# #2001957718 - Medication Adherence Given Individual SystemCHANGE(TM) in Advancing Nephropathy (MAGICIAN) Pilot Study

## Protocol Information

| Review Type | Status | Approval Date | Continuing Review Date |
|---|---|---|---|
| **Expedited** | **Approved** | **Oct 31, 2023** | **Apr 09, 2020** |

| Expiration Date | Initial Approval Date | Initial Review Type |
|---|---|---|
| **--** | **Apr 09, 2020** | **Expedited** |

## Feedback

Approval Comment

Amendment A016

This research is approved under the following expedited categories:

- Category 5
- Category 6
- Category 7

# Protocol Amendment Form

### Amendment Request

4000

## Select your Protocol Type

Expedited/Full Board

4012

## Amendment Number

A016

4001

## Select the types of changes being made.

Other changes

4003

## Select the appropriate status of the study.

Closed to Enrollment – Research interventions continue

4004

## Describe the changes being made.

Those currently participating in the control intervention will be recruited to participate in the SystemCHANGE Intervention. IFC updated to reflect this change.

4005

## Why are these changes being made (i.e. what is the rationale for these changes)?

To increase understanding of how SystemCHANGE can increase medication adherence in those who have chronic kidney disease. Previous enrollment numbers are not significant for complete data analysis. Even though not a true crossover design, the increased enrollment in the SYstemCHANGE intervention will lead to better discoveries to yield R01 funding.

4006

## Will any previously enrolled subjects be informed of these changes?

No

4011

## Explain why subjects will not be informed.

Only those currently enrolled in the Main Study Control Intervention will be made aware of these changes and re-consented. Others who have completed the study will not be eligible for this change.

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**General Information**

## Principal Investigator

Ellis, Rebecca

## Lead Unit

IN-NURS - NURSING

## Protocol Title

Medication Adherence Given Individual SystemCHANGE(TM) in Advancing Nephropathy (MAGICIAN) Pilot Study

**Personnel**

Person

Ellis, Rebecca

Email Address

rjbartle@iu.edu

Researcher Role

Principal Investigator (PI)

Home Unit

IN-NURS - NURSING

Contact Roles

Permissions

Full Access

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI<br>01/30/23 - 01/30/28 | Biomedical Researcher - Stage 2 - CITI<br>09/19/22 - 09/18/27 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Hill, James

Email Address

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI | 10/13/20 - 10/12/25 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Kerley, Denise

Email Address

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

**Training**

Behavioral/Social Science Researcher - Stage 1 - CITI
03/25/20 - 03/24/23
Expired

Biomedical Researcher - Stage 1 - CITI
02/22/17 - 02/22/20
Expired

**COI Disclosure**

Status: Approved

**Personnel Attachments**

**Attachment**

Kerley_2020_citiCompletionReport1927386.pdf

**Name**

Citi

**Attachment Type**

Other

**Comments**

**Attachment**

Kerley_032420_updated Conflict Of Interest.pdf

**Name**

COI

**Attachment Type**

Site Specific Personnel List

**Comments**

Person

Perkins, Susan

Email Address

sperkin1@iu.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Biomedical Researcher - Stage 1 - CITI<br>09/27/22 - 09/26/27 | Behavioral/Social Science Researcher - Stage 4 - CITI<br>09/27/22 - 09/26/27 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Russell, Cynthia

Email Address

russellc@umkc.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Affiliation Type

Non-Affiliated

Training

Cynthia Russell has no training courses on file.

COI Disclosure

Status: Not Disclosed

Personnel Attachments

Attachment

1R21NR019348-01.pdf

Name

Summary Statement

Attachment Type

Other

Comments

Person

Sinha, Arjun

Email Address

adsinha@iu.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

Biomedical Researcher - Stage 1 - CITI
11/15/22 - 11/15/27

VA Training - CITI
11/17/17 - 11/17/21
Expired

COI Disclosure

Status: Approved

Personnel Attachments

Person

Zvonar, Sarah

Email Address

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Researcher Role

Key Personnel

Contact Roles

Permissions

Full Access

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 4 - CITI | 08/31/21 - 08/30/26 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Elomba, Charles

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chelomba@iu.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

Behavioral/Social Science Researcher - Stage 1 - CITI
05/16/22 - 05/15/27

Biomedical Researcher - Stage 1 - CITI
05/07/22 - 05/06/27

COI Disclosure

Status: Approved

Personnel Attachments

Person

Hays, Matthew

Email Address

maedhays@iupui.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

**Training**

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI<br>09/13/21 - 09/12/26 | Biomedical Researcher - Stage 1 - CITI<br>09/13/21 - 09/12/26 |
| Biomedical Researcher - Stage 2 - CITI | 08/30/21 - 08/29/26 |

**COI Disclosure**

Status: Approved

**Personnel Attachments**

**Person**

Lillie, Matthew

**Email Address**

malillie@iu.edu

**Researcher Role**

Other Research Staff

**Contact Roles**

**Permissions**

Read-Only

**Affiliation Type**

IU

**Training**

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI<br>09/10/21 - 09/09/26 | Biomedical Researcher - Stage 1 - CITI<br>09/10/21 - 09/09/26 |

COI Disclosure

Status: Not Disclosed

Personnel Attachments

Person

Carpenter, Janet

Email Address

carpentj@iu.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

Behavioral/Social Science Researcher - Stage 1 - CITI
08/27/10 - 08/26/13
Expired

Biomedical Researcher - Stage 1 - CITI
05/06/22 - 05/05/27

COI Disclosure

Status: Approved

Personnel Attachments

Person

Draucker, Claire

Email Address

cdraucke@iu.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 4 - CITI | 12/18/20 - 12/17/25 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Short, Danielle

Email Address

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

Behavioral/Social Science Researcher - Stage 1 - CITI
09/06/19 - 09/05/22
Expired

Biomedical Researcher - Stage 1 - CITI
05/11/21 - 05/10/26

COI Disclosure

Status: Expired

Personnel Attachments

Person

Wilson, Sylvia

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI | 06/04/22 - 06/03/27 |

COI Disclosure

Status: Expired

Personnel Attachments

Person

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

**Training**

Behavioral/Social Science Researcher - Stage 1 - CITI 11/15/21 - 11/14/26

**COI Disclosure**

Status: Approved

**Personnel Attachments**

**Person**

Smith, Grace

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smithgrc@iu.edu

**Researcher Role**

Key Personnel

**Contact Roles**

Protocol Viewer

**Permissions**

**Affiliation Type**

IU

**Training**

Behavioral/Social Science Researcher - Stage 1 - CITI 05/19/22 - 05/18/27

**COI Disclosure**

Status: Expired

**Personnel Attachments**

Person

Williams, Alexis

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aljewill@iu.edu

Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI | 06/16/22 - 06/15/27 |

COI Disclosure

Status: Expired

Personnel Attachments

Person

Vires, Mandy

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI | 06/29/22 - 06/28/27 |

COI Disclosure

Status: Expired

Personnel Attachments

Person

Kerley, Basia

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

Behavioral/Social Science Researcher - Stage 1 - CITI
09/03/22 - 09/02/27

Biomedical Researcher - Stage 1 - CITI
02/18/20 - 02/17/23
Expired

COI Disclosure
Status: Approved

Personnel Attachments

Person

Elliott, Shannon

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

**Training**

Behavioral/Social Science Researcher - Stage 1 - CITI
09/19/22 - 09/18/27

Biomedical Researcher - Stage 1 - CITI
09/19/22 - 09/18/27

**COI Disclosure**

Status: Approved

**Personnel Attachments**

**Person**

Miller, Courtney

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**Researcher Role**

Key Personnel

**Contact Roles**

**Permissions**

**Affiliation Type**

IU

**Training**

Behavioral/Social Science Researcher - Stage 1 - CITI 01/01/23 - 01/01/28

**COI Disclosure**

Status: Approved

**Personnel Attachments**

Person

Bustin, Rebecca

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI | 01/27/23 - 01/27/28 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Kapunan, Andrei

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Behavioral/Social Science Researcher - Stage 1 - CITI | 02/26/23 - 02/26/28 |

COI Disclosure

Status: Approved

Personnel Attachments

Person

Hoffman, Colin

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Researcher Role

Key Personnel

Contact Roles

Permissions

Read-Only

Affiliation Type

IU

Training

| | |
|---|---|
| Biomedical Researcher - Stage 1 - CITI | 08/03/22 - 08/02/27 |

COI Disclosure

Status: Approved

Personnel Attachments

Protocol Type

## Select Protocol Type

Expedited

Participant Type

## Participant Information

Participant Type

Total

Participant Number

150

Organizations

## Organizations List

Organization

IU HEALTH

Organization

ESKENAZI HEALTH

Organization

INDIANA UNIVERSITY (UA)

Funding

**Will the study be funded, fully or partly by, any of the following sources (this includes pass through funding)? *Select all that apply.***

Federal funding

## Funding Sources

Funding Source

NATIONAL INSTITUTE OF NURSING RESEARCH

Conflicts of Interest

q134

**Are any of the investigators listed in the personnel section aware of an institutional conflict of interest which could affect or be affected by this research?**

No

q24901

**Do any of the investigators listed in the Personnel section (or their immediate family members) have a significant financial interest which could affect this research?**

No

q24905

**Does the Principal Investigator affirm all investigators listed as personnel on this protocol have agreed to participate in this project, are aware of their status and role, and have been adequately trained to participate in the project?**

Yes

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**A-Level of Review**

q720

**Does any research activity in this study present more than minimal risk to human subjects?**

No.The research may qualify for Expedited review if all research procedures fall into one of the categories below.

q721

## Check all category(ies) which apply to this research.

Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
Category 6 - Collection of data from voice, video, digital or image recordings made for research purposes
Category 7 - Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

q724

## Will the researchers be using a data collection form?

Yes. It is/will be attached.

q23340

## Would identification of subjects and/or their responses reasonably place them at risk for any of the following (check any that apply):

None

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**B-Lay Summary Research Design**

q22122

## Describe the purpose of this study in lay terms, including research question(s) and hypothesis.

The purpose of this-group, randomized, controlled trial is to evaluate the refined SystemCHANGE™ against attention control patient education in CKD patients taking RAAS medications. Patients will be recruited from two sources: 1) the largest and most comprehensive health care system in the state and 2) one of the largest essential health care systems in the country. Data are collected at baseline, 8 weeks(immediately post-intervention)and 12 weeks. Specific aims are to: Aim 1. Estimate acceptability, outcome expectancy and credibility of the refined SystemCHANGE™ Intervention and for the attention control at 8 and 12 weeks after baseline. Aim 2. Estimate preliminary efficacy of SystemCHANGE™ Intervention versus attention control on medication adherence (primary outcome) and personal systems behavior (mechanism of action) at 8 and 12 weeks among people with CKD taking a once-daily RAAS inhibiting medication. The immediate impact of this study will be data to inform the design of a future, fully powered, efficacy trial. If findings are as expected, we will proceed to an R01 application. If findings are not as expected (e.g., negative), we will work to improve the SystemCHANGE™ intervention or move to a different intervention in future trials. The long-term impact of this line of research will be additional empirical evidence for novel medication adherence interventions in this population to inform future evidence-based guidelines, position statements, and practice recommendations.

q22123

## List and describe all research interactions and/or interventions, including the frequency and duration of procedures, and length of participation for individual subjects.

WHAT WILL HAPPEN DURING THE STUDY? This study has 3 phases- the screening phase, the intervention phase, and the maintenance phase. Before being invited to participate in this study, you will be asked questions from the 6-item cognitive screening survey to make sure you qualify for the study. Screening Phase If you are eligible to take part in the study, we will begin by reviewing your medical records for medications you take, what level of renal impairment you have, and may periodically review your records if you have medication changes or visits with your doctor or hospital. After this review, with the study nurse, we will ask you to fill out a demographics form. After this, we will monitor how you take your medication by giving you a pill bottle to use that has an electronic cap that will let us know when and how often you open the pill bottle to take a pill. For two months, you will use this special pill bottle and remove the cap when you normally take your medication. After you take your medication, you will put the cap back on the bottle. You will also be given a discrepancy log to make notes on your medication taking. The first and the fourth week the study nurse will call you to ask how you are using the pill bottle and cap to make sure you are not having any problems using it. At the end of the two-months, someone from our study team will call you and tell you how to mail the empty bottle and cap back to the study team. At this time, we will ask you survey questions about using the Mems and the patient activation measure (PAM-13). The study team will give you a pre-paid envelope to return the bottle and cap. Then you can mail it back to us by putting the sealed envelope in a US postal mailbox. The study investigator will then look at the information from the cap and if you have a medication score of less than 0.85, we will ask you to continue in the study. If your score is 0.85 or greater, we will thank you for your participation and you will end the study. If you are invited to participate in the next phase of the study, we will randomly assign you to treatment group 1 or treatment group 2. Random assignment is like flipping coin-heads put you in one group and tails puts you in the other group. Both groups will get an intervention for improving kidney health. Intervention Phase The intervention phase is next. If you are invited to continue the study, we will arrange a time to contact you via telephone or

virtually. Before that meeting, your electronic cap, and the bottle will be returned to you and you will be asked to use it for 12 more weeks. You will also be asked to complete additional surveys. These surveys include 1) Acceptability Scale, 2) Outcome Expectancy, 3) Treatment Credibility Questionnaire. You will again use a special bottle and cap to keep and take your medication. You will also be given a special mobile phone for this study. Each week for 6 weeks, you will place the phone near the bottle to send data to the study team. After the data is received, you will get one text message on the provided mobile phone each week for 6 weeks. These text messages are education about your disease and disease process. A member of our study team will call you each week to ask you questions and make sure the equipment is working correctly. The study team member will also discuss information from the first visit with you. We will also ask you about any healthcare visits that you have with your healthcare provider. This might include a visit to your providers for a checkup and any time spent in the hospital or a visit to the emergency room. Treatment group 1 will receive education that will help to learn more about caring for your chronic kidney disease. You will receive your first materials during the research nurse's visit to your home. You will receive a telephone call from the research nurse to review and discuss the educational materials throughout the study. In addition, the research nurse will ask you if you have had any changes to your medications and what healthcare providers you have seen recently. Treatment group 2 will receive training by a research nurse who will work with you to learn about SystemCHANGE™. You will get a printer report from the MEMS cap to see how you are doing with taking your medications. Part of this intervention involves completing time worksheets together with the study nurse (Important People Form, Life Routine Form, Solutions Form). This helps you identify people who are important in helping you with taking your medicines, and identify your daily routines, specifically the routines around the times that you are scheduled to take your medicines. The research nurse will ask you to think about possible changes in your routines that may make it easier for you to take your medicines every day on time without having to remember. The research nurse will call you to discuss the important people you marked on the Important People Form and which solutions you have decided to use from the Solution Form. Throughout the study, the research nurse will send your personal medication-taking report. The research nurse will then telephone you to discuss how you are doing with taking your medicine every day on time using the forms. Together, you will discuss

possible solutions for improving your medication taking. You will try out the ideas and then see if your medication-taking is getting better from your personal medication-taking report. In addition, the research nurse will ask you if you have had any changes to your medications and what healthcare providers you have seen. Amended procedures. We are inviting participants who have completed Treatment group 1 to complete Treatment Group 2 intervention as well. Participation in this additional study of Treatment group is voluntary. If you chose to also participate in Treatment Group 2, you will follow the procedures outlined above, starting with the intervention phase after you have consented to participate. You will be asked to keep using the electronic pill bottle for 12 more weeks. You will also be asked to complete additional surveys. These surveys include 1) Acceptability Scale, 2) Outcome Expectancy, 3) Treatment Credibility Questionnaire. You will keep using the special mobile phone for this study. Each week for 6 weeks, you will place the phone near the bottle to send data to the study team, like you have been doing. After the data is received, you will get one text message on the provided mobile phone each week for 6 weeks. These text messages are education about your disease and disease process. A member of our study team will call you each week to ask you questions and make sure the equipment is working correctly. The study team member will also discuss information from the first visit with you. We will also ask you about any healthcare visits that you have with your healthcare provider. This might include a visit to your providers for a checkup and any time spent in the hospital or a visit to the emergency room. The group who has completed Treatment group 1 will follow the protocol for Treatment group 2. Participants will receive training by a research nurse who will work with you to learn about SystemCHANGE™. Part of this intervention involves completing time worksheets together with the study nurse (Important People Form, Life Routine Form, Solutions Form). This helps you identify people who are important in helping you with taking your medicines, and identify your daily routines, specifically the routines around the times that you are scheduled to take your medicines. The research nurse will ask you to think about possible changes in your routines that may make it easier for you to take your medicines every day on time without having to remember. The research nurse will call you to discuss the important people you marked on the Important People Form and which solutions you have decided to use from the Solution Form. Throughout the study, the research nurse will send your personal medication taking report to your phone. The research nurse will telephone you

to discuss how you are doing with taking your medicine. Together, you will discuss possible solutions for improving your medication taking. You will try out the ideas and then see if your medication taking is getting better from your personal medication taking report. In addition, the research nurse will ask you if you have had any changes to your medications and what healthcare providers you have seen. Maintenance Phase In both groups, at 6 weeks, someone from the study staff will call you and ask you some of the same questions as before about your medication and your kidney health, as well as repeat the previous surveys. They will also ask you some questions about participating in the study. In this final phase, you will continue to use the electronic cap and bottle to take your medications. At the end of the twelve weeks, you will once again take the surveys as before. You will receive a postage-paid envelope to return the cap to the study nurse. At this time, you will also take part in a semi-structured interview. In both groups, all of the interactions that you have with the study nurse over the telephone and virtually will be audiotaped so that the investigator can make sure the study nurse is following the research study steps. At the completion of the twelve weeks, you will have no additional testing in the study and you will continue to follow-up with your providers.

q23358

## Will any non-English study documents be uploaded?

No

q24919

## Is this research funded by, or has a funding application been submitted to, a federal agency? This includes federal pass-through funding.

Yes

q25019

Provide the name of the federal funding agency.

q25019

Provide the name of the federal funding agency.

National Institute Nursing Research

q23234

## List inclusion criteria - eligibility criteria for subjects.

(1) age > 18 years, (2) prescribed at least 1 daily RAAS inhibiting medication, (3) CKD diagnosis eGFR category G1 to G4, (4) RAAS inhibiting medication adherence of <.85 documented during screening (5) proteinuria defined as a urine Protein-to-Creatinine ratio > 150 mg/g or urine Albumin-to-Creatinine ratio >30mg/g (6) able to speak, hear, and understand English determined by the ability to participate and comprehend conversation about potential inclusion in the study, (7) self-reported ability to open a pill cap, (8) able to self-administer RAAS inhibiting medications, (9) willing to use a study phone, (10) has no cognitive impairment as determined by a score of 4 or greater on the 6-item Telephone Mental Status Screen Derived from the Mini-Mental Status Exam73 (cognitive screener), (11) has no other diagnoses that may shorten life span, such as metastatic cancer, (12) is not hospitalized, (13) receives care through IUH or Eskenazi.

q23235

## List exclusion criteria (any criteria which would exclude otherwise acceptable subjects).

Participants with kidney failure defined by GFR <15 mL/min/1.73m2.13 Participants will be excluded if they are receiving dialysis or have dialysis access placed (e.g., graft or arteriovenous fistula) in anticipation of starting dialysis. Kidney and kidney-pancreas transplant recipients will be excluded. Participants will be excluded if they have another medication adherence strategy in place (e.g., medication adherence pill packs or blister packs from a pharmacy).

q23346

**Will subjects be paid for their participation in the study? Payment includes reimbursement of expenses (other than compensation for injury).**

Yes

q23347b

**Describe the payment arrangement, including amount and timing of disbursement.**

Participants will be paid $20 honorarium at screening completion. We will pay participants in the intervention and attention control groups $30 at the study end to thank them for their time. For those who participate in both treatment groups. As a thank you, you will receive $30 at the completion of the 12-week educational intervention as well as $30 at the completion of the 12-week SystemCHANGE™ intervention. This will be mailed to you within 10 days of receipt of the study materials.

q23348

**Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation.**

The amount recognizes the commitment time by the participant, yet a relatively minimal amount that is consistent with other behavioral studies.

q23349

**Will partial payment be provided if the subject withdraws prior to completion of the study?**

No

q23350

## Explain why failure to offer partial payment will not unduly influence subjects to complete the study.

Payments are associated with specific phases of the study and a minimal amount, and providing partial payments would not reflect positively to patient participants. Payment compensations are provided after each phase.

q23352

## Does this research involve (choose all that apply):

- the STUDY of any of the following products (regardless of FDA approval status). “The study of” means at least one objective of the study is related to obtaining data about the product
- USE of any of the following products which have not been cleared or approved by the FDA for use in the US
- USE of any of the following products for open label extension, treatment, or compassionate use

NONE

q23454a

## This research involves (check all that apply):

None of the Above

q25049a

## Is this research considered a prospective clinical study?

Yes - This study may require entry in OnCore.

q30000a

## Is this community-engaged research?

No

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C-Sites and Collaborations

q700

## Are there additional locations of research, not already listed?

No

q704

## Are you requesting that IU provide IRB approval for any researchers who are NOT IU affiliates?

No

q710a

## Is this a multi-center study or multi-site clinical trial?

No

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**D-Recruitment Methods**

q23236

## Describe how potential subjects will be initially identified.

There will be multiple forms of recruitment. Eligible patients will be identified by Regenstrief recruitment core based on inclusion criteria. Co-I Sinha will obtain permission from nephrology colleagues through IUHP for permission to contact their patients using an opt-out recruitment strategy with letters mailed to eligible individuals home address. Letters will be mailed to eligible patients introducing the opportunity to participate in the study. Patients who wish to opt-out or opt-in do so by contacting the phone number identified on the recruitment materials and/or following the instructions on the mailed letter. After these letters are mailed, participants will be contacted in randomized order from this Regenstrief list of potential participants. In addition to the self-referral, opt-out procedures, and phone calls from the Regenstrief list; participants will be recruited in the clinics in a face-to-face fashion. Physicians and staff will identify potential participants, with the help of the research assistant, and ask potential participants if they would be willing to speak with the research assistants about potential involvement. Research assistants present in the clinic will be wearing attached buttons.

q30002

## Check any of the following sources of information which will be used to identify potential subjects.

Subject self-referral in response to recruitment materials
Medical records or clinic schedules
Physician/provider referral
Other

q30002C5Text

## Explain the Other source(s) of information which will be used to identify potential subjects.

Regenstrief Data Core Clinic Schedules Medical Records

q30003

## Describe how potential subjects will be initially contacted.

Regenstrief will generate a patient list. The resulting list of patients will be used as a sampling pool. Using a computer-generated list of random numbers the biostatistician produces, the RA will randomly select each potential subject from the list. The RA will contact identified patients and ask if they are willing to discuss possible participation in a study. Brochures will be utilized to introduce the participants briefly to the study and introduce them to the study team. Participants will be identified prior to their scheduled clinic visit from clinic schedules then verified with medical records for inclusion and exclusion criteria. Flyers in the patient facing areas will give general information about qualifications and process of the MAGICIAN study, as well as information to contact MAGICIAN team. A physician and staff flyer will give general information for the staff if general questions are asked when a research assistant is not present or with another potential participant.

q23237

## Check any of the following recruitment materials which will be used to contact potential subjects.

Direct Mail/Email
Flyers/Brochures
Verbal Scripts

q25426b

## Select any of the following circumstances which apply to this research.

None of the above.

q23245

## Would participation in this study preclude subjects from participating in other research studies?

No

q23296

## List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research.

While participating in the study, the risks, side effects, and/or discomforts include: • Possible frustration when using the electronic medication monitoring (EMM) cap • Fatigue (physical or mental during answering the questions • Possible loss of confidentiality • Uncomfortable answering personal questions

q23297

## Describe procedures for protecting against, or minimizing, the potential risks listed above. Include any procedures that are already being performed on subjects for diagnostic, treatment, or standard purposes.

We will minimize these risks by: • Hiring Research Assistants and Nurse Intervenors who have education and experience working with people with health conditions • Making sure you are comfortable using the EEM cap before starting this study and checking on you weekly for issues. • To minimize possible fatigue, you will be asked every 20 minutes during the interviews if you would like to take a break. • Keeping all files in a locked, secure, location available only to the research team. • If uncomfortable with questions, tell the researcher you do not want to answer that particular question • Face-to-face recruitment will be in an area away from the other patients and staff in the clinic setting.

q23299

## Explain how research data will be protected so that only approved persons have access to subjects' identifiable data (i.e. confidentiality of data).

The PI will be responsible for all data management. Study participants' (Pps) confidentiality will be maintained using the following techniques: (1) each Pp will be given a unique study identification code to enable data source merging, e.g. demographics, MEMs Capmedication adherence data, (2) the unique study identification codes will be stored in a locked separate file, (3) all electronic data will be stored in password-protected files, in password-protected computers. All data hard copies will be stored in the PIs' locked office, in locked file cabinets, and (4) all Pp names and other identifiers will be removed from the data upon assignment of a study identification code

q23300

## Explain how subjects' physical privacy will be protected, both during recruitment/screening and during participation in the research.

The patients' physical privacy will be maintained by recruitment materials sent to possible participants' homes. Potential participants arriving in the clinic will interact with the research staff in a private area with MAGICIAN research assistants who have passed required CITI training as well as background checks. Interviews throughout the study are conducted via phone or virtually. Interactions of text messages and phone calls will be during the participants choosing.

q23301

## Is there a potential for subjects to benefit directly from participation in the study?

Yes

q23302

## Describe the potential benefits to be gained by the individual SUBJECT. Please note that payment for participation is not considered a benefit.

As a result of this study, we anticipate that the participants may take their medications better, contributing to better adherence.

q23303

## State the potential benefits or information which may accrue to SCIENCE or SOCIETY in general as a result of this work.

The immediate impact of this study will be data to inform the design of a future, fully powered, efficacy trial. If findings are as expected, we will proceed to an R01 application. If findings are not as expected (e.g., negative), we will work to improve the SystemCHANGE™ intervention or move to a different intervention in future trials. The long-term impact of this line of research will be additional empirical evidence for novel medication adherence interventions in this population to inform future evidence-based guidelines, position statements, and practice recommendations.

---

**F-Data Safety Monitoring**

q23304

## Describe the provisions for monitoring the data to ensure the safety of subjects.

Complete plan in attachment.

---

**H-Informed Consent**

q901

## Will all or some subjects consent to participate in the research?

All subjects (or their legally authorized representative) will consent to participate in the research

q909

## For those subjects who will consent to participate, explain how subjects (or subjects' legally authorized representative) will be presented with the information needed to decide to participate, including all elements of informed consent.

Recruitment sites will generate lists of potentially eligible patients using electronic health record data to ensure a match with eligibility requirements with regard to prescribed RAAS inhibitors, diagnosis and stage of CKD and proteinuria. The study staff will randomly select each potential participant from the list using a biostatistician produced list of random numbers, and mail letters to identified patients describing the study and opt-out procedures to avoid being contacted by the study staff. The study staff will contact patients by phone to discuss possible study participation and, if interested, verify study eligibility including administering the cognitive screener. If interested and eligible, the study staff will mail consent documents with instructions for returning them by mail/email. After receiving the signed consent, the participant will move into the screening phase. Staff will record reasons for those not eligible or not interested in the study.

q903

## Describe any informed consent tools which will be used to present information to potential subjects (i.e. consent documents, videos, brochure, drug/device information, etc) and how they will be used.

Informed consent documents will be mailed to the participants and asked to be mailed back after the initial screening of inclusion/ exclusion criteria and an informal agreement to participate. The initial screening via telephone will provide details of the study including any risks or benefits as well as answer any questions pertaining to the study. The informed consent documents also provide an opt-out at any time by contacting the primary investigator (Rebecca Ellis) at (317)274-0047. In clinic recruitment participants will complete the informed consent at time of contact.

q925

## Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Because the initial screening takes place via telephone and informed consent is to be obtained via mail for participation, there is a period of days between the telephone call, returned signed consents, and an initial visit via phone or virtually. This ensures that participation is voluntary, there is sufficient time to consider participation, and multiple opportunities to discuss involvement further, as well as change their decision.

q30127a

## Will you include all required elements of consent in your consent process?

Yes

q921

## Indicate in what language(s) the consent conversation will be conducted.

English

q926

## Explain how you will ensure potential subjects understand the information you have presented to them before they agree to participate in the study.

We will leave time for questions with potential participants. We will utilize the "teach back" method to allow participants a chance to explain the information given to them about the study in their own terms.

q929

## Briefly describe any training provided to investigators who are obtaining informed consent.

Staff will be trained rigorously in study procedures. Prior to the start of the study, staff will engage in role-play and simulation. All staff working on this study have completed CITI training.

q931

## Does the research include any minimal risk procedures to which subjects will not consent?

No

q23678a

## For those subjects who will consent to participate, choose whether the consent process will be documented by a written signature from subjects.

All consented subjects will provide a written signature as documentation of consent.

q30129a

**Will subjects participate in any study activity prior to physically signing a consent document?**

No

q940a

**Explain the process for obtaining a written signature from subjects.**

After names are given by the provider, then randomly selected to be contacted for potential participation in this study, the participants are contacted via telephone for initial screening of inclusion/ exclusion criteria. The consent form is mailed to participants and the signed consent form will be mailed back with a provided self-addressed, stamped envelope before participation in this study. Those recruited in the clinic setting will be informed of the study procedures and two informed consents, one to sign and one to maintain for their records.

---

## K-HIPAA

q23253

**Are you part of a covered entity (health care provider that transmits health information electronically) or are you receiving information from a covered entity as part of your research?**

Yes

q23254

**Will protected health information be utilized, accessed, collected, or generated as part of the study?**

Yes

q30347a

**Select the electronic systems to be used for the collection and/or storage of protected health information (ePHI). Choose all that apply.**

REDCap

---

q23257

**Will you be accessing or collecting protected health information for RECRUITMENT purposes?**

Yes

q23258

**Choose all that apply to the recruitment plans.**

Health information provided by clinicians not part of the study team

q23271

**Will the clinician direct the potential subject to contact the study team?**

Yes

q23277

**HIPAA applies to your study, and requires that you obtain authorization for PARTICIPATION in research, or that you request a waiver. Check all that apply.**

I will obtain written, signed authorization from subjects prior to their participation

q23278

**Will you be collecting information from subjects' medical records?**

Yes, I have uploaded an Authorization template to the Attachments section.

## Attachments

Attachment Type

Data Collection Instrument

Attachment

EMM Discrepancy Log.docx

Name

EMM Discrepancy Log

Comments

Attachment Type

Data Collection Instrument

Attachment

13 Health Care Use Form Revision 3.docx

Name

Health Care Use, Medical Appointments Form

Comments

Attachment Type

Data Collection Instrument

Attachment

9BIntervention Steps 1 and 2 Important People Etc. Forms Revision 2.docx

Name

Important People Form, Life Routine Form, Solutions Form

Comments

Attachment Type

Data Collection Instrument

Attachment

9C Intervention Steps 3 and 4 Questions.docx

Name

Questions for SystemCHANGE

Comments

Attachment Type

Data Collection Instrument

Attachment

PAM-13 .docx

Name

PAM-13

Comments

Attachment Type

Data Collection Instrument

Attachment

RO1_Ellis_Medical History.docx

Name

Medical Record Form

Comments

Attachment Type

Data Collection Instrument

Attachment

Social Support Appraisal.docx

Name

Social Support Appraisal

Comments

Attachment Type

Data Collection Instrument

Attachment

Acceptability Scales to add to appendix JSC.docx

Name

Acceptability Scale

Comments

Attachment Type

Data Collection Instrument

Attachment

R21_Acceptability_Scale (1).docx

Name

Accept

Comments

Attachment Type

Data Collection Instrument

Attachment

EllisAppendix-3.pdf

Name

Mental Status Screen, Systems Thinking, Demographic Form, Electronic Medication Monitoring Discrepancy Log, Medical History data collection form questionnaire, Perceived Health Status

Comments

Attachment Type

HIPAA Authorization Form

Attachment

MAGICIAN HIPPA.docx

Name

HIPPA

Comments

Attachment Type

Protocol

Attachment

R21_MAGICIAN_Intervention Figure2 Updated.xlsx

Name

Figure 2 restart

Comments

Attachment Type

Recruitment Materials

Attachment

Recruitment Script 10.31.2023.docx

Name

Script for phone calls

Comments

Attachment Type

Recruitment Materials

Attachment

Brochure MAGICIAN Final.pptx

Name

Brochure for participants

Comments

Attachment Type

Recruitment Materials

Attachment

Recruitment Letter Final- restart.docx

Name

Recruitment letter

Comments

Attachment Type

Recruitment Materials

Attachment

Amended_MAGICIAN_DSM.docx

Name

Comments

Attachment Type

Recruitment Materials

Attachment

MAGICIAN_STUDY-physician flyer 7.11.22.png

Name

Comments

Attachment Type

Recruitment Materials

Attachment

Magician Patient Pamphlet copy.png

Name

Comments

Attachment Type

Recruitment Materials

Attachment

KIDNEY DESIGN.pdf

Name

Comments

Attachment Type

Other

Attachment

MAGICIAN IFC amended letter.docx

Name

Comments

Attachment Type

Recruitment Materials

Attachment

MAGICIAN Study Image Flow _RJE.docx

Name

Imagery for recruiting to streamline conversations with potential participants.

Comments

Attachment Type

Recruitment Materials

Attachment

Clinic RA Screening Tool.docx

Name

Screening tool to facilitate conversations between RA's and Physicians

Comments

Attachment Type

Informed Consent Statement

Attachment

Final _MAGICIAN_IFC_10.31.2023.docx

Name

Comments

**End of Protocol Form**

KC IRB History

approvalDate

April 9, 2020

**FOR HSO OFFICE USE ONLY**

## Action History

Description

Expedited Approval

Date

January 8, 2021

**Action Date**

January 8, 2021

**Comments**

Amendment-004: Approved

**Updated By**

slbenken

**Update Time**

2021-01-08T12:00:00.000Z

**Description**

Assigned to Agenda

**Date**

January 8, 2021

**Action Date**

January 8, 2021

**Comments**

Amendment-004:

**Updated By**

slbenken

**Update Time**

2021-01-08T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

January 6, 2021

**Action Date**

January 6, 2021

**Comments**

Amendment-004: Submitted to IRB

**Updated By**

rjbartle

**Update Time**

2021-01-06T12:00:00.000Z

**Description**

Returned To PI

**Date**

December 8, 2020

**Action Date**

December 8, 2020

**Comments**

Amendment-004: Open for Incomplete Submission

**Updated By**

shream

**Update Time**

2020-12-08T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

December 7, 2020

**Action Date**

December 7, 2020

**Comments**

Amendment-004: Submitted to IRB

**Updated By**

szvonar

**Update Time**

2020-12-07T12:00:00.000Z

**Description**

Amendment Created

**Date**

December 7, 2020

**Action Date**

December 7, 2020

**Comments**

Amendment-004: Created

**Updated By**

szvonar

Update Time

2020-12-07T12:00:00.000Z

Description

Administrative Correction

Date

August 2, 2020

Action Date

August 2, 2020

Comments

updating funding

Updated By

larcohen

Update Time

2020-08-02T12:00:00.000Z

Description

Amendment Deleted

Date

July 13, 2020

Action Date

July 13, 2020

**Comments**

Amendment-003: Deleted - Delete amendment 3. (2001957718A003) I didn't realize Cynthia Russell was on there already. I do not have anything new to add.

**Updated By**

szvonar

**Update Time**

2020-07-13T12:00:00.000Z

**Description**

Amendment Created

**Date**

July 13, 2020

**Action Date**

July 13, 2020

**Comments**

Amendment-003: Created

**Updated By**

szvonar

**Update Time**

2020-07-13T12:00:00.000Z

**Description**

Expedited Approval

**Date**

July 13, 2020

**Action Date**

July 13, 2020

**Comments**

Amendment-002: Approved

**Updated By**

pattonle

**Update Time**

2020-07-13T12:00:00.000Z

**Description**

Assigned to Agenda

**Date**

July 13, 2020

**Action Date**

July 13, 2020

**Comments**

Amendment-002:

**Updated By**

pattonle

**Update Time**

2020-07-13T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

July 13, 2020

**Action Date**

July 13, 2020

**Comments**

Amendment-002: Submitted to IRB

**Updated By**

pattonle

**Update Time**

2020-07-13T12:00:00.000Z

**Description**

Returned To PI

**Date**

July 13, 2020

**Action Date**

July 13, 2020

**Comments**

Amendment-002:

**Updated By**

pattonle

Update Time

2020-07-13T12:00:00.000Z

Description

Submitted to IRB

Date

July 9, 2020

Action Date

July 9, 2020

Comments

Amendment-002: Submitted to IRB

Updated By

szvonar

Update Time

2020-07-09T12:00:00.000Z

Description

Returned To PI

Date

July 6, 2020

Action Date

July 6, 2020

Comments

Amendment-002: Open for Intake Pre-review

Updated By

shream

Update Time

2020-07-06T12:00:00.000Z

Description

Submitted to IRB

Date

July 2, 2020

Action Date

July 2, 2020

Comments

Amendment-002: Submitted to IRB

Updated By

szvonar

Update Time

2020-07-02T12:00:00.000Z

Description

Amendment Created

Date

July 2, 2020

Action Date

July 2, 2020

**Comments**

Amendment-002: Created

**Updated By**

szvonar

**Update Time**

2020-07-02T12:00:00.000Z

**Description**

Expedited Approval

**Date**

April 29, 2020

**Action Date**

April 29, 2020

**Comments**

Amendment-001: Approved

**Updated By**

pattonle

**Update Time**

2020-04-29T12:00:00.000Z

**Description**

Assigned to Agenda

**Date**

April 29, 2020

**Action Date**

April 29, 2020

**Comments**

Amendment-001:

**Updated By**

pattonle

**Update Time**

2020-04-29T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

April 29, 2020

**Action Date**

April 29, 2020

**Comments**

Amendment-001: Submitted to IRB

**Updated By**

pattonle

**Update Time**

2020-04-29T12:00:00.000Z

**Description**

Returned To PI

**Date**

April 29, 2020

**Action Date**

April 29, 2020

**Comments**

Amendment-001:

**Updated By**

pattonle

**Update Time**

2020-04-29T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

April 21, 2020

**Action Date**

April 21, 2020

**Comments**

Amendment-001: Submitted to IRB

**Updated By**

szvonar

**Update Time**

2020-04-21T12:00:00.000Z

**Description**

Returned To PI

**Date**

April 21, 2020

**Action Date**

April 21, 2020

**Comments**

Amendment-001: Open for Intake Pre-review

**Updated By**

shream

**Update Time**

2020-04-21T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

April 20, 2020

**Action Date**

April 20, 2020

**Comments**

Amendment-001: Submitted to IRB

**Updated By**

szvonar

Update Time

2020-04-20T12:00:00.000Z

Description

Amendment Created

Date

April 20, 2020

Action Date

April 20, 2020

Comments

Amendment-001: Created

Updated By

szvonar

Update Time

2020-04-20T12:00:00.000Z

Description

Expedited Approval

Date

April 9, 2020

Action Date

April 9, 2020

Comments

**Updated By**

pattonle

**Update Time**

2020-04-09T12:00:00.000Z

**Description**

Assigned to Agenda

**Date**

April 9, 2020

**Action Date**

April 9, 2020

**Comments**

**Updated By**

pattonle

**Update Time**

2020-04-09T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

April 9, 2020

**Action Date**

April 9, 2020

Comments

Submitted to IRB

Updated By

pattonle

Update Time

2020-04-09T12:00:00.000Z

Description

Returned To PI

Date

April 9, 2020

Action Date

April 9, 2020

Comments

Updated By

pattonle

Update Time

2020-04-09T12:00:00.000Z

Description

Submitted to IRB

Date

April 8, 2020

**Action Date**

April 8, 2020

**Comments**

Submitted to IRB

**Updated By**

szvonar

**Update Time**

2020-04-08T12:00:00.000Z

**Description**

Returned To PI

**Date**

April 6, 2020

**Action Date**

April 6, 2020

**Comments**

**Updated By**

pattonle

**Update Time**

2020-04-06T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

April 6, 2020

**Action Date**

April 6, 2020

**Comments**

Submitted to IRB

**Updated By**

szvonar

**Update Time**

2020-04-06T12:00:00.000Z

**Description**

Returned To PI

**Date**

March 30, 2020

**Action Date**

March 30, 2020

**Comments**

**Updated By**

pattonle

**Update Time**

2020-03-30T12:00:00.000Z

**Description**

Submitted to IRB

**Date**

March 23, 2020

**Action Date**

March 23, 2020

**Comments**

Submitted to IRB

**Updated By**

szvonar

**Update Time**

2020-03-23T12:00:00.000Z

**Description**

Protocol Created

**Date**

January 24, 2020

**Action Date**

January 24, 2020

**Comments**

Protocol created

**Updated By**

szvonar

Update Time

2020-01-24T12:00:00.000Z

# Administrative Details Form

## Protocol Details

9031

**Protocol Type**
Expedited

**Billing Account #**

**Study Status**

## Submission Details

9000

**Submission Review Level**
Expedited

9030

**Expedited Category.**
Category 5: Data or specimens that have been or will be collected for nonresearch purposes
Category 6: Data from voice, digital, or image recordings
Category 7: Survey, interview, focus groups, human factor, group behavior or characteristics

9002

**Criteria for Approval. Select to confirm.**
Approved: The criteria for approval of the research are satisfied in accordance with IU HRPP Policies, and applicable federal regulations.

## Protocol Determinations

9003

**Protocol Level of Risk.**

Minimal risk

9020

**Is renewal required for this research?**

No

9004

**Check all determinations that need to be made.**

Certificate of Confidentiality

9025

**Certificate of Confidentiality.**

The research is subject to the NIH Policy for Issuing Certificates of Confidentiality and therefore has been issued a Certificate.

9028

**Other Determinations.**