. Given their success in the community, mentoring programs have been empirically evaluated in other populations, such as adult chronic illness14,15 and parents of children with chronic illness.16,17 Studies have documented a desire for peer mentoring among youth with diabetes, asthma, allergies and IBD, but these studies also noted a lack of such programs.18-20 Youth mentoring programs are very different from adult programs given child development, safety and family issues, and youth with chronic conditions face very different challenges than their parents, adults with chronic illnesses and healthy children. Mentoring programs designed to help children with chronic illnesses should be tailored to their specific needs and should be evaluated empirically in their own right.

Youth mentoring programs are common in the general population, and meta-analyses provide support for their effectiveness in improving a range of functional domains, including social, emotional and academic functioning, all of which contribute to successfully managing life with IBD.21,22 The effectiveness of mentoring programs has been well-researched in healthy youth. A meta-analysis in 200221 identified 55 independent studies, 75% of which were controlled trials. Moderators of effects were identified, which led to refinement of practical, empirically-based "best practices" for mentoring programs. The authors followed up with another meta-analysis in 201122 and included only controlled trials, identifying 73 studies. Moderators were identified as well, which led to refinement of best practices recommended for mentoring programs. These moderators include matching mentors and mentees based on interests, including structured activities mentor training, expectations for frequency of contact, mentor support, monitoring of overall program implementation, and including parents.

Much less attention has been given to the mechanisms by which youth mentoring programs achieve their success, despite the wealth of research on the effectiveness and related moderators. The

prevailing theoretical models describe the mentee-mentor relationship as promoting self-efficacy, coping, and positive identity development, which result in positive outcomes.21-23 Few studies have tested these mediating relationships however. In mentoring, the mentor models adaptive coping strategies and disease management, within the dyadic relationship and in the group activities, and all within typical life activities. A mentoring program can also provide educational opportunities for learning about the disease and strategies for managing it, further decreasing illness uncertainty, so that in combination with the mentor-mentee relationship, the mentee's self-efficacy, coping and disease uncertainty improve. Improved disease-related self-efficacy, coping, and disease uncertainty may result in better QOL, typical life functioning, and even disease outcomes. In fact, in other chronic conditions, self-efficacy, illness uncertainty and coping skills are significantly associated with improved QOL, functional ability, and disease outcomes24-33

Stigma might be another important, and innovative, mediator. Health-related stigma has been investigated in adults with IBD, with 84% reporting feelings of stigma.34 Perceptions of stigma occur even when the disease is in remission, and it is associated with decreased QOL and psychological distress.34 However, perceived stigma has received very little attention in children or adolescents (with or without IBD). The overwhelming majority of stigma research has examined the beliefs of others about stigmatized groups, often using vignettes in study designs. Mentoring may be a unique opportunity to reduce perceived stigma via the one-on-one relationship and group activities with similar peers, although no research has investigated stigma as a mediator in mentoring research.

Mechanisms related to parental roles in child outcomes have not been investigated, although the inclusion of parents has been identified as a moderator and best practice for mentoring programs. Parents of children with IBD report feeling a lack of social support,35 and mentoring programs that offer a parent support component may result in increased parent social support36 and self-efficacy,37,38 and decreased illness uncertainty and parenting stress,36 likely via mechanisms similar to those in the child's mentoring program. As has been shown in IBD and elsewhere, parent psychosocial functioning is tied to child functioning, including functional disability and QOL.39,40 This suggests that adding a parent component to a mentoring program for youth with IBD has the potential to improve parent functioning, thereby enhancing the likelihood of improved child functioning. Parental QOL may improve as well,41 particularly in the impact that IBD has on the family.

Finally, mentors may benefit from the program as well. Research on mentor benefit is surprisingly lacking, but mentors report benefits of personal satisfaction, gaining new skills and insight, and friendship with other mentors.42-44 In our preliminary data, all but one mentor agreed that they had "grown personally as a result of my participation in this experience" twelve months after meeting their mentees.

1. Loftus EV, Jr. Clinical epidemiology of inflammatory bowel disease: Incidence, prevalence, and environmental influences. Gastro. 2004;126(6):1504-1517.
2. Casati J, Toner BB, de Rooy EC, Drossman DA, Maunder RG. Concerns of patients with inflammatory bowel disease: a review of emerging themes. Digest Dis Sci. 2000;45(Jan):26-31.
3. Taft TH, Keefer L, Leonhard C, Nealon-Woods M. Impact of perceived stigma on inflammatory bowel disease patient outcomes. Inflamm Bowel Dis. 2009;15(8):1224-1232.
4. Mackner LM, Crandall WV. Brief report: Psychosocial adjustment in adolescents with inflammatory bowel disease. J Pediatr Psychol. 2006;31(3):281-285.
5. Greenley RN, Hommel KA, Nebel J, et al. A meta-analytic review of the psychosocial adjustment of youth with inflammatory bowel disease. J Pediatr Psychol. 2010;35(8):857-869.
6. Mackner LM, Bickmeier RM, Crandall WV. Academic achievement, attendance, and school-related quality of life in pediatric inflammatory bowel disease. J Dev Behav Pediatr. 2012;33(2):106-111.
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9. Park KT, Bass D. Inflammatory bowel disease-attributable costs and cost-effective strategies in the United States: a review. Inflamm Bowel Dis. 2011;17(7):1603-1609.
10. Shepanski MA, Hurd LB, Culton K, Markowitz JE, Mamula P, Baldassano RN. Health-related quality of life improves in children and adolescents with inflammatory bowel disease after attending a camp sponsored by the Crohn's and Colitis Foundation of America. Inflamm Bowel Dis. 2005;11(2):164-170.
11. Szigethy E, Hardy D, Craig AE, Low C, Kukic S. Girls connect: effects of a support group for teenage girls with inflammatory bowel disease and their mothers. Inflamm Bowel Dis. 2009;15(8):1127-1128.

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18. Lu Y, Pyatak EA, Peters AL, et al. Patient perspectives on peer mentoring: type 1 diabetes management in adolescents and young adults. Diabetes Educ. 2015;41(1):59-68.
19. Mackner LM, Ruff JM, Vannatta K. Focus Groups for Developing a Peer Mentoring Program to Improve Self-Management in Pediatric Inflammatory Bowel Disease. J Pediatr Gastroenterol Nutr. 2014.
20. Stewart M, Letourneau N, Masuda JR, et al. Support Needs and Preferences of Young Adolescents With Asthma and Allergies: "Just No One Really Seems to Understand". J Pediatr Nursing. 2012;27(5):479-490.
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23. Lerner RM, Napolitano CM, Boyd MJ, Mueller MK, Callina KS. Mentoring and positive youth development. In: DuBois DL, Karcher MJ. Handbook of Youth Mentoring, 2nd Edition. Los Angeles: Sage; 2014.
24. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Ann Behav Med. 2003;26(1):1-7.
25. Compas BE, Connor-Smith JK, Saltzman H, Thomsen AH, Wadsworth ME. Coping with stress during childhood and adolescence: problems, progress, and potential in theory and research. Psychol Bull. 2001;127(1):87-127.
26. Wright L, Afari N, Zautra A. The illness uncertainty concept: A review. 2009;13:133-138.
27. Mishel MH, Germino BB, Gil KM, et al. Benefits from an uncertainty management intervention for African-American and Caucasian older long-term breast cancer survivors. Psychoonc. 2005;14(11):962-978.
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29. Fortier MA, Batista ML, Wahi A, Kain A, Strom S, Sender LS. Illness Uncertainty and Quality of Life in Children With Cancer. Journal of Pediatric Hematology Oncology. 2013;35(5):366-370.
30. Cramm JM, Strating MMH, Roebroeck ME, Nieboer AP. The Importance of General Self-Efficacy for the Quality of Life of Adolescents with Chronic Conditions. Soc Indicators Res. 2013;113(1):551-561.
31. Culos-Reed SN, Brawley LR. Fibromyalgia, physical activity, and daily functioning: The importance of efficacy and health-related quality of life. Arthrit Care Res. 2000;13(6):343-351.
32. Gallant MP. The influence of social support on chronic illness self-management: A review and directions for research. Health Educ Beh. 2003;30(2):170-195.
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associated with health-related quality of life in pediatric inflammatory bowel disease. J Pediatr Gastroenterol Nutr. 2011;52(3):295-299.
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44. Philip K, Hendry LB. Making sense of mentoring or mentoring making sense? Reflections on the mentoring process by adult mentors with young people. J Comm Applied Soc Psych. 2000;10(3):211-223.

2.0 * Describe the significance of the proposed research:

This proposal is innovative in pediatric chronic illness by 1) focusing on areas of significant dysfunction that remain impaired even when the disease is in remission. QOL and functional disability have been neglected by other interventions but likely continue to adulthood if not addressed; 2) reducing the associated stigma with both the disease and professional help,1 and investigating the innovative mediator of perceived stigma, which has received very little empirical attention in children or adolescents; 3) Using a multifaceted peer mentoring program, which have been successful in the community but have not been used for youth with chronic conditions; 4) providing opportunities to engage in typical life activities in the youth's own community, promoting generalization and independence; 5) providing a longer-term approach than other interventions (e.g., a week at camp). Most interventions are clinic-based and much shorter than this year-long mentoring relationship, and have not demonstrated long-term effects; and 6) including parent involvement, which may increase the likelihood of improvement in child outcomes.2,3 Despite being identified as a best practice, most mentoring programs do not incorporate a parent component.4

Using a peer mentoring program to improve self-management in a pediatric chronic condition is also innovative in the youth mentoring field: 1) The mechanisms by which youth mentoring programs achieve their success have not been well investigated; 2) Parents have been neglected in youth mentoring programs. Parents rarely report their child's or their own functioning. Furthermore, this program is particularly innovative because it includes an intervention component for parents; 3) The mechanisms related to parental roles in child outcomes have not been investigated; and 4) Mentor benefit is rarely investigated.

1. Taft TH, Keefer L, Leonhard C, Nealon-Woods M. Impact of perceived stigma on inflammatory bowel disease patient outcomes. Inflamm Bowel Dis. 2009;15(8):1224-1232.
2. DuBois DL, Holloway BE, Valentine JC, Cooper H. Effectiveness of mentoring programs for youth: a meta-analytic review. Am J Community Psychol. 2002;30(2):157-197.
3. Eccleston C, Palermo TM, Fisher E, Law E. Psychological interventions for parents of children and adolescents with chronic illness. Cochrane Database Syst Rev. 2012;8:CD009660.

3.0 * State the primary and secondary objectives of the study:

1. Primary Aims: Examine the immediate and sustained effects of a multifaceted Mentoring Program in youth with IBD compared to an Educational Activity control group.
2. Secondary Aims: Examine the effects of the Mentoring Program on (a) the parents of youth with IBD compared to the Educational Activity group and (b) the mentors participating in the Mentoring Program.
3. Exploratory Aim: Investigate the mechanisms that may contribute to the effects of the Mentoring Program.

4.0 If this research is hypothesis driven, succinctly state the hypothesis:

Hypothesis 1a: Participants in the Mentoring Program will have significantly improved QOL compared to those in the Educational Activity group post-intervention and 6 months later.
Hypothesis 1b: Participants in the Mentoring Program will have significantly improved functioning in typical life activities (i.e., functional abilities) and better disease outcomes (e.g., less severe disease as measured via biomarker and standardized indices) post-intervention and 6 months later.
Hypothesis 2a: Parents in the Mentoring Program will have significantly improved QOL compared to those in the Educational Activity group post-intervention and 6 months later.
Hypothesis 2b: The QOL of the mentors will significantly improve from baseline to post-intervention.

Hypothesis 3: Parent and child self-efficacy, illness uncertainty, coping, social support and child perceived stigma will mediate relationships between mentoring and outcomes. Sex will be explored as a moderator.

5.0 Upload your study protocol, if applicable:

6.0 Upload the DHHS-Approved sample informed consent document (if applicable). This may not be the actual consent document used for this study

Nature of the Research

1.0 * **Please check the boxes that most accurately describe the scope of the research.**

	Nature of the Research
☑	**Clinical Research involving any therapeutic or diagnostic intervention**
☐	Prospective collection and analysis of data obtained from medical records or other sources of clinical data. This would include patient data registries, the ongoing review of medical records to identify treatment patterns or trends, etc.
☐	Prospective collection and/or analysis of human specimens. This would include the establishment of tissue registries or repositories.
☐	Analysis of specimens and/or data that have already been collected for clinical purposes. This would include Case Studies, retrospective records review, etc.
☐	Analysis of specimens and/or data collected under a separately approved research protocol. Research does not involve direct interaction with participants.
☐	Interviews, questionnaires, survey instruments or similar assessments
☐	Core Laboratory
☐	Genetic Research

Study Phase

*

Study Phases (select one):

	Study Phase	Description
☐	Phase I	The initial introduction of an investigational new drug into humans. Typically conducted in healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness.
☐	Phase II	Controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study and to determine the short-term common side effects and risks associated with the drug.
☐	Phase III	Administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. Performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall risk-benefit relationship of the drug, and to provide an adequate basis for physician labelling.

	Study Phase	Description
☐	Phase IV	Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain postmarketing (Phase IV) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase II studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.
☑	**Not Applicable**	

Methods

1.0 * **Outline the major steps and methodologies in the clinical protocol(s).**
If necessary, include a description of any procedures being performed already for diagnostic or treatment purposes.
Clearly differentiate between these procedures:
Study Design: This is a multi-site randomized controlled clinical trial in which 200 participants ages 10–17 years will be randomly assigned to the Mentoring Program or an "Educational Activity" comparison group, with baseline assessments occurring prior to randomization. Mentors and mentees are introduced and their relationship lasts 1 year. Follow-up assessments occur post-intervention (12 months after mentor-mentee introduction and 6 months later). Youth in the Educational Activity group will be yoked to those in Mentoring Program, and the timing of their follow-up assessments will correspond to their yoked peer, which is a design we have used successfully in three prior projects.

Mentoring Program: The Mentoring Program is based on our NIH-funded pilot study (R21), our previous focus group data, empirically-derived best practices, recommendations from our local BBBS, and information from national mentoring resources (MENTOR, www.mentoring.org). The format consists of year-long, 1:1 mentor-mentee relationships with group self-management activities, a private program website, a parent support component, and mentor support. Mentors and mentees have weekly contact (e.g., text, phone), with in-person contact at least once a month. Group activities occur bimonthly. Educational activities alternate with "fun" activities that provide informal opportunities for learning self-management skills. Educational topics include nutrition, disease management, and school issues, and are taught by experts in each content area (e.g., dietitian, pediatric gastroenterologist).

Matching mentors and mentees is based on gender (same), age, geographical proximity, ethnicity, and interests if possible. Mentors and mentees are expected to have weekly contact (e.g., text, phone), with in-person contact 1 – 2 times per month. Mentors, mentees and parents of those ≤18 years sign an agreement that establishes the nature of the relationship and the expectations. Closure procedures, conflict resolution, grievance and relationship termination policies based on BBBS and MENTOR policies have been developed, and are in the Mentoring Program handbook given to participants.

Mentor screening and training: Mentors will be ≥16 years, ≥1 year post-diagnosis of IBD and managing their IBD well. They will be rigorously screened via an online application, interview, checks of references, driving records and social media, and a background check. They must also successfully complete a 3-hour training conducted by an Investigator and Program Coordinator that includes program policies, relationship development and maintenance, appropriate goals and expectations for the relationship, appropriate roles/boundary issues, self-management, and confidentiality, including limits of confidentiality such as suicidal ideation. All training topics are addressed in the context of mentoring a child with a chronic illness (e.g., understanding limitations in role as mentor, not medical professional), and include role plays with feedback.

Program support: Mentors will track contacts with mentees via a private, secure website that was developed for the pilot study. Contact is logged weekly. Mentors will receive regular supervision: Mentors ≤18 years will receive weekly phone supervision for the first month, then twice monthly supervision. Mentors >18 years will receive twice monthly phone supervision for the first 2 months,

then monthly supervision. More frequent supervision will be provided if needed, and the tracking systems will assist in identifying any issues. Supervision will be documented via structured supervision notes. Phone supervision will be provided by Program Coordinators, who will be supervised by study investigators. An "Urgent Response" phone will be staffed at all times by site investigators or Program Coordinators for any situations that might require immediate assistance (e.g., suicidal ideation). Mentees and their parents will be contacted by phone by the Program Coordinator monthly to monitor satisfaction and to address any issues that arise. These phone calls will also be documented. Mentees and parents also have access to the "Urgent Response" phone number.

Program website: The private, secure program website includes educational information, a method to contact the study staff, and the aforementioned mentor-contact tracking section through which mentors log contacts with mentees. Each site will have its own program website, hosted by NCH.

Parent support: Parents meet in a support group while the mentors and mentees are engaging in fun activities or while eating lunch before an educational activity. They participate in the educational activities together with the mentors and mentees. Parents also receive monthly phone calls from program staff to address any program-related issues.

Educational Activity group: To determine whether peer mentoring is effective, the comparison group consists of 1) educational group events, 2) educational information posted online, and 3) monthly encouragement to engage in activities in the community. The comparison group will participate in the same educational group activities as the mentoring group (separately). Participants also have access to the secure website that has the "Living Well with Inflammatory Bowel Disease: A Self-Management Handbook for Patients and Families with IBD," links to educational videos, and materials from each educational activity. Participants can ask questions about the educational materials on the website, which triggers an email to the program coordinator. To control for some attention aspects of the mentoring program, participants in the comparison group will also be encouraged to engage in activities with a friend at least once a month. Similar to the phone calls that mentees and parents receive each month, comparison youth and parents will receive a monthly phone call encouraging this activity.

Procedures: After recruitment, parents and youth will complete measures at baseline. Data will be collected in participants' homes to reduce the number of hospital visits required for families. Then they will be randomized into the mentoring program or comparison group. Youth randomized into the mentoring program will be matched with a mentor, and they will meet each other via a structured introduction. This begins their year-long participation in the program. Youth randomized into the Educational Activity comparison group will be yoked to those in the Mentoring Program so the timing of their educational activities and assessments correspond with their yoked peer.

Follow-up assessments will occur post-intervention and 6 months post-intervention. School absences will be obtained from each child's school at the baseline and post-intervention assessments. Chart reviews will be conducted for disease and outcome information including number of relapses, number of hospitalizations, number of days hospitalized, number of procedures, number of clinic appointments scheduled, and clinic attendance ratio (number of appointments attended/number scheduled). Medications will also be recorded. Disease severity will be assessed via standardized measures of disease activity (Pediatric Crohn's Disease Activity Index or the Pediatric Ulcerative Colitis Activity Index), physician global assessment (PGA; overall assessment of current disease severity based physical examination and patient report, categorized into remission, mild, moderate or severe disease activity), and the biomarker of fecal calprotection, a commonly used biomarker in IBD.

Stool will be collected at baseline and post-intervention for the fecal calprotectin, which will be analyzed at CCHMC by site co-I Ted Denson. A stool collection kit will be mailed to participants prior to the study visit, with instructions to collect the stool sample within 24 hours of the upcoming visit. A reminder phone call will be made the day before. Research staff will transport the sample back to the hospital and send it to CCHMC.

2.0 * **Identify the variables to be measured and how they will be statistically evaluated:**
Formal Analysis of our Primary Hypotheses: First, the two arms will be compared on all variables at baseline to determine if statistically significant differences are present. If differences are found on baseline measures, they will be examined as covariates in all statistical models of interest in exploratory analyses. Importantly, only the pre-specified covariates of baseline outcome variable, gender, and site will be included in the primary and secondary analyses. For comparing the

Mentoring Program to the Educational Activity group on pre-post change for our primary analysis, the baseline measure of QOL for youth with IBD along with the gender and site will be included as covariates in the primary analysis, regardless of the results of statistical tests for baseline group differences. The following repeated measures (RM) model, similar to an analysis of covariance (ANCOVA), will be employed, yit=Bo + BiTimei +B2Timet x Trti + B3Genderi + B4Sitei + eit, where implicitly it is assumed that there is no main effect of Trti, yit is the QOL for youth i at time t, timei is coded as 0 for the pretest and 1 for the post-intervention measure, and the primary effect of interest is B2, which corresponds to the difference between the groups on change in youth's QOL. In this RM model, the baseline measure of QOL for youth is constrained to have equal means across groups by assuming there is no main effect for trti. This constraint yields a statistical test for B2 analogous to the test of a treatment group main effect in an ANCOVA, controlling for baseline QOL. The main advantage of the RM model is that it can be estimated in SAS PROC MIXED using maximum likelihood estimation by treating Timei as a repeated measures factor with two levels, whereas an ANCOVA model would require listwise deletion to account for missing data.
Formal Analysis of our Secondary Hypotheses: The same approach and statistical models employed for our primary hypotheses will be used for our secondary hypotheses within Hypotheses 1, 2, and 3. The main difference between the precise models used will be (a) the specific outcome variable and (b) the time point, post-intervention or 6 month follow-up, employed to form the change score for the hypothesis of interest.
Formal Analysis of our Exploratory Hypotheses: For Hypothesis 1, the RM model specified in our primary hypothesis will be employed, with the exception that the only effect in the model will be a main effect of Time, and the model will only be employed within the Mentoring Program group, since mentors are only available within this study arm. For Hypothesis 2 contained within our exploratory aim, we will employ a longitudinal mediation model with multiple mediators. Specifically, the figure illustrates the model of interest for examining the indirect effects of Mentoring Program compared to Educational Activity on QOL at the 6 month follow-up via the pathway of social support measured at the intermediate time point between baseline and post-intervention. The advantages of longitudinal data to examine mediation models have been well-documented in the methodological literature, yielding a unique opportunity for us to test these pathways over time within an RCT. We will use Mplus 7.31 and its state-of-the-art bootstrapping procedures to statistically test parent and child self-efficacy, illness uncertainty, coping and social support as mediators for the outcome of interest both individually and simultaneously, the latter being useful for determining if a particular mechanism accounts for substantially more variance in the treatment effect. We will follow the guidelines specified for testing longitudinal mediation within Cole and Maxwell and MacKinnon. We will allow for the possibility of a residual direct effect within our models. This same general approach will be used to examine all our mediators. For Hypothesis 3, sex will be examined as a moderator of the treatment effect by examining the three-way interaction between sex, time, and treatment group, while also including all two-way effects and the main effect associated with sex, into the statistical model employed for the primary hypothesis.

Sample Size Information

1.0 Complete the table below to reflect the minimum number of human subjects required to complete this research:

* **Proposed overall sample size:** 300
* **Proposed local sample size:** 105

2.0

If applicable, provide a statistical sample size justification stated in terms of study power or confidence interval width.

Our power analysis is based on our primary hypothesis that the Mentoring Program will provide a significantly greater increase in QOL compared to the Educational Activity group from baseline to post-treatment. We use a Type I error rate of .05 to test this primary hypothesis. For examining statistical power, we assume an independent samples t-test is used to test this hypothesis with a minimum of 80% power to obtain a sufficient per group sample size (n), which is assumed equal across groups. Consequently, the standardized mean difference is the effect size required to obtain power and sample size. Our primary analysis also allows for the inclusion of site, gender and the baseline measure of the outcome as covariates, which will allow for an n equal to or smaller than that reported here for the same level of statistical power.

The results of our pilot study are used to estimate effect size for our power analysis. We found a standardized mean difference of .52 on the QOL total scale when examining group differences in pre-post change. We found effect sizes of .52 and 1.08 on the functional disability score and on the QOL social scale respectively, thus generally illustrating that we should expect effect sizes in the medium to large range for the current R01. Our sample size of n=100 per group (mentoring vs. comparison) would provide 94% power for a medium effect size of d=.5 and more than 99% power to detect a large effect size of d=.8. Even with 20% attrition, we would still have 88% power to detect a medium effect size and over 99% power to detect a large effect size. Thus, our sample size of n=100 is sufficient for detecting treatment effects that we would expect.

Special Subjects Population

1.0 * **Check all that apply to describe your study population:**

	Study Population
☑	**Children or Adolescents (minors)**
☐	Pregnant Women or Fetuses
☐	Fetal Tissue
☐	Adults Who May Lack Capacity to Consent
☐	Employees or Students of the Investigators
☑	**Patients of the Investigators**
☐	Other Patients from CCRI or other Institution
☐	Prisoner
☐	Economically Disadvantaged
☐	Non-English Speaking
☐	Not Applicable

2.0 **If any of the above are selected, describe additional safeguards included in the protocol to protect the rights and welfare of these special populations:**

Informed consent from parents and assent from youth will be obtained from all participants prior to beginning any study procedures. No one will participate unless both consent and assent are given. They will be given time to ask questions and to consider whether or not to participate. Consent and assent forms are written in language understandable to parents and children. Since some of the participants may be patients of the investigators, all study staff will be trained in procedures to minimize the possibility of coercion or undue influence.

Minor Subjects

1.0 * **Please check one box below that is most applicable to your research:**

	Child Category
○	Level 1 - Research not involving greater than minimal risk.
◉	**Level 2 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual**
○	Level 3 - Research involving greater than minimal risk and no prospect of direct benefit to individual, but likely to yield generalizable knowledge about the subject's disorder or condition.
○	Level 4 - Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affected the health or welfare of children.

2.0 * **Please discuss your rationale for the classification you have chosen above in Question 1:**

There is a risk of loss of confidentiality, since participants will be engaging in group activities with other participants. There is risk for emotional or physical harm for mentees participating in the Mentoring Program. Another potential risk is that of cost for those participating in the Mentoring Program. Participants will be reimbursed for data collection, but not for participating in the Mentoring Program itself. Finally, there is a risk that the web-based components (e.g., program

website) could be "hacked" and sensitive information accessed. However, there is the prospect of direct benefit: Participants in the program may experience improved self-management, quality of life and functional ability.

3.0 * Describe how you will obtain both parental permission and the minor's assent for the minor to participate in the research:

Consent and assent will be obtained before completion of any questionnaires. Study personnel will explain the purpose of the study and procedures in simple language. All questions will be answered. Parents and mentors >18 years old will sign consent forms and all youth will sign assent forms. Any participant who has turned 18 years old during the course of this longitudinal study will sign a consent form at the next opportunity after his or her birthday (e.g., group event or post-intervention study visit).

Finding Subjects

1.0 * Please check the box(es) below that best reflect how patients will be identifed and recruited for participation.

	How subjects will be identified
☑	**Potential subjects will self-refer in response to advertisements.**
☐	Subjects will roll-over from another research study.
☑	**Potential subjects will be identified from a registry of individuals interested in research opportunities.**
☑	**Medical records and/or other Institution sources (databases, billing records, pathology reports, admission logs, etc.) will be reviewed to identify potential participants. May involve access of records by individuals not involved in the patient's care.**
☑	**Potential subjects will be identified by their treating physicians and referred to the researchers. Patients' private and identifiable information will not be shared prior to receiving permission from the patient to do so.**
☑	**Potential subjects will be identified and approached during an inpatient or outpatient clinical visit by a member of the research team**
☑	**Other**

2.0 * Do you assure the IRB that you acknowledge the need to address the potential for coercion and that you will employ reasonable and appropriate steps to emphasize the voluntary nature of participation?

◉ **Yes** ○ No

Informed Consent

1.0 * Check one box below to indicate whether informed consent will be obtained or whether you are requesting a waiver of the requirement for informed consent or documentation of informed consent:

	Informed Consent Category
◉	**Subjects will be asked to sign a study consent form after receiving a complete explanation of the study.**
○	Subjects will receive a complete explanation of the study and will be asked to consent verbally. Subjects may receive a written summary of the research as outlined in the attached written Study Information Sheet. Subjects will not be asked to sign a consent form. (Waiver of Documentation of Consent)
○	Subjects will not be asked to consent to participation. A waiver of the requirement for written and verbal informed consent is requested.
○	Consent to collect and analyze the samples and/or data to be used for this research was/will be obtained under a separately approved protocol. The analysis to be done falls within the parameters of the consent originally provided by the participant.

Informed Consent Process

1.0 * **Who will obtain informed consent from subjects for this research?**
Study personnel who have been trained in consent procedures.

2.0 * **Describe how, when, and where the consent process will be initiated:**
All participants will be consented prior to the initiation of any study procedures.

Youth: Adolescents with IBD will be consented prior to the initial study visit, either in clinic or immediately prior to collecting baseline data.

Mentors: Mentors will participate in a 2-step consent process. The first consent is for the online mentor application (which serves as the baseline data collection). Then, if they are accepted into the program as a mentor, they will provide consent for the mentoring program and post-intervention data collection.

The application/baseline data collection for mentors will be completed on a secure website (REDCap). Interested applicants will contact study staff who will then give them the link for the website via secure email. For applicants ≥18 years old, they will provide consent on the website. For applicants who are 16 – 17 years old, study staff will first discuss the study with them and their parents via phone or in clinic, send/give parents the consent forms, and the parents will send/give signed consent forms back to us. After we receive the signed consent forms from the parent, we will give the applicant the link for the website. The consent process on the website will serve as assent for these participants.

Applicants who pass the screening process and wish to participate in the mentoring program as a mentor will provide consent to do so when we meet with them prior to introducing them to a mentee. For mentors who are 16 – 17 years old, study staff will send their parents this consent form and answer any questions via phone. Parents will send the signed consent form back, or the mentor will bring it with him/her when we meet. The mentor will sign an assent form at this time.

2.1 **Describe any waiting period between informing the prospective subject and obtaining consent:**
N/A

2.2 * **Describe the steps taken to minimize the possibility of coercion or undue influence:**
Potential participants will be informed that they may refuse to be in the study or quit the study at any time, and standard medical care will still be available without a penalty or loss of benefits to them.

2.3 * **Who will give consent or permission for this research? (Ex. Parent, Self, Legal Guardian):**
Adult participants and the parent or legal guardian of minor participants will sign consent forms for this research. Adolescents will provide assent for this research.

3.0 * **Do you plan to include subjects who do not speak English?**
○ Yes ◉ **No**
***If 'Yes', answer 3.2; if 'No', answer 3.1**

3.1 **If Non-English speaking subjects will be excluded, provide a scientific rationale for their exclusion:**
Not all questionnaires have been validated in other languages.

3.2 **If Non-English speaking subjects will be included, check all that apply to describe how consent will be obtained and documented:**

Translation Method
☐ A complete translation of the approved English consent form will be submitted to the IRB.
☐ Not anticipated. Will contact the IRB if necessary for short form guidance.

3.3 **If Non-English speaking subjects will be enrolled, describe the translation services available for the conduct of the consent process and the conduct of the research:**

4.0 Consent Forms - Approved:

Name	Version
CCHMC adult mentor program consent.doc	0.01
CCHMC Minor Mentor APP Consent.docx	0.01
CCHMC Minor Mentor PROGRAM Assent.doc	0.01
CCHMC Minor Mentor PROGRAM Consent.docx	0.01
CCHMC Youth Assent.doc	0.01
CCHMC Youth Consent.docx	0.01
CHW adult mentor program consent.doc	0.01
CHW Minor Mentor APP Consent.docx	0.01
CHW Minor Mentor PROGRAM Assent.doc	0.01
CHW Minor Mentor PROGRAM Consent.docx	0.01
CHW Youth Assent.doc	0.01
CHW Youth Consent.docx	0.01
R01 adult mentor program consent.doc	0.01
R01 Minor Mentor APP Consent.docx	0.01
R01 Minor Mentor PROGRAM Assent.doc	0.01
R01 Minor Mentor PROGRAM Consent.docx	0.01
R01 Youth Assent.doc	0.01
R01 Youth Consent.docx	0.01

Inclusion and Exclusion Criteria

1.0 * List the specific study inclusion criteria:
Youth: Age 10 – 17 years with diagnosis of IBD

Mentors: Age 16-35 years, ≥1 year post-diagnosis, and pass screening process including a written application, background check, sex offender, social media, and child abuse registry check, interview, and character references

2.0 * List the specific study exclusion criteria:
(1) Documented neurodevelopmental disorder, or
(2) History of hospitalization for a psychiatric or behavioral disorders, or
(3) Documented significant behavioral/emotional problems that would interfere with appropriate participation in the program, for example, behavioral/emotional problems that would interfere with group activities and/or would be beyond the scope of the training and supervision provided to mentors.

3.0 * Will participation in the research be limited to individuals who meet specific criteria related to age, gender, race, preferred language or any other demographic or socio-economic condition:
Yes

4.0 If you answered yes to question 3, please provide a justification for the limitations on enrollment of subjects:
The study is designed to look at the adolescent population, when many patients are often diagnosed and when self-management is often a challenge. Therefore age is limited due to aims of study.

Benefits and Risks

1.0 * **Describe the potential benefits (physical, psychological, social, or other) that may be gained by the subject, as well as by society in general:**
Participants may experience improved self-management in the areas of QOL and functional ability via improved self-efficacy, illness uncertainty, coping, and social support.

2.0 * **Risks - Describe and assess any potential risks (physical, psychological, social, legal, financial or other) and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used:**
Questionnaire data collection
It is feasible that some of the questions could cause some distress or anxiety, but it is unlikely to have severe or long-lasting effects on the respondent.

Loss of confidentiality
A mentoring program by its very nature imposes some limits on confidentiality as mentors and mentees are expected to share personal information. Participants will also be engaging in group activities with other participants. The risk is that this private information will be shared with others outside of the mentoring relationship or group activity. For our R21 proposal, we realized that the likelihood of this risk of unintentional or unwanted disclosure was difficult to determine, so our program coordinator currently asks about confidentiality concerns during her "check-in" calls with mentors, mentees and parents. No one has reported any concerns. This could potentially be a serious risk given the information shared.

There is a risk that the web-based components (e.g., program website) could be "hacked" and sensitive information accessed. This risk is low given the precautions in place (see below) and has never occurred at NCH.

Cost
Another potential risk is that of cost for those participating in the Mentoring Program. Participants will be reimbursed for data collection, but not for participating in the Mentoring Program itself. Mentors and mentees are expected to have in-person contact, not necessarily engage in activities that incur a cost, but it is possible that they will spend money on activities.

Emotional or physical harm
There is risk for emotional or physical harm for mentees participating in the Mentoring Program. According to Big Brothers Big Sisters, "The rate of reports made to local Big Brothers Big Sisters affiliates for each calendar year from 2000-2010, alleging that anyone within our organization perpetrated child sexual abuse or exploitation on a child associated with our organization, amounts to a fraction of a percentage point per year, based on children served annually. Included in those reports are incidents that may have occurred years or even decades before the report was submitted."3 Anecdotal reports also suggest that mentoring programs that incur incidents often have not screened mentors appropriately.4 The likelihood of this risk is probably low, but it is serious.

3.0 * **Risk Minimization - Describe procedures for protection against or minimizing potential risks, and assess their likely effectiveness. All proposals should describe steps to be taken to ensure confidentiality regarding the collection, analysis, and storage of data, specimens, etc.:**
Confidentiality
Confidentiality is a particular issue for mentoring programs, since mentors and mentees are expected to share personal information. We will regularly highlight its importance: in mentor training, during the mentee/parent orientation that occurs prior to the mentor-mentee introduction, and at each group activity. In both the mentor training and mentee/parent orientation, we will discuss specific confidentiality situations, including communication via the specific types of social media they use, group events, and other situations.
Additionally, confidentiality was a concern for the R21 preceding this proposal. We realized that the likelihood of the risk of disclosure was difficult to determine, so our program coordinator asked about confidentiality concerns during her "check-in" phone calls with mentors, mentees and parents. No one reported any concerns. The program coordinator will continue to ask about confidentiality concerns during "check-in" calls with mentors, mentees and parents, which likely serves as a reminder about confidentiality as well.

The program websites will be accessed via a study-specific password, and NCH has many safeguards in place to protect it from unauthorized access. For example, SSL will be used for encryption, and Apache will be used to protect the site's configuration file and prevent directory browsing. Core system directories will be secured via proper file permissions. Data files, log files and all of the application files will be protected to ensure that they are not readable or writable by unauthorized parties. The application server will reside in the demilitarized zone to add an additional layer of security, and the database server will be hosted behind the NCH firewall.

Cost
To offset costs for those participating in the Mentoring Program, we have budgeted some funds for the group activities. We will also work to identify foundations that may be interested in donating funds to the program to further offset costs. We will also use a strategy similar to BBBS's of sending lists of free and inexpensive activity ideas directly to mentors each week for mentor's one-on-one meetings with their mentees.

Emotional or physical harm
The specific risks we will be monitoring are those described in the Child Welfare Information Gateway (www.childwelfare.gov) publication "What is Child Abuse and Neglect? Recognizing the Signs and Symptoms." These include mentor behaviors such as blaming, belittling or berating the mentee, describing the mentee in very negative terms, and being secretive regarding the mentee. Potential mentee signs of harm include reluctance to be with the mentor, unexplained injuries, and reporting nightmares or bedwetting.

Multiple safeguards on multiple levels are in place to minimize risk to participants:

Mentor screening: Careful screening of mentors is one of the most important ways to mitigate risk. Friends for Youth's Mentoring Institute provides education on recommended best practices in the mentoring field. Their minimum and recommended screening standards can be found at http://friendsforyouth.org/wp-content/uploads/2013/09/MentorScreening_RecommendedSteps.pdf. Our mentoring program's procedures match and even exceed their minimum and recommended standards.

Using a multifaceted approach to identify appropriate mentors, there are four phases mentor applicants must pass prior to acceptance:

(1) A written application that includes open-ended questions about motivations for being a mentor and 3 measures: A quality of life measure (PedsQL) assessing the areas of physical health, and school/work, social and emotional functioning; a measure of self-efficacy for managing IBD; and the Volunteer Functions Inventory, which assesses motivations to volunteer.
(2) An in-person interview that includes questions derived from national mentoring resources, including questions about motivations to be a mentor, information the applicant hopes to share with the mentee, how various challenges would be handled with a mentee (with specific examples), what qualities the applicant would like in a mentee, previous experience with children, and questions about the applicant's answers on the written application, including the measures.
(3) Background and other checks that include 3 character references, preferably people who have seen the applicant work with children. We will ask for additional references if the ones provided have not seen the applicant with children. We will conduct federal and state criminal background checks, search sex offender and child abuse registries, and conduct social media searches.
In the social media searches, we look for clues that the mentor applicant may not be a good role model for a child with IBD. For example, the goal of the mentoring program is to "live well with IBD." The public blog of one applicant framed her IBD experience in a self-pitying, hopeless and socially-limiting manner. Certainly, these are valid feelings when one has a chronic illness such as IBD, but this was the theme of the entire blog. Someone who may be a better fit as a mentor for the program may have written about coping with these feelings, and/or would also have blog posts that demonstrated living well with IBD.
(4) Behavioral observation that is part of our training session was a particularly useful screening approach in our pilot study. The training session is conducted in a group format and includes behavioral observation of role plays acted out by the applicants in various situations that mentors and mentees may encounter. In one session, this resulted in the rejection of an inappropriate applicant who had passed the prior three phases of screening.

We do not hesitate to reject inappropriate applicants. Of the 26 people who completed the written application in our pilot study, 4 withdrew during the screening process due to insufficient time or relocation to another state, and 4 were rejected due to poor disease management, serious psychiatric history, inappropriate social media, and disagreement with the program's expectations

for the mentor role. This rate of 31% for rejections/withdrawals is similar to BBBS's rate of 30%.2 We would much rather turn down a potentially inappropriate mentor than potentially expose a mentee to risk.

Mentee screening: Eligibility criteria for mentees provide some protection from risk for both mentees and mentors. Eligibility criteria include no documented neurodevelopmental disorder or history of hospitalization for a psychiatric or behavioral disorder. Mentors are meant to be role models for living well with IBD, not peer psychotherapists. Children and adolescents who might need a higher level of support than the mentors can provide are not eligible for the study.

Many of the Friends for Youth Mentoring Institute screening recommendations occur after mentors have been screened and accepted into the program. We also have multifaceted safeguards in place for mentee safety after mentors have been screened and accepted into the program:

(1) Pre-match mentor training. The pre-match training session topics include relationship development and maintenance, communication, appropriate goals and expectations for the relationship, appropriate roles/boundary issues, self-management, and confidentiality, including limits of confidentiality such as abuse and self-harm. Procedures for managing these issues are detailed (briefly, the mentor is to call the program's "Urgent Response" phone line, and licensed program staff will manage the situation; more procedural detail is available). The training includes detailed descriptions of the program policies that applicants sign as a "commitment statement" when they become mentors. Mentors are given a program procedures manual as well as a folder for additional readings and the handouts they receive during the training session. These materials are also available on the program website.
(2) Post-match mentor training occurs approximately 6 months after the mentor and mentee introduction. This training addresses continued relationship development, communication, appropriate expectations and problem-solving. This information is also available online.
(3) Mentee and parent/caregiver training occurs prior to the structured mentor-mentee introduction and includes information about program expectations, expectations about the mentoring relationship, appropriate roles/boundary issues, tips for parents of mentees, and confidentiality, including limits of confidentiality such as abuse and self-harm. Mentees and parents are informed about the Urgent Response phone line (see below). Mentees also sign a "commitment statement."
(4) Urgent response phone line. A 24-hour "Urgent Response" line will be staffed by the Program Coordinator and Investigators for any participant (mentor, mentee, parent) to call at any time. Program Coordinators will typically have a background in social work and/or counseling and will be trained to manage situations that may arise via the Urgent Response line.
(5) Weekly reporting of mentee contact. Mentors will track the contact they have with their mentees every week via a secure online tracking system. The tracking system is a private section of the program website, making it easy for mentors to track their contact with their mentees. The tracking system consists of drop-down and text boxes in which the mentor describes the date and type of contact (e.g., in person, phone, text), overall rating of the contact, and what activity they participated in if it was an in-person contact. This information is automatically sent as an email to the Program Coordinator. No other mentors see this information. The contact will be monitored daily by the Program Coordinator and discussed with the Investigators in weekly meetings.
(6) Ongoing mentor check-ins. Mentors will receive supervision at least once per month via phone calls by the Program Coordinator which will be discussed with the Investigators in weekly meetings. There will be distinct processes for youth volunteers: Mentors ≤18 years will receive weekly phone supervision for the first month, then twice monthly supervision. Mentors >18 years will receive twice monthly phone supervision for the first 2 months, then monthly supervision. More frequent supervision will be provided if needed, for example, if a mentee is shy and the mentor would benefit from additional assistance in working with him or her, or if a family is disorganized and the mentor and mentee family would benefit from problem-solving aimed at developing strategies for scheduling weekly and in-person contact. The need for more frequent supervision will be determined by the Program Coordinator and PI, along with the mentor and/or mentee and family. The online tracking system will assist in identifying any issues. Supervision will be documented via structured supervision notes.
(7) Ongoing mentee check-ins. Mentees will be called once per month by the Program Coordinator, and these phone calls will be documented and discussed weekly with the Investigators. Mentees will be asked about activities they have participated in with their mentors as well as questions about their relationships with their mentors (e.g., "how are you and your mentor getting along?"). The final broad question is "do you have any (other) concerns?" in case the previous questions have not been sufficient to address any issues. Program Coordinators will have been trained via the Child Welfare Information Gateway publication "What is Child Abuse and Neglect? Recognizing the Signs and Symptoms" to recognize any responses that are concerning and suggest additional follow-up.
(8) Ongoing parent check-ins. Parents will be called once per month by the Program Coordinator,

and these phone calls will be documented and discussed weekly with the Investigators.
(9) Behavioral observation by the Investigators (licensed clinical psychologists) and Program Coordinators of mentor-mentee interactions will occur during the program's educational and recreational group events. Any observations of harm or potential harm (e.g., risky behavior at a recreational event) will be acted on immediately. Observations of interactions that are concerning (e.g., a mentee does not seem comfortable around a mentor) may be addressed at the event and/or addressed via check-in phone calls with the mentor, mentee, and parent, with calls made before regularly scheduled ones as needed.
(10) Specific program policies prohibiting harm are described during training and are listed in the program procedures manuals given to mentors, mentees and parents. Similarly, mentors and mentees are prohibited from being alone together, and must be in the company of others for their in-person get-togethers.

4.0 Describe the clinical criteria for withdrawing an individual subject from the study due to safety or toxicity concerns:

Mentors
Potential mentors can be withdrawn from the screening process at any time. As stated in the program procedures manual given to mentors, mentees and parents, mentors in the program must follow all program policies and procedures that are detailed in the mentor training and the manual. Any unacceptable behavior, as specified by but not limited to the Mentor Agreement, will result in a verbal or written warning and/or termination from participating mentoring program.

Mentees
Any mentees whose behavior becomes unsafe and interferes with appropriate participation in the program (i.e., behavior that now meets exclusion criteria) will be considered for withdrawal.

Clinical Research Summary

1.0 * Does this research involve a washout from medication taken prior to enrollment or assignment of subjects to a placebo or no-treatment arm?
○ Yes ◉ **No**

2.0 * Will subjects in this research undergo any procedures involving radiation exposure?
○ Yes ◉ **No**

3.0 * Will subjects in this research be exposed to radiation beyond that to which they would be exposed with standard care?
○ Yes ◉ **No**

4.0 * Does this research involve the use of investigational drugs or biologics, that are not FDA-approved OR, if approved, not for this indication?
○ Yes ◉ **No**

5.0 * Does this research involve the evaluation of an FDA-approved drug (regardless of whether it is to be used in accordance with its approved labeling)?
○ Yes ◉ **No**

6.0 * Does this research involve the use of an investigational medical device, one that is not FDA-approved?
○ Yes ◉ **No**

7.0 * Does this research involve the use of an FDA-approved medical device?
No

8.0 * Does this study involve a therapeutic intervention?
◉ **Yes** ○ No

9.0 * Will a study sponsor cover all costs associated with drugs and/or devices used and all procedures performed under this protocol?
◉ **Yes** ○ No

10.0 * Will any data and/or specimens be collected for genetic research?
○ Yes ◉ **No**

11.0 * **Does this research involve healthy subjects?**
No

Therapeutic Alternatives

1.0 * **What are possible therapeutic alternatives to participation in this study?**
Psychotherapy

2.0 * **Are you aware of any competing protocols which target the same subject population locally?**
○ Yes ◉ **No**

If yes, please describe how you will prioritize subject entry among the various competing protocols:

Data and Safety Monitoring Plan

1.0 * **Check response below that will accurately reflect who monitors the data:**

	Name
○	The study will be monitored only by the study investigators and/or sponsor.
○	The study will be monitored by at least one individual who is not associated with the study, but not by a formally constituted Data and Safety Monitoring Board (DSMB).
◉	**A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.**

2.0 **If this research involves more than minimal risk to participants, provide a detailed description of provisions for monitoring data to ensure the safety of participants. Include: what are the qualifications of those who will monitor the data, what data will be monitored, how often will data be monitored and what endpoints will be monitored.**
The study statistician, Joe Rausch will monitor the study data. He has significant expertise in clinical trials and has collaborated on the design, power analysis and data analytic considerations for this proposal. Every 6 months, he will generate a random sample of 10% of the cases for whom data was collected in the previous 6 months at each site for audit. These cases will be audited for compliance with IRB requirements, conformance with informed consent requirements, verification of source documents, and investigator compliance. This is in addition to other routine checks in place such as double data entry and post-study-visit protocol and data checks. These checks will be conducted by PI's and research assistants.

3.0 * **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns:**
Stopping or changing the study protocol will be discussed with the investigators and DSMB when/if any adverse events occur.

4.0 * **Are there any plans to perform an interim efficacy analysis?**
○ Yes ◉ **No**

If you answered yes, please describe the plans to conduct an interim analysis:

Independent Monitor or DSMB

1.0 * **List the affiliations and qualifications of those monitors who are not associated with the study or describe the composition of the DSMB:**
The study will be monitored by a Data and Safety Monitoring Board (DSMB) comprised of the following members who have accepted positions on the DSMB:

Michael Para, MD, will serve as the Chair of the DSMB. Dr. Para is an expert in the ethics of clinical research and the work of DSMBs. He has served as the Associate Dean for Clinical Research in the College of Medicine and the Director of Regulatory Knowledge and Ethics for the Center for Clinical and Translational Science at the Ohio State University. In these roles, he has provided guidance on a range of issues regarding the ethics of clinical research and the work of DSMBs. He has conducted many clinical trials in the area of HIV.

Julie Panepinto, MD, MSPH, will serve as the Executive Secretary of the DSMB. Dr. Panepinto is a Professor of Pediatric Hematology and the Director of the Center for Clinical Effectiveness Research of the Children's Research Institute at the Medical College of Wisconsin/Children's Hospital of Wisconsin. She has experience with DSMBs, and with her own clinical trials as well as those those conducted in the Center for Clinical Effective Research, which she directs.

Scott Powers, PhD, ABPP, FAHS, will be the clinical trials expert on the DSMB. He is a Professor in the Department of Pediatrics of the University of Cincinnati, Cincinnati Children's Research Foundation Endowed Chair, and Scientific Director of Clinical Research and Trials at Cincinnati Children's. Dr. Powers has conducted multiple clinical trials, the results of which have been frequently cited and published in prestigious journals. He also trains future scientists in the conduct of clinical trials via the training grants he has received and the career development grants his early career mentees have received.

Michael Kappelman, MD, MPH, will serve as the expert in the clinical aspects of the disease being studied. Dr. Kappelman is a pediatric gastroenterologist with clinical and research interests in pediatric inflammatory bowel disease. He is a Professor of Pediatrics at the University of North Carolina. He has received funding from NIH, PCORI, foundations and industry for clinical trials and research on patient-reported outcomes in pediatric IBD.

Nanhua Zhang, PhD, will be the biostatistician for the DSMB. He is an Associate Professor in the Department of Pediatrics at the University of Cincinnati. His areas of expertise include comparative effectiveness, clinical trial design, behavioral interventions, community-based interventions, and health disparities. He has conducted clinical trials for multiple types of behavioral interventions, including relatively long-term interventions with multiple follow-up points1 and a community-based intervention using lay health advisors to increase organ donations.2

Kathleen Lemanek, PhD, will be the final member of the DSMB. She is a Pediatric Psychologist at Nationwide Children's Hospital (NCH) and a Professor of Clinical Pediatrics at The Ohio State University College of Medicine. Dr. Lemanek has conducted clinical trials for behavioral interventions in sickle cell disease, cystic fibrosis, and chronic pain, and she is familiar with mentoring as she has been involved in the NCH sickle cell peer mentoring program.

2.0 * **Describe how frequently the independent monitor(s) or DSMB will meet and/or review study data:**
After an initial meeting shortly after the start of the study (within 3 months), the DSMB will meet every 6 months for the length of the study.

3.0 * **Describe the type of data (e.g., blinded or unblinded) to which the independent monitor(s) or DSMB will have access:**
The DSMB will have access to unblinded data.

Confidential Health Information

1.0 * **Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.**

	Category
☑	**Demographics (age, gender, educational level)**
☑	**Diagnosis**
☑	**Laboratory reports**
☐	Radiology reports
☐	Discharge Summaries
☑	**Procedures/Treatments Received**

	Category
☑	**Dates related to course of treatment, (admission, surgery, discharge)**
☐	Billing Information
☑	**Names of drugs and/or devices used as part of treatment**
☐	Location of treatment
☑	**Name of treatment provider**
☐	Surgical Reports
☑	**Other information related to course of treatment**
☐	None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
Recruitment, and they are potential covariates, and outcomes of the study.

3.0 * Is the health information to be accessed and reviewed what is minimally necessary to achieve the goals of this research?
◉ **Yes** ○ No

4.0 * Will it be necessary to record information of a sensitive nature?
◉ **Yes** ○ No

5.0 * Do you plan to obtain a federally-issued Certificate of Confidentiality as an means of protecting the confidentiality of the information collected?
○ Yes ◉ **No**

Protected Health Information Recording

1.0 * Please indicate which subject identifiers will be recorded for this research.

	Name
☑	**Name**
☑	**Complete Address**
☑	**Telephone or Fax Number**
☐	Social Security Number
☑	**Dates (treatment dates, birth date, date of death)**
☑	**Email address , IP address or url**
☑	**Medical Record Number or other account number**
☐	Health Plan Beneficiary Identification Number
☐	Full face photographic images and/or any comparable images (x-rays)
☐	Account Numbers
☐	Certificate/License Numbers
☐	Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
☐	Device Identifiers and Serial Numbers
☐	Biometric identifiers, including finger and voice prints
☐	Other number, characteristic or code that could be used to identify an individual
☐	None (Complete De-identification Certification Form)

2.0

2.0 Check the appropriate category and attach the required form* below. (choose one)

	Description
☑	**Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of template) in the consent form OR attach the "HIPAA Authorization" form.)**

	Description
☐	Protocol meets the criteria for waiver of authorization. (Attach the "Waiver of Authorization Request" form.)
☐	Protocol is using de-identified information. (Attach the "De-Identification Certification" form.) (Checked "None" in 1.0 above)
☐	Protocol involves research on decedents. (Attach the "Research on Decedents Request" form.)
☐	Protocol is using a limited data set and data use agreement. (Complete the "Data Use Agreement" form, obtain other party's signature. Keep in study file."

***View Category Descriptions Here: HIPAA Categories Description**

2.1 Add the appropriate HIPAA forms:

Name	Date Modified

There are no items to display

3.0 * How long will identifying information on each participant be maintained?

Length of the study

4.0 * Please describe any plans to code identifiable information collected about each participant.

Only research staff will have access to research data. The study coordinator will keep a password-protected database of all subjects who participate. Study data will be kept separately and filed with only a number for identification. The list of names associated with the identifying numbers will be kept separate and labeled with a code in such a way so that others cannot understand it. Access will be allowed for study personnel only.

5.0 * Please check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research.

	Name
☑	**Research records will be stored in a locked cabinet in a secure location**
☑	**Research records will be stored in a password-protected computer file**
☑	**The list linking the assigned code number to the individual subject will be maintained separately from the other research data**
☑	**Only certified research personnel will be given access to identifiable subject information**

6.0 * Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)

There are risks related to loss of privacy and confidentiality, since participants will be interacting with other participants and potentially engaging in group activities. The privacy risk is well-described in the consent and assent forms. Participants will be informed that they will be interacting with other patients if they decide to participate in the program, thus other people will know that they have IBD and are participating in this project. If this is a concern, they can decline to participate with no adverse effects. Every effort will be taken to maintain confidentiality. In the mentoring program, confidentiality will be emphasized in training, supervision and group activities. Confidentiality reminders will occur at the beginning and end of group events. Confidentiality issues will also be an on-going topic during mentor supervision.

Recruitment and Retention Tools

1.0 * Describe local recruitment strategies/plans for potential study subjects and where recruitment will be done:

Youth participants: After diagnosis is confirmed, patients at two sites (NCH, CCHMC) participate in a "teaching visit" or educational group visit to learn about the disease and the clinic. On-going research at the clinic is also discussed, so we will approach patients about enrolling in the project at this time. Other potential youth participants will be approached via recruitment letter, brochure, phone call and/or clinic visit.

Mentors:
-Potential mentors will be identified via the pediatric and adult gastroenterology clinics. Patients will be approached via recruitment letter, brochure, phone call and/or clinic visit, and we will hang flyers in clinics. We will also use hospital social media to advertise.
-We will distribute flyers and other materials (e.g., balloons, pins) at Crohn's and Colitis Foundation and other IBD-related events. We will advertise on Crohn's and Colitis Foundation and other IBD-related social media.
-We will advertise at local colleges via newsletters, service/volunteer fairs, bulletin boards, email lists, social media, student organizations such as the Psychology Club, and other media.
-Previous mentors and previous mentees who have turned 16 may be asked if they are interested in participating again as mentors.
-We will advertise the study to hospital employees (e.g., sending an "Everyone" email, advertising on internal hospital media).
-We will use ResearchMatch and VolunteerMatch.
-We will advertise on our lab websites and lab newsletters.

2.0 * **Will the study use advertisements or other recruitment materials to recruit potential participants?**

(●) **Yes** ( ) No

3.0 **Please upload all advertisements, recruitment tools, and retention tools here:**

Name	Description
Adult GI doc letter.pdf	
adult mentor recruit letter.docx	
hospital mentor email.docx	
Mackner Laura--RESEARCHMATCH RECRUITMENT MESSAGE IBD mentoring.doc	
Mentor info sheet 5-3-18.pdf	
Mentor Recruitment Version 1.pdf	
Mentor Recruitment Version 2.pdf	
Mentor Recruitment Version 3.pdf	
Mentor Recruitment Version 4.pdf	
minor mentor recruit letter 5-22-18.docx	
R01 Youth Particpant Recruitment Letter.docx	
VolunteerMatch ad.docx	
Youth Brochure (R01).pdf	

4.0 **Please check all that apply to describe how the attached advertisement(s) will be used.**

	Name
☑	**Exchange/E-mail**
☑	**Posted internally**
☑	**Posted externally**
☑	**Pamphlet or brochure to be distributed**
☑	**Newspaper or other print media**
☐	Radio or television
☑	**Mailed to patients**
☑	**Mailed to non-patients**
☑	**Mailed to other physicians**
☑	**Website**
☑	**Other**

5.0 * **Will participants be paid for participation or receive reimbursement for study-related expenses?**

(●) **Yes** ( ) No

If applicable, please indicate the amount that each participant will be paid and describe

the payment schedule to be followed:
Youth participants (mentee/comparison): $50 for baseline and post-intervention home visits, $25 for online 6 month follow-up
Mentors: $20 for online post-intervention assessment

Final Page

Please hit "Finish" to finalize and exit the application. Doing so will NOT submit the application for review.

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must select "SUBMIT" in the study workspace.

You can track the ongoing status of your submission by logging into the study workspace.

Please feel free to contact the IRB with any questions or concerns.