Electronic RESEARCH INTEGRITY AND COMPLIANCE THE UNIVERSITY OF UTAH

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IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
1. Contacts and Title

1. Study Introduction

1. **Responsible Investigator:**
Flory Nkoy

Email	Training	CoI Date
flory.nkoy@hsc.utah.edu	10/16/2019 SMG	6/14/2021

a. **Position of the Investigator:**

- (●) **Faculty or** Non-Academic Equivalent
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

2. **Contact Persons for the Responsible Investigator:**

Name	Email	Training
Angela Zhu	angela.zhu@hsc.utah.edu	7/14/2020 SMCG

3. **Guests of the Responsible Investigator:**

Last Name	First Name	E-Mail

There are no items to display

4. **What type of application is being submitted?**
New Study Application (or Amendment/Continuing Review)

5. **Title Of Study:**
SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

6. **Study Purposes and Objectives:**

Our Specific Aims are: Aim 1. Partner with caregivers to develop the MyChild^{CMC} application: 1.a. Assess caregiver needs, preferences and capability for CMC self-management through focus groups; 1.b. Develop the MyChild^{CMC} application to engage caregivers in ongoing monitoring of crosscutting symptoms, alerting the clinic care coordinator if a child's symptoms worsen to prompt timely interventions, and monitoring caregiver burden to prevent burnout; and 1.c. Explore the MyChild^{CMC} usability to incorporate user suggestions and enhance user acceptance and performance of the application. Aim 2. Assess the impact of the MyChild^{CMC} app by comparing outcomes for the: 2.a. child (QOL and ED/hospital admissions); 2.b. caregiver (satisfaction, self-management skills, QOL and burden); and 2.c. health care provider (satisfaction), between child/caregiver dyads randomized to either MyChild^{CMC} or usual care. Aim 3. Assess whether the effect of the MyChild^{CMC} intervention on child outcomes varies across caregiver characteristics (ethnicity, education, health literacy, and insurance).

7. **Is this a multi-site study, where more than one site needs IRB approval?**
   ○ Yes ● **No**

8. **Background and Introduction:**

Year 1. Focus Groups (only) there are only consents for the Focus Groups participants, in year 2 we will amend the IRB to add PP and other consents to enroll participants.

Year 2. Usability Testing

Year 3. Participants to use tool

Participants **included in this retrospective portion will be consented to participate in the research project. Consents will happen prior to the retrospective portion of the study. Collecting retrospective will be clearly outlined in the consent/parent permission**

The first year of the CMC study is the development of the self-management tool. In that first year we will hold 3 two hour focus groups is to assess your opinion, preferences and the usefulness of developing an electronic mobile application to support care and Self-Management for Children with Chronic Medical Complexity (MyChild^{CMC}).

About 1 in 7 U.S. children < 18 years are classified as children with special health care needs (CSHCN) and require health services beyond routine care. Among CSHCN is a vulnerable subgroup, known as children with medical complexity (CMC), who has life-threatening, complex, multisystem conditions, frequent emergency department (ED) and hospital admissions, and account for 1/3 of pediatric health care expenditures. CMC often have severe neurological impairment, marked intellectual and physical disabilities, and depend on technology to sustain life. CMC prevalence among hospital admissions is increasing nationally, mainly due to improved survival of children with conditions previously incompatible with life. Once discharged, CMC continue to experience frequent acute deteriorations of their health status often for potentially avoidable causes and/or technology malfunctions that lead to recurrent ED/hospital admissions. Overall, CMC have significant ongoing care needs and require substantial care coordination and constant caregiver attention. Long-term caregiving can stress family caregivers and impose a significant caregiver burden, leading to burnout, which may affect caregivers' health and thereby ability to provide care to CMC, setting up a vicious cycle of negative outcomes. To reduce the risk of acute deteriorations of a chronic condition, self-management is recommended. Better support for self-management improves outcomes. Existing self-management support interventions focus primarily on non-complex, single system conditions. No intervention exist to address the variable, multisystem diagnoses of CMC or to target caregiver burden. Despite variable diagnoses, CMC are often admitted to the ED/hospital for common, crosscutting symptoms. Such similarity presents an opportunity for innovative self-management interventions, appropriate to CMC. We propose to develop and test the impact of a mobile health application to engage caregivers in self-management of CMC (MyChild^{CMC}), targeting crosscutting symptoms coupled with ongoing monitoring of caregiving burden to promote timely decision-making.

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2. Study Location and Sponsors

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1. **Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).**

   Click the appropriate button(s) below to add locations:

	Site Name	Investigators Name	Covered Entity	Sub Sites
View	Intermountain Primary Children's Hospital	Flory Nkoy	Yes	

2. **Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study for the sites listed in this application?**
   ○ Yes ● **No**

3. **Indicate the source(s) of funding obtained or applied for to support this study.**

	Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type
View	HRSA MATERNAL & CHILD HEALTH BUREAU	Federal Government	Marie Y Mann, MD, MPH, FAAP Senior Medical Advisor/Acting Deputy Director Division of Services for Children with Special Health Needs Maternal and Child Health Bureau 301-443-4925 office 202-498-8178 mobile mmann@hrsa.gov		

4. **Does this study have functions assigned to a Contract Research Organization (CRO)?**
   ○ Yes ● **No**

5. **Does this study involve use of the Utah Resource for Genetic and Epidemiologic Research (RGE)?**
   Examples: Utah Population Database (UPDB), Utah Cancer Registry (UCR), All Payers Claims Database (APCD), etc.
   ○ Yes ● **No**

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IRB_00088596
View/Edit

Addition of a Site

1. **Site Name:**
   Intermountain Primary Children's Hospital

2. **Site Principal Investigator**
   ☑ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   Flory Nkoy

Email	Training	CoI Date
flory.nkoy@hsc.utah.edu	10/16/2019 SMG	6/14/2021

   a. **Position of the Site Principal Investigator**
   Faculty or Non-Academic Equivalent

   b. **Will the Site PI consent participants?** ○ Yes ● **No**

3. **Site Contact Persons, if different from the Site PI:**
   ☑ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training
Angela Zhu	angela.zhu@hsc.utah.edu	7/14/2020 SMCG

4. **Site Staff and Sub-Investigators**

Name	Email	Training	Obtaining Consent	CoI Date
Bernhard Fassl	bernhard.fassl@hsc.utah.edu	1/8/2020 MG	☐	4/14/2021
Namita Mahtta	namita.mahtta@hsc.utah.edu	7/11/2018 SMG	☑	5/27/2021
Grace Perry	grace.perry@hsc.utah.edu	6/20/2019 SMV*CG	☑	5/4/2021
Bryan Stone	bryan.stone@hsc.utah.edu	10/16/2019 SMCG	☐	3/9/2021
Angela Zhu	angela.zhu@hsc.utah.edu	7/14/2020 SMCG	☑	4/20/2021

5. **Site Guests:**

Name	Email	Training

There are no items to display

6. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

7. **Select the study procedures that will be conducted at this site:**

Recruitment

Consent/Enrollment

Data collection

Data analysis

Do you have an enrollment goal or anticipated enrollment number for this site?

● **Yes**

○ No

Enrollment Number:
300

8. **Select the University of Utah department responsible for this research:**
PEDIATRICS

9. **Add any additional sites that are part of this performance group**
There are no items to display

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IRB_00088596
IRB Smart Form

Sponsor Information

Please review these previously entered fields as you fill out the new form:

Sponsor: HRSA MATERNAL & CHILD HEALTH BUREAU
Contact: Marie Y Mann, MD, MPH, FAAP Senior Medical Advisor/Acting Deputy Director Division of Services for Children with Special Health Needs Maternal and Child Health Bureau 301-443-4925 office 202-498-8178 mobile mmann@hrsa.gov
Grant Number: HHSH25020170038G
Awardee: University of Utah, Flory Nkoy
Effective Date Start: 12/19/2018

a. Are you receiving award or contract management for the sponsored funds through the University of Utah Office of Sponsored Projects?

● **Yes** ○ No

If yes, select the associated OSP Proposal ID/DSS through eAward to link it to the ERICA system.

You must have a fully approved Proposal ID/DSS number through eProposal which will show up in eAward after OSP has integrated the ID. To access the eAward application, use the instructions on the OSP website.

Link to a Proposal ID/DSS through eAward

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IRB_00088596
3. Participants

3. Participants

1. Ages of Participants:

Less than 7 years old	(Parental permission form needed)
7 to 17 years old	(Parental permission and assent form needed)
18 and older	(Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):
Children age 1-20 years old with complex medical conditions and their parent caregivers

3. Indicate any vulnerable participant groups (other than children) included:

Individuals with Cognitive or Decisional Impairment

If "Other", please specify:

If "None" and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
○ Yes ● **No**

4. Number of participants to be included and/or enrolled in this entire study, across all study locations: 300

At Utah prior to October 2019: 300

5. Characteristics of Participants/Inclusion Criteria:

1. Complex Medical Conditions ages 1-20 years with their caregivers (primary person caring for the child)

2. been seen at Primary Children's Hospital within 365 days,

3. own a smartphone or a tablet computer with Internet access

4. English speaking.

Since we are recruiting from Primary Children's Hospital, we will use physician diagnosis to determine CMC

Focus Groups/ Decision Support/ Usability
1. Parents of children with CMC

6. Participant Exclusion Criteria:

1. Critically ill children in imminent death.

2. Non English Speakers

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?

○ Yes ● **No**

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IRB_00088596
- Vulnerable Populations

Vulnerable Populations

Justification Requirements for the Inclusion of Vulnerable Populations

1. **How does the nature of the research require or justify using the proposed subject population?**
About 1 in 7 US children < 18 years or 10.2 million are classified as children with special health care needs (CSHCN) and require health services beyond routine care. Among CSHCN is a subgroup, known as children with medical complexity (CMC), who have complex, multisystem diseases, frequent emergency department (ED) and hospital admissions, and consume about 1/3 of pediatric health care costs. CMC often have severe neurological impairment, marked intellectual and physical disabilities, and depend on technology to sustain life.
The prevalence of CMC among hospital admissions is increasing, mainly due to advances in health care, leading to improved survival of children with conditions previously incompatible with life. At home, CMC continue to have significant ongoing care needs, requiring substantial care coordination and constant caregiver attention. Care coordination is beneficial, but also time consuming and limited by lack of payer support, lack of training and nursing shortages. Long-term caregiving imposes a significant caregiver burden, which may affect caregivers' health and ability to provide care, setting up a vicious cycle of negative outcomes. Caregivers often feel unsupported, overwhelmed, and are not trained to detect early signs of deterioration of their child's health and/or technology malfunction, and lack tools to guide them in early recognition and decision making. Thus, many CMC continue to have frequent ED/hospital admissions for avoidable acute deteriorations of health.
To reduce the risk of acute deteriorations of chronic conditions, self-management is recommended. In pediatrics, self-management enables caregivers, in collaboration with a health care provider (HCP), to assume a primary role in managing their child's condition at home including monitoring symptoms, identifying signs of deteriorations, using medications appropriately, and determining when medical attention is needed. Better self-management support improves outcomes.

2. **Would it be possible to conduct the study with other, less vulnerable subjects?**
○ Yes ● **No**

If yes, justify the inclusion of vulnerable subjects:

3. **Is this population being included primarily for the convenience of the researcher?**
○ Yes ● **No**

If yes, explain:

4. **Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?**

● **Yes** ○ No

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4. Study Information

4. Study Information

1. **Design of Study (select all that apply):**

   - [x] **Non-Experimental and/or Descriptive Research Design:**

     Secondary/Archival Data Analysis or Retrospective Chart Review
     Interviews and Focus Groups
     Observational Research

   - [x] **Experimental and/or Interventional Research Design:**

     Prospective Biomedical Intervention or Experiment

   - [ ] **Development of a research resource (repositories, databases, etc.)**

   - [x] **Other**

     If Other, describe:
     Quality Improvement

2. **Does your study involve the use of any placebo?**
   ○ Yes ● **No**

3. **Length of entire study, from initiation through closeout:**
   5 years

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**

   In-person contact (e.g., patients, students, etc.)

   Written or electronic record review

   Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   Study timeline:

   Year 1. Focus Groups

   Year 2. Usability Testing

   Year 3. Participants to use tool

   Participants **included in this retrospective portion will be consented to participate in the research project. Consents will happen prior to the retrospective portion of the study. Collecting retrospective will be clearly outlined in the consent/parent permission**

   The first year of the CMC study is the development of the self-management tool. In that first year we will hold 3 two hour focus groups is to assess your opinion, preferences and the usefulness of developing an electronic

mobile application to support care and Self-Management for Children with Chronic Medical Complexity (MyChild^{CMC}).

In the second year there will be two usability testing sessions to get input and feedback about the usefulness of the self-management tool.

In the third year we will invite participants to join the study. We will run a pilot study for feasibility for 3 months.

Focus Groups and Usability testing session will generate valuable input/feedback about the how the MyChild^{CMC} tool will be develop and used. We will add IRB amendments for the parent permission consent when we are ready to add participants. Because we cannot anticipate all the changes we have just added the first consent (attached) for the Focus Group.

Focus Groups: three focus groups (6-8 parent participants per session) with 24 parent participants in Year 1 and two usability testing cycles, each assessing 6 parent participants (for a total of 12 parent participants) in Year 2. Participants will receive participant remuneration equivalent to a $50 gift card after participating in each focus group and usability testing. The PI and all members of the Research Team will adhere to all University of Utah Payments to Human Research Participants rules and regulations.

A written flyer describing the study will be displayed in Comprehensive Care Clinic at Primary Children's Hospital (Dr. Nancy Murphy (Co-I) is the medical director in this clinic) to recruit potential participants. If a parent is interested in participating, a research staff will approach them to consent and enroll in the study.

Patients/Parents will be identified by the CMC study coordinator (Angela Zhu, Nancy Murphy) in CMC clinics or the inpatient at PCH, or those who express interest in participating in the study after seeing the written flyer posted in the clinic. The family will then be approached by the study coordinator to participate in the study if they meet criteria. The study coordinator will obtain a signed consent form from the patient/parent to participate in the study. After enrollment, patients/parents will be trained during the formal education about the MyChild^{CMC} app, the dynamic run chart report (including definitions of the scale and colors) as well as the Patient Portal. Participants will download the MyChild^{CMC} app onto their smartphones and create a log-in account. Patients will be trained in how to use the system. Patients also will be encouraged to bring the form to their primary care provider at the time of follow-up visit. A contact number will available for questions and support regarding any technical aspects of the MyChild^{CMC}.

5. **How will consent be obtained?**

Informed Consent Process (with or without a document)

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

The MyChildCMC app will be uploaded into the Apple and Google Play app store for participants to download. As part of the app store publishing process, a legal privacy policy is required and was uploaded. In the privacy policy, there is a link where a potential participant may access the approved consent document to review before downloading the app.

Participant Recruitment and Enrollment: Screening will occur using inclusion/exclusion criteria. Potential participants will be directly approached or invited to participate in the study by project coordinators. Enrollment will be conducted in a private location in the clinic (e.g., exam room). Patient/parent dyads meeting eligibility and agreeing to participate will complete an informed consent document (for parents) and parental permission (for their child). Because the children participants have cognitive impairment, no assent will be obtained. All participants will receive general training on self-management of crosscutting symptoms, how to take measurement and how to identify acute deteriorations. Those randomized to MyChild^{CMC} will receive additional training about MyChild^{CMC} use.

While use of the children participants' PHI is required to achieve the aims and objects of this research, the children will not be asked to complete or perform any study related interventions or interactions.

Randomization Procedure: Randomization will be performed using a computer-generated randomized allocation sequence made available online for the clinic care coordinator, and will be stratified by WeeFIM score as mild (18-54), moderate (55-90) and severe (≥ 91) disability, and age group (1-11 and 12-18 years), and performed using random permuted blocks to ensure assignment of subjects to the intervention and usual care groups is balanced over time. Participants randomized to MyChild^{CMC} will receive support to install the app, a temporary password (modified upon login) and full MyChild^{CMC} access. At the first login (in the clinic), the care coordinator will guide participants through baseline surveys and first assessment of crosscutting symptoms/ caregiver burden, thereafter caregivers will use the MyChild^{CMC} app over 3 months. All alerts about changing patient health status/caregiver burden will be directed to the care coordinator, who will follow-up with families to determine if an action, or a visit with a HCP or social worker is needed. The care coordinator will also access the dashboard to see participants not adherent with MyChild^{CMC} use and follow-up with those in need of supports. Participants randomized to usual care will receive general self-management education, be encouraged to monitor their child's symptoms/caregiver burden and identify deteriorations but without MyChild^{CMC}, and will complete surveys and provided incentive on the same schedule as the intervention group.

Data Collection: Upon first login, caregivers will complete a demographic survey (only once), including caregiver education level, a series of baseline surveys assessing the child (QOL) and caregiver (satisfaction, self-management skills, QOL and burden). Also, we will collect caregiver health literacy (only once) to be used in analysis of spec aims 3, and severity of child disability using WeeFIM which will be used in analysis of aims 2 and 3. 2 Baseline and follow-up surveys will be collected online by RedCAP within 3 months.

Validated surveys will be used to collect data, including a 37-item Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD) Questionnaire (child QOL), 12-item Parent satisfaction questionnaire, which includes one open-ended question assessing participant's perception of burden related to MyChild^{CMC} use, 13-item Patient Activation Measure (caregiver self-management skills), 12-item Short Form health survey (caregiver QOL), and a 6-item Newest Vital Sign (NVS) for caregiver health literacy. At each QOL, we will also collect caregiving burden summary over the past month for both the intervention and control groups. All HCP caring for CMC during the study period will be surveyed at the end of the study to assess their satisfaction with care using the 6-item HCP Satisfaction Questionnaire. ED and hospital admissions will be collected using the Intermountain enterprise data warehouse (EDW),152 an integrated database linking data of 22 hospitals in Utah and Idaho. Intermountain Healthcare provides services for > 95 % of children in Utah.

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ● **Yes** ○ No

   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ● **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   Data Analysis. We will assess Feasibility, using family's participation, retention, adherence, and dropout rates. We will also assess parent responses to interactive activities such as response to reminders and alerts, to inform the future enhancement, and the appropriateness of the alerts triggered by the MyChild^{CMC} app. Preliminary Impact: The primary outcome is QOL score, obtained at baseline, 1 and 3 months. Secondary outcomes are QOL sub-domains (comfort, emotions, communication and social interaction, health, and overall QOL), ED/hospital admissions and caregiver satisfaction. Further detail will be provided during phase 2.

   AIM 2

   Data Analysis: The primary outcome is the CPCHILD total score, which will summarize the child's QOL at baseline, and at 3, 6, 9 and 12 months of follow-up. Secondary outcomes include additional CPCHILD sub-domains beyond the total CPCHILD (comfort and emotions; communication and social interaction; health; and overall QOL), child ED/hospital admission, and caregiver satisfaction, self-management skills, caregiver burden, and HCP satisfaction. The primary and secondary analyses will be performed in accordance with intention-to-treat, with patients analyzed in accordance with the randomized treatment assignment irrespective of compliance. Numeric outcome variables exhibiting positive skewness may be transformed to better approximate normality. Analyses will be performed with SAS version 9.4 or higher. Standard statistics including means, standard deviations, medians, and interquartile ranges for continuous variables and frequencies and percent for categorical variables will be used to compare characteristics of randomized vs. non-randomized patients and to compare baseline characteristics between randomized groups. Open-ended questions of caregiver and HCP satisfaction will be analyzed using standard qualitative analysis as described in Aim 1.

The primary analysis of the CPCHILD total score will be performed by applying a linear mixed effects model to compare the mean QOL score over the 3, 6, 9 and 12-month assessments between the intervention and control groups. The mixed effects model will incorporate an unstructured covariance matrix to account for serial correlation within the same patients, and will include fixed effect terms for the randomized treatment assignment, the baseline CPCHILD total score, Clinic, and the WeeFIM and age group randomization strata as well as interaction terms between each of these factors and follow-up visit. Adjustment for the baseline CPCHILD total score will account for any baseline imbalances in the outcome variable and regression to the mean, thereby increasing statistical power. In addition to the primary comparison of the mean CPCHILD total score over all 4 follow-up assessments between the randomized groups, secondary contrasts will be constructed to estimate treatment effect on the mean total score at each individual follow-up visits and to compare the size of the treatment effects between different follow-up visits to determine if the treatment effect attenuates or increases over time. Secondary outcomes will be compared between the randomized groups using similar linear mixed models for numeric outcomes (e.g., other CPCHILD subscales, caregiver/HCP satisfaction, PAM score, and burden score) or generalized linear models with use of robust empirical standard errors for categorical outcomes. Similar analysis will be used to compare caregiver burden subscales (stress and coping). The rate of ED visits and hospital admissions will be compared between randomized groups using negative binomial regression, possibly augmented to account for 0-inflation if the proportion of subjects with 0 ED events or hospitalizations exceeds that accounted for by the negative binomial model

Statistical Power: Cohen et al. 19 reported a standard deviation (SD) of 15.4 in the CPCHILD total score in 81 children with complex comorbidities. Assuming SD = 15.4 and allowing for up to 10% loss to follow-up, a sample size of 220 will provide at least 85% power with a 2-sided α=0.05 to detect a mean relative reduction of 6.59 points, representing a moderate effect size of 43% of 1 SD. The calculation is conservative because it does not account for repeated follow-up assessments or an expected positive correlation between the baseline and follow-up CPCHILD scores. For example, if the average correlation between the baseline and follow-up scores is at least 0.5, the detectable effect size will be reduce to no more than 5.73 points, or 37% of 1 SD.

AIM 3

Data Analysis: The CPCHILD total score for Aim 2 will also be treated as the primary endpoint for testing for the presence of baseline effect moderators. Each baseline moderator will be investigated in separate analyses by including the moderator and interaction terms between the moderator and an indicator variable for treatment assignment as additional predictor variables in the linear mixed model for the primary outcome in Aim 2. Forest plots will be constructed to display 95% confidence intervals for the treatment effects for subgroups defined by each potential moderating factor, with p-values for treatment by moderator interactions included on the plots. Given limits in statistical power in subgroup analyses, the p-values will not be directly adjusted for multiple comparisons. However, additional assessments will be performed using bootstrap resampling to indicate the probabilities of 1, 2, 3 or more nominally significant results to aid in the interpretation of results.159 Exploratory analyses of the presence of baseline moderators for treatment effects will be performed for other QOL indices and the caregiver burden score by applying similar linear mixed effects models with interaction terms for the hypothesized baseline effect moderators to these outcomes. In exploratory analyses, the possibility of effect moderation by frequency of e-AT use will be investigated by subdividing the intervention group based on those who satisfy the 60% threshold for frequent use, and then applying a linear mixed model to relate the CPCHILD total scores to indicator variables defined by the infrequent and frequent user's groups, with the control group serving as the reference. Because the classification of frequent users is a post-randomization covariate, these as-treated analyses will incorporated covariate adjustment for an extended set of baseline covariates to reduce confounding, and results will be interpreted with appropriate caution.160 Application of marginal structural models incorporating adjustment for time dependent confounding may also be considered.

Statistical Power: Under the same assumptions described for the primary analysis of the CPCHILD total score, the sample size of 220 randomized subjects will provide 85% power with 2-sided α = 0.05 to detect relative reductions of 12.0, 9.3, or 7.9 in the total score for the intervention compared to the control arms within subgroups including 30%, 50%, or 70% of randomized subjects. The minimum detectable interaction effects are given by differences in total score ranging from 13.2 to 14.4 points for subgroups of the same size.

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IRB_00088596
- Consent Process

Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Study Location and Sponsors Page):**

Namita Mahtta	Intermountain Primary Children's Hospital
Grace Perry	Intermountain Primary Children's Hospital
Angela Zhu	Intermountain Primary Children's Hospital

List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).

2. **Describe the location(s) where consent will be obtained.**
PCH, Outpatient Clinics

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**
Participants included in this retrospective portion will be consented to participate in the research project. Consents will happen prior to the retrospective portion of the study. Collecting retrospective will be clearly outlined in the consent/parent permission

Patients/Parents will be identified via Patient Tracker while in the hospital or during Complex Medical conditions clinic (Dr Murphy's clinic). Family will then be approached by the study coordinator to participate in the study.The study coordinator will obtain a signed consent form from the patient/parent to participate in the study. After enrollment, patients/parents will be trained about the MyChildCMC app.the dynamic run chart report (including definitions of the scale and colors) as well as the Patient Portal. A Web link to the Patient Portal and temporary password will be given to the patient/caregiver to access the system and establish a permanent password. Patients will be trained in how to use the system and its potential benefits before discharge. Patients also will be encouraged to bring the form to their primary care provider at the time of follow-up visit. A contact number will available for questions and support regarding any technical aspects of the MyChildCMC app.

Re-consent process: Patients over the age of 18 will be contacted via phone/email to be re-consented using their LAR and updated consent documents will be mailed to them for them to review, sign, and send back. A copy of the consent form will be provided to them.

For the Focus & Usability Groups:
Participants will be asked to sign a consent document before participation and will be given the opportunity to ask questions to the members of the study team.

All participants will be given the opportunity to ask questions to the members of the study team.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
Parents/patients and providers will be explained that participation will be voluntary and will not influence the care that their child receives. It will also be explained that they may withdraw from the study at any time. A copy of the consent form will be provided to them.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
All questions will be answered by a member of the research team or study coordinator. If the parent pr provider wishes, they may think about participating in the study and contact the research team later if they decide they want to participate.

6. **Will a legally authorized representative (LAR) be used?**

● **Yes** ○ No

Describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period.
We are adding the use of a legally authorized representative (LAR) for when participants over the age of 18 who are cognitively and/or decisionally impaired are enrolled into the study and are unable to give consent and authorization themselves to participate in the study. We expect ~10% of all enrolled participants to use an LAR.

Re-consent process: Patients over the age of 18 will be contacted via phone/email to be re-consented using their LAR and updated consent documents will be mailed to them for them to review, sign, and send back.

7. **Will a language other than English be used to obtain consent?**
○ Yes ● **No**

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**
○ Yes ● **No**

If yes, complete the following:

a. **Explain why the waiver of consent documentation is being requested.**

b. **Justification for the waiver is one of the following:**
There are no items to display

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
- - Additional Consent Considerations

Additional Consent Considerations

Individuals with Cognitive or Decisional Impairment or Mental Disability

1. **Please describe the nature of the cognitive/decisional impairment or mental disability and how this affects decision-making ability:**
   Children with medical complexities (CMC) have life limiting, complex, multisystem chronic diseases, and often have medical technology dependencies and substantial daily care needs. CMC targeted for this pilot also have severe neurological impairments with marked intellectual and physical disabilities that affect their decision-making capacity.
2. **In the opinion of the principal investigator, is an assent process appropriate for these individuals, along with informed consent from a legal representative?**
   ○ Yes ● **No**

   Please justify your response:
   Neurologically and cognitively impaired children with medical complexities (CMC) and severe multi-system chronic health conditions, and medical technology dependencies will not be able to participate in an assent process. For those CMC patients over the age of 18, we will obtain the informed consent and authorization of their Legally Authorized Personalized Representative (normally their guardian appointed to make medical decisions for them).
3. **In the opinion of the principal investigator, is it possible that cognitively/decisionally impaired participants may recover an adequate amount of decision-making capacity during the course of the study (N/A for mentally disabled persons)?**
   No

   If yes, are there plans to obtain full informed consent from the participant at that time?
   ○ Yes ○ No

   Please justify your response:

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
5. Data Monitoring

5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:

   Discussing the study with participants individually instead of in front of a group

   The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

   Other or additional details (specify):

   Other or additional details (specify):
   We will respect the privacy of patients to help them feel safe while participating in the study by speaking quietly when discussing the study in a waiting room or other public area, we will avoid using participant's names in public hallways and elevators, and conduct procedures that may be uncomfortable or embarrassing to participants in non-public locations. We will interview participants about sensitive topics individually instead of in front of a group. We will limit access to study data to only a few members of the study team.

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:

   Storing research data on password protected computers or in locked cabinets or offices

   Complete de-identification of study data

   Other or additional details (specify):
   The raw data from surveys, chart review, administrative databases will be stored on the PI's secure computer in his secured office at PCH. Only he and his research assistant will have access to data containing PHI.

   Web-based reports will be stored within the Intermountain firewall, which includes authentication and authorization protection. A specific provider will only see his/her performance using his/her user name and password.

   All data analyses will be performed on data sets created with identifiers, allowing linkage of individual patients to their records. Individual identifier information will be removed from study data files as soon as possible in the data processing steps.

   All source/legacy data files will be stored behind the Intermountain fire wall and will be accessed only by staff members working on the study. Only the PI and the research assistant will know who the subjects are.

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

   ○ Yes ● **No**

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:

Periodic review and confirmation of participant eligibility

Periodic review of informed consent documentation

Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

Other additional details (specify):

5. **Who will be the primary monitor of the study data and documentation?**

Select all that apply:

Principal Investigator

Study Coordinator or Research Nurse

Other or additional details (specify):

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
Monthly on a continued bases

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
6. Risks and Benefits

6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

We recognize that there are some potential patient risks related to the study. We will work closely with the Institutional Review Board at the University of Utah to ensure that procedures are in place to protect the rights and welfare of patients and parents. Use of the Self-Management for Children with Medical Complexity (MyChild^{CMC}) application will not interfere with or change health care provider usual care of the patient's conditions other than by increasing parent engagement in the care of their child's complex chronic conditions and by providing additional objective data for health care providers to augment their ability to make informed medical decisions for timely treatments. No adverse events that would harm study participants are anticipated. Participation in ongoing assessments of crosscutting symptoms and caregiver burden is voluntary and individuals can discontinue participation at any time. The principal risks to participants of this research are loss of privacy and confidentiality, including use of electronic databases for potential subject identification, and potential breach of confidentiality through disclosure of protected health information for parents responding to the ongoing assessment of crosscutting symptoms. Installing rigorous security protections on data management, issuing regular reminders to project staff to change their passwords often, and adherence to HIPAA and IRB privacy and data security requirements will mitigate these risks. We will monitor positive and potential adverse outcomes that may arise to participants in this study.

2. Describe the potential benefits to society AND to participants (do not include compensation):

This study will facilitate early identification of acute deteriorations of crosscutting symptoms to facilitate timely decision-making in order to prevent an ED or hospital admission. We are not making any claims that participants will benefit directly from participation in this study. However, based on our preliminary studies with the electronic-AsthmaTracker showing significant reduction in ED/hospital admissions, it is likely that patient in the current study will have improved outcomes, including improved QOL and reduced ED/hospital admissions. In addition, we anticipate that parents will have improved satisfaction, self-management skills, QOL, and reduced impact of caregiving. Further, the health care provider will benefit from additional objective data to facilitate timely decision-making. Our project will provide useful information about factors critical to caregiver self-management engagement and burnout that can be addressed to facilitate broad dissemination of self-management support interventions to improve the care of CMC at home. We anticipate that our interventions, tools, measurement systems or versions of them, may be adopted by clinics and health care organizations nationwide to improve care of CMC overall.

3. Are there any costs to the participants from participation in research?

○ Yes ● **No**

If yes, specify:

4. Is there any compensation to the participants?

● **Yes** ○ No

a. If yes, answer the following:

Specify overall amount:

Participants in the focus group and usability testing will receive $50 gift card for participating.

Participants enrolled to use the MyChildCMC app will be compensated in total $120 in gift cards:
$40 for completing enrollment and baseline surveys
$40 each for 2 follow-up surveys that will be sent via RedCAP.
All participants enrolled to use the MyChildCMC app will receive a new pulse oximeter (valued at $20) to measure their child's blood oxygen level as part of the study.

Participants randomized to MyChildCMC group will receive a stethoscope (valued at $5) to measure their child's respiratory rate as part of the study.

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):
Participants in focus group and usability testing will receive $50 gift card at then end of the session.

Participants enrolled to use the MyChildCMC app will receive $40 gift card and a new pulse oximeter and a stethoscope at end of enrollment and completing baseline surveys. Thereafter, they will receive $40 gift card as they complete two follow-up surveys that will be sent via RedCAP. The gift cards will be sent by email once confirming that the follow-up surveys have been completed.

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):
$40 at enrollment, pulse oximeter at enrollment, $40 for first follow-up survey completion, $40 for second follow-up survey completion.

d. If applicable, explain plan for prorating payments if participant does not complete the study:
Not applicable.

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
7. HIPAA & the Covered Entity

7. HIPAA and the Covered Entity

1. **Does this study involve Protected Health Information (PHI) or de-identified health information?**
   ● **Yes** ○ No
   a. **Select the method(s) of authorization that will be used:**
   (Consent and) Authorization Document
   Waiver or Alteration of Authorization
   b. **Will PHI be disclosed outside the Covered Entity?**
   ○ Yes ● **No**

Does this study involve any of the following:

2. **The investigational use of a drug?**
   ○ Yes ● **No**
3. **The investigational use of a medical device?**
   ○ Yes ● **No**
4. **Is this an investigator-initiated drug or device trial lead by the Principal Investigator?**
   ○ Yes ● **No**
5. **Exposure to radioisotopes or ionizing radiation?**
   ○ Yes ● **No**
6. **A Humanitarian Device Exemption (HDE)?**
   ○ Yes ● **No**
7. **Genetic testing and/or analysis of genetic data?**
   ○ Yes ● **No**
8. **Creating or sending data and/or samples to a repository to be saved for future research uses?**
   ○ Yes ● **No**
9. **Are you:**
   - **Collecting samples of blood, organs or tissues from participants for research purposes;**
   - **Introducing Recombinant or Synthetic Nucleic Acids (e.g. viral vectors, oligonucleotides) or cells containing recombinant nucleic acids (e.g. CAR-T) into participants; OR**

- **Introducing other biological materials (e.g. bacteria, viruses) into participants.**

◯ Yes ● **No**

10. **Does this study involve any of the following?**
    - **Cancer Patients**
    - **Cancer Hypothesis**
    - **Cancer risk reduction**
    - **Cancer prevention**

    ◯ Yes ● **No**

11. **Any component of the Center for Clinical and Translational Science (CCTS)?**

    ◯ Yes ● **No**

    The Clinical Services Core (CSC)?

    ◯ Yes ● **No**

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
- Request for Waiver of Authorization

Request for Waiver or Alteration of Authorization

Request for Waiver of Authorization for Recruitment Only

This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.

Other Requests for Waivers of Authorization:

- *Click "Add" below to add a new waiver request to this application.*
- *Click the waiver name link to edit a waiver that has already been created.*
- *To delete a waiver request, contact the IRB.*

	Date Created	Type of Request	Purpose of Waiver Request
View	1/12/2016	Waiver of Authorization	Record review for recruitment and chart review for all data collection through EDW.

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
IRB Smart Form

Request for Waiver or Alteration of Authorization

1. **Purpose of the Waiver Request:**
   Record review for recruitment and chart review for all data collection through EDW.
2. **Type of Request:**
   Waiver of Authorization
3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc).**
   EMPI, Encounter, Admit Date, Discharge Date, Date of Birth, Age, Sex, Race, Weight, Height, PCP, Insurance Code, Composite Score, Length of Stay, Cost, Hospital/ED Readmissions
4. **Explain why the *PHI* to be used or disclosed is the minimum necessary to accomplish the research objectives:**
   The PHI is a prerequisite to identifying and pulling charts for manual review, and for administrative database information retrieval. The PHI we are collecting will be used to improve our ability to provide high quality complex medical care and will provide critical information for quality improvement.
5. **Explain why the research could not practicably be conducted without the waiver of authorization.** *For example, complete the following sentence: "If I had to obtain authorization, the research could not be conducted because..."*
   The PHI accessed through chart review will provide Quality Improvement (QI) data as it will be given to pediatric clinical program leaders. Impacts of QI interventions on hospitalization outcomes and patient related measures targeted at reducing re-admissions have not been evaluated. By obtaining authorization, selection bias is introduced, which minimizes the generalizability of the study outcomes.
6. **Describe your plan to protect the identifiers from improper use and disclosure, and indicate where the *PHI* will be stored and who will have access:**
   All investigators and project staff sign confidentiality pledges annually and receive IRB and HIPAA privacy and data security compliance training annually. All source/legacy data files regarding patient EDW data will be stored behind the Intermountain fire wall and will be accessed only by staff members working on this study.
7. **The identifiers must be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe how and when you will destroy the identifiers, or justify their retention:**
   Individual identifier information will be removed from study data files as soon as possible in the data processing steps. Unique study-specific identifiers will be assigned to support accurate linkage of data on the same individual across multiple data files. We will maintain a data dictionary linking the study identifier to the personal identifiers until 7 years after the IRB approval for the study expires (to permit re-analysis of the data files to respond reviewers comments for publication purposes).
8. **Describe the measures you will take to ensure the PHI will not**

be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research approved by the IRB:

Installing rigorous security protections on data management, and adherence to HIPAA and IRB privacy and data security requirements will help mitigate potential risks. At the completion of the study and after publication of results, all data will be destroyed.

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
8. Resources and Responsibilities

8. Resources and Responsibilities

1. * **State and justify the qualifications of the study staff:**

   The clinical research coordinator ,Angela Zhu, will be consenting and collecting data from participants. This individual is qualified by education, training, and experience to perform the delegated tasks.

2. * **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   The PIs Dr. Nkoy, Stone, Murphy, Hofmann and Fassl as well as the clinical research coordinator, Angela Zhu, will be involved in research-related activities. Meetings will occur between the PI and other members of the research team weekly regarding study procedures and research-related duties. The PI and staff have completed all required training regarding regulatory requirements including proper conduct of research.

3. * **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**
   Inpatient floors at PCH, Outpatient Services PCH

4. * **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
   Not Applicable

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
Documents and Attachments

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document(Highlighted Changes)

Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Parental Permission Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Assent Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

VA Consent Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Grant Application:

The Federal Government is a direct or indirect sponsor of your research. You are required to provide a copy of the grant proposal, grant award, or sub-award.

By submitting to the IRB, you are confirming the grant and the study protocol are consistent (Design, Study Population, Study Objectives and Goals, Test Interventions and Procedures, etc.)

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Literature Cited/References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
Nkoy_NIH_Biosketch_Dec_2012(0.01)	0.01	12/18/2012 10:38 PM	12/18/2012 10:38 PM	

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

IRB_00088596 **Created:** 12/9/2015 12:01 PM

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

IRB_00088596
- Primary Children's Information Form

Intermountain Primary Children's Hospital
The Child First and Always®

PCH Administrative Research Questions

You have indicated Primary Children's Hospital is a study location. Please complete the following questions so Primary Children's can confirm that your study:

1. Aligns with Primary Children's Mission, Vision and Values
2. Receives approval from the Primary Children's resources impacted (e.g.: lab, radiology, infant unit, etc.); and
3. Identifies Primary Children's study related charges from standard of care charges

If you have any questions or concerns regarding this form or the associated Primary Children's approval process, please contact us with the contact information below:

Email: PCHResearch@imail.org
Phone: 801-408-1991 opt 1

Principal Investigator: Flory Nkoy, 801-588-3927, flory.nkoy@hsc.utah.edu
Contact Person(s):

Last Name	First Name	E-Mail	Phone
Zhu	Angela	angela.zhu@hsc.utah.edu	801-662-3675

IRB_00088596
Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY
Description of Study:

Our Specific Aims are: Aim 1. Partner with caregivers to develop the MyChild^{CMC} application: 1.a. Assess caregiver needs, preferences and capability for CMC self-management through focus groups; 1.b. Develop the MyChild^{CMC} application to engage caregivers in ongoing monitoring of crosscutting symptoms, alerting the clinic care coordinator if a child's symptoms worsen to prompt timely interventions, and monitoring caregiver

burden to prevent burnout; and 1.c. Explore the MyChild^{CMC} usability to incorporate user suggestions and enhance user acceptance and performance of the application. Aim 2. Assess the impact of the MyChild^{CMC} app by comparing outcomes for the: 2.a. child (QOL and ED/hospital admissions); 2.b. caregiver (satisfaction, self-management skills, QOL and burden); and 2.c. health care provider (satisfaction), between child/caregiver dyads randomized to either MyChild^{CMC} or usual care. Aim 3. Assess whether the effect of the MyChild^{CMC} intervention on child outcomes varies across caregiver characteristics (ethnicity, education, health literacy, and insurance).

Assigned IRB Coordinator: Beth Kollman
Anticipated Length of Study: 5 years

1. **Describe how this study furthers excellence in the provision of health care for children.**
   The current project capitalizes on our prior experience in developing and implementing the eAT to support self-management at 12 primary care clinics in Utah and our ability to sustain parent engagement. The variable, multisystem diagnoses of CMC, makes it difficult to implement self-management interventions. Our project will introduce a novel, but practical approach to supporting CMC self-management, that focuses on crosscutting symptoms leading to ED/hospital admissions among CMC rather than an unrealistic approach targeting multiple diseases individually. Our study is the first to address CMC self-management and will establish a systematic approach to routinely screen and address caregiver burden to prevent burnout. We will identify factors critical to caregiver engagement that can be addressed to facilitate use of SM-CMC beyond our study population. If successful, our approach will serve as a model for improving CMC care and reducing acute health care use and costs that can also be generalized to adults with multiple chronic conditions who also disproportionally use health care resources.

2. **In simple, brief and specific terms, tell us what this study will be doing.**
   To reduce the risk of acute deteriorations of chronic conditions, self-management is recommended. To date, no self-management intervention for CMC exists. While evidence of mHealth tool use for supporting self-management of non-complex, single diseases is substantial, no tool exists to address the complex needs of CMC self-management. Our project will implement and test the effectiveness of a novel approach to support CMC self-management, by targeting crosscutting symptoms, while monitoring

caregiver burden. If successful, our approach will serve as a model for improving CMC care and reducing costs that can be generalized to adults with multiple chronic conditions who also disproportionally use health care resources.

3. **Project Funding Type:**

	Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type
View	HRSA MATERNAL & CHILD HEALTH BUREAU	Federal Government	Marie Y Mann, MD, MPH, FAAP Senior Medical Advisor/Acting Deputy Director Division of Services for Children with Special Health Needs Maternal and Child Health Bureau 301-443-4925 office 202-498-8178 mobile mmann@hrsa.gov		

   a. **Identify funding type (grant, contract, subcontract, other):**
   grant

   b. **Explain any specific billing requirements (e.g: hold all charges, etc):**
   none

   c. **Has the project funding already been approved by the sponsor or funding agency?**
   Approved

   d. **Location of Research in addition to Primary Children's (i.e., PCH Riverton, or other Intermountain facilities**

   None

4. **Will data be pulled from any PCH or Intermountain electronic system(s)?**
   ● **Yes** ○ No

5. **Do you need a qualified data analyst from intermountain to query an Intermountain or PCH database in order to produce a limited data set for your study?**
   ○ Yes ● **No**

6. **Will individuals associated with this study need to be granted access to PCH or Intermountain information systems?**
   ○ Yes ● **No**

7. **Will patient consent be obtained for access to the patient information?**
   ○ Yes ● **No**

8. **Could there be any inventions developed from this research?**
   ◯ Yes ● **No**

9. **Does this study involve inpatients?**
   ● **Yes** ◯ No
   Check all that apply:
   Infant Medical Surgical Unit (IMSU)
   Children's Medical Unit (CMU)
   Pediatric Intensive Care Unit (PICU)

10. **Does this study involve outpatients?**
    ● **Yes** ◯ No
    a. **Percent Inpatient:**
       20
    b. **Percent Outpatient:**
       80
    c. **Check all that apply:**
       Other (List)
       If Other, please list:
       Outpatient Services

11. **Will ANY of the participants be non-English speaking?**
    ◯ Yes ◯ No

12. **Does this study involve any other PCH departments?**
    ◯ Yes ● **No**

13. **Will the PI, study coordinator, research assistant or other person associated with this proposal need access to PCH facilities, systems, or equipment that they don't already have?**
    ◯ Yes ● **No**

14. **Will PCH staff be required to perform any duties associated with this study in addition to routine patient care activities?**
    ◯ Yes ● **No**

15. **Are diagnostic studies required as part of this study?**
    ◯ Yes ● **No**

16. **Are any diagnostic studies requested above standard of care intended to be charged to an institutional account?**
    ◯ Yes ● **No**

17. **This study is not an investigational drug study.**
    This study is not an investigational use of a medical device study.

    Participants PCH 1st year:
    24
    Participants PCH total study:
    300

18. # Cybersecurity Questions for Intermountain

Intermountain CyberSecurity conducts risk assessments on research projects involving Intermountain Data. Intermountain Data is considered to be any information that originates from an Intermountain owned and/or managed information system. For example: iCentra, HELP2, Intermountain's EDW, SelectHealth, etc. The following set of questions is designed to gather study-specific information regarding data handling and security considerations for any component of the research project using Intermountain Data or systems and should be answered within this context.

Chart Review

For the purposes of this study will you export, transcribe, abstract, or otherwise copy information from an Intermountain information system?

● **Yes** ○ No

19. ## Data Storage

Where will the Intermountain Data that you have obtained for use in the study be stored?

There are no items to display

20. **Describe all entities that will have access to Intermountain Data:**

21. ## Data Sharing:

How will Intermountain Data be sent or provided to the University of Utah?

There are no items to display

22. **Approximately how many Intermountain patient records will be shared with the University of Utah for this study?**

23. **The University of Utah will utilize which of the following Intermountain Data types/elements:**

There are no items to display

24. **Will you send Intermountain Data to an individual or entity outside of Intermountain or the University of Utah?**

○ Yes ○ No

25. **Will Intermountain be required to send Intermountain Data directly to entities other than the University of Utah (e.g. spreadsheet, database, electronic documents)?**

○ Yes ○ No

26. **Will any data be transferred, stored, or accessed outside the United States?**

○ Yes ○ No

27. ## Additional Questions:

Will the sponsor or other participating organizations provide medical devices that will require access to Intermountain networks?

◯ Yes ◯ No

28. **Will the sponsor or other participating organizations provide computer hardware (e.g. laptops, tablets, mobile devices) for this study that will store Intermountain Data or require access to Intermountain networks?**
◯ Yes ◯ No

29. **Will the study require the use or installation of computer software/applications on Intermountain computing devices (e.g. laptops, workstations)?**
◯ Yes ◯ No

30. **Will you need support from PCH in the creation, deployment, modification, or configuration of software?**
◯ Yes ● **No**

Please contact us with any questions or concerns regarding completion of this. Please note both IRB approval and PCH administrative approval is required prior to starting the project. Thanks again for your support as together we put the *Child First and Always.*
PCHResearch@imail.org || 801-408-1991 opt 1

IRB_00088596 **Created:** 12/9/2015 12:01 PM **IRB_00088596 Finish**

PI: Flory Nkoy MD, MS, MPH **Submitted:** 2/12/2016

Title: SELF-MANAGEMENT INTERVENTION FOR CHILDREN WITH CHRONIC MEDICAL COMPLEXITY

Finish Instructions

Finish Instructions

1. **To view errors, select the "Validate" option at the top-left of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**