A Pilot Study of *The CKM JumpStart Tool*

Funding Agency: Doris Duke Charitable Foundation

Award: Clinical Scientist Development Award

Principal Investigator: Susan P.Y. Wong, MD

Protocol

2/15/2023

Abstract

Objective(s) and Hypotheses:
Conservative kidney management (CKM) is an important therapeutic alternative for patients who do not wish to pursue dialysis for their advanced chronic kidney disease (CKD). Conservatively managed patients can survive several years after their decision to pursue CKM and experience sustained quality of life until late in the course of illness.[1] Conservatively managed patients also spend less time in the hospital,[2-5] less often experience burdensome procedures,[2,5] and less often die in the hospital setting than patients treated with dialysis.[5-9] Despite a growing body of evidence and clinical services to support patients who do not wish to pursue dialysis,[10,11] patients rarely recall discussing more conservative options with their providers and are typically presented dialysis as the default treatment option for their advanced CKD.[12,13] This study aims to test the acceptability and feasibility of a novel communical tool, The CKM JumpStart Tool. We hypothesize that the CKM JumpStart Tool will be feasible and acceptable to patients with advanced CKD and their providers and will help to support informed and shared decision-making for treatment of advanced CKD.

Research Design:
This is a randomized pilot study of patients with advanced CKD and their close persons who are receiving care at University of Washington (UW) Medicine and VA Puget Sound Health Care System (VAPSHCS). The study utilizes medical record review, qualitative interviews, and standardized questionnaires to assess the feasibility and acceptability of the CKM JumpStart Tool and to explore differences in decisional conflict and goal concordant care between patients and who receive the decision aid and those who do not.

Methodology
We will recruit 76 patients aged 18 years and older with advanced CKD as defined as an estimated glomerular filtration rate (eGFR <25 ml/min/1.73m2 from UW Medicine and VAPSHCS. We will randomize patients in a 1:1 fashion to either usual care or receipt of the CKM JumpStart Tool. Patients will complete study procedures by phone or in-person, over a total of 3 study visits. We will also recruit providers of patients who received the CKM JumpStart Tool about their experiences using the the CKM JumpStart Tool.

Relevance
An important step to towards helping patients choose the right treatment for them and their advanced CKD is to promote discussion of the different treatment options with their providers. The proposed study has the potential to lead to the creation of a cost-effective, time-saving and scalable intervention to improve the care of patients with advanced CKD.

List of Abbreviations

CKD: chronic kidney disease

Conservative Kidney Management: CKM

eGFR: estimated glomerular filtration rate

UW: University of Washington, Seattle WA

VAPSHCS: VA Puget Sound Health Care System, Seattle WA

KRI: Kidney Research Institute, University of Washington, Seattle WA

VACOIN: VA Center of Innovation, Seattle WA.

Contents

1.0 Study Personnel

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2.0 Introduction

Chronic kidney disease (CKD) afflicts 1 in 7 Americans. Although dialysis is commonly regarded as a life-prolonging therapy for advanced CKD, there is growing recognition that dialysis is not always beneficial. Decisions about dialysis often involve difficult trade-offs between the potential gains in longevity and symptom management and the burdens of treatment including the

substantial time spent on dialysis, complications related to treatment, frequent interaction with healthcare system and loss of independence.

Conservative kidney management (CKM) is an important option for patients who choose not to pursue dialysis that focuses on slowing the decline in renal function, active symptom management, advance care planning and the provision of appropriate palliative care. Conservatively managed patients can survive several years after their decision to pursue CKM and experience sustained quality of life until late in the course of illness.[1] For adults aged ≥75 years with significant comorbidity and functional impairment, dialysis might not improve survival[2,9,14-17] and quality of life[18-20] beyond what can be achieved with a more conservative approach for advanced CKD. Conservatively managed patients also spend less time in the hospital,[2-5] less often experience burdensome procedures,[2,5] and less often die in the hospital setting than patients treated with dialysis.[5-9]

Despite a growing body of evidence and clinical services to support patients who do not wish to pursue dialysis,[10,11] patients rarely recall discussing more conservative options with their providers.[12,13] Although it is a professional obligation that all available treatment options are discussed with patients,[21] many providers find it difficult or are reluctant to discuss conservative options for advanced CKD.[22,23] Qualitative interviews with providers suggest that many feel ill-equipped to have a conversation about CKM or worry that if they do not offer dialysis, it would be perceived as "no care" or "giving up."[10,22]

The current application is to support a pilot study to test the acceptability and feasibility of a novel communication tool to help providers "jumpstart" a conversation about CKM with their patients that was created by the principal investigator (PI, Wong). The CKM JumpStart Tool has the potential to be a cost-effective, time-saving and scalable intervention to improve the care of patients with advanced CKD.

3.0 Objectives

We aim to conduct a randomized pilot study to test the feasibility and acceptability of a novel communication tool, called The CKM JumpStart Tool*,* and explore preliminary outcomes, including decisional uncertainty and goal concordant care to inform a future clinical trial. We hypothesize that the decision aid will be feasible and acceptable to patients and their providers.

4.0 Resources and Personnel

Study Sites:
This study will involve VAPSHCS and the UW. Study subjects will be recruited from UW Medicine and VAPSHCS in Seattle. UW will be used only as a recruitment site for non-Veteran patients, and this protocol covers VA research activity only. Original study data collected with UW Medicine will be stored and at the KRI. Original study data collected at VAPSHCS will be stored at the VACOIN. Deidentified UW patient data will be moved to VA Puget Sound to facilitate pooled analysis. All data analyses will occur at VACOIN. No VA data will be shared with the UW.

Study Team Personnel
Susan Wong, MD, Principal Investigator: She will provide overall project leadership and supervision of study performance and progress. She will oversee all aspects of the study subject

recruitment and follow-up, data collection and management, analyzing and interpreting data, and preparing study findings for publication and presentation. She will have access to protected health information.

Taryn Oestreich, MPH, Research Coordinator: She will assist with contacting and recruiting subjects, obtaining subject informed consent, administering the intervention and surveys, interviewing subjects, and collecting and analyzing study data. She will have access to protected health information.

Rachel Smith, BA, Research Coordinator: She will assist with all aspects of study coordination. She will also assist with recruitment and data collection and analysis. She will transcribe audio-recorded interviews collected for this study. She not have access to protected health information.

David Prince, PhD, Biostatistician: He will perform the data analysis. He will have access to protected health information.

5.0 Study Design

We will conduct a randomized pilot study to test the feasibility and acceptability of the CKM JumpStart Tool among patients with advanced kidney disease and their providers using interview methodology and questionnaires. We will also explore preliminary outcomes including decisional uncertainty and goal concordant care to inform a future clinical trial.

5.1 Study arms

Patients will be randomized in a 1:1 fashion using a random number generator (www.randomizer.org) to either 1 of 2 groups, CKM Jumpstart Tool or Usual Care. All enrolled patients will complete surveys within 2 weeks of their following clinic visit with their provider (T2), and about 3 months after this clinic visit (T3). All study procedures will be conducted either by phone or in-person, at the patient's convenience. Each visit will take about 20 minutes.

<u>The CKM JumpStart Tool</u>
The CKM JumpStart Tool is a 1-page handout that describes the values of a patient and words that a provider can try with the patient to explore the patient' values more and to provide a values-based introduction to CKM. The values describes in the CKM JumpStart Tool is based on a patient's response to a single validated question that asks the patient, if they had to choose, do they value care directed at longevity or comfort. A patient may also indicate whether they are unsure what kind of care they value more. Because there are 3 potential responses to the values question (longevity, comfort, unsure), there are 3 different versions of the CKM JumpStart Tool. (Appendix A.1 Intervention Materials: CKM JumpStart Tool Versions). The CKM JumpStart Tool does not contain any identifying information about the patient.

Patients who are randomized to receive the CKM Jumpstart Tool will be surveyed at T1. Using the patient's answer to the values question, study staff will generate a CKM JumpStart Tool prior to their upcoming clinic visit with their provider. Study staff will inform the patient that their response to the values question will be shared with their provider prior to their next clinic visit and that their providers might bring up their values and treatment options for kidney disease, if the

situation permits. We will share the CKM Jumpstool with their provider by encrypted email (Appendix A.2. Intervention Materials: Provider Email Notification) prior to the visit. The email will contain a link to a brief video demonstrating the use the CKM JumpStart Tool (bit.ly/CKMJumpstart) and an attachment which describes the study in more detail (Appendix B.8: Provider Study Information Document). We will also provide the providers with a paper copy of the CKM JumpStart Tool on the day of their visit with the patient and remind them how to use the CKM JumpStart Tool using a standard script (Appendix A.3. Intervention Materials: Provider Script Notification). In both in email and in-person, we will assure the provider that they are not obligated to use CKM JumpStart Tool or discuss their patient's values and CKM and that they are free to do so if they choose. We will also assure the provider that the patient consented to a potential discussion of their values and CKM if it should arise during their clinic visit.

Usual care

Patients randomized to usual care will also will be surveyed at T1 but **will not** have a CKM JumpStart Tool generated describing their values and their response to the values question will not be shared with their providers. They will receive care as they usually do from their provider.

5.2 Potential Risks and Benefits

Anticipated risks:
The principal risk posed to patients is the potential *loss of confidentiality*. The proposed work requires the collection of protected health information to identify and recruit eligible patients and contact and maintain follow up with participating patients. We will also audio-record interviews with subjects during which personal information might be spoken. To minimize this risk, we have outlined steps below to safeguard patient confidentiality. These include restricting data analyses to only de-identified data files, keeping separate a crosswalk file linking study ID with personal identifiers and data analysis files, storage of data on password-protected secure servers and key-locked filing cabinets accessible to only study team members who have completed training in the protection of human subjects, and the aggregation of study data for presentations and publications in order to conceal the subjects' identities.

It is possible that patients might feel *unease with discussing their illness experience*. To minimize discomfort, patients will be assured that they can decline to answer any question they wish and will be free to discontinue the interview at any time. All patients will be reminded that they have the right to refuse to withdraw from the study at any time.

It is possible that providers might worry that participation, not participating, and/or being candid in interviews might *affect their standing at work*. We will assure providers that their participation is entirely voluntary and that they are under no obligation to use the Tool or answer any question during the study. Their participation or lack thereof will not be reported to their supervisor, and we will keep all data collected on providers confidential. Any personal identifiers will be kept separate from the data collected and that analyses will only be conducted with de-identifed data. Results will be reported in aggregate and therefore be anonymous.

Potential Benefits:
Patients and providers may benefit from this research directly and indirectly. This study will explicitly allow participants the opportunity to describe their experiences, which may give participants an important outlet for describing both their concerns and successes. Participants may also gain satisfaction from participating in a research project designed to improve the quality

of care for patients with advanced CKD, which gives a sense that they are active contributors to important quality improvement processes. For patients who know little or nothing about CKM, discussion about CKM can be an educational experience for them. For clinicians who find it difficult to engage in goals-of-care conversations and discuss CKM, they might also learn new communication skills modelled by the CKM JumpStart Tool.

With the measures outlined, we believe that the potential risks associated with the proposed work will be mitigated and will not outweigh the potential benefit to study subjects and the greater CKD population. The findings of this study will inform ongoing development of a novel communication tool to support shared decision-making for patients with advanced CKD and their providers.

5.3 Recruitment Methods

We aim to enroll up to 76 patients with advanced CKD and up to 30 of their providers in this study.

Patients
We are requesting a waiver of consent and HIPAA authorization to access the electronic medical records of patients to identify eligible patients for this study and to obtain their name and contact information for recruitment purposes only.

We will mail an *Introductory Letter* (see Appendix B.1: Recruitment Materials: Patient Introductory Letter) introducing the study. We will then follow up with a phone call about 1 week later to confirm that patients receive the letter, introduce the study, and determine if they are interested in participating in the study using a standard script (see Appendix B.2. Recruitment Materials: Patient Introductory Script).

We will not make more than 3 attempts to reach each patient by phone after mailing the introductory letter.

Providers
For enrolled patients who are randomized to the intervention, we will approach their providers in-person after their visit with their enrolled patients to inquire whether they had used the CKM Jumpstart Tool during their visit with the patient, and if so, invite them to participate in a brief phone or in-person interview about their experience using the CKM JumpStart Tool. We will use a standard script to recruit providers (Appendix B.3 Recruitment Materials: Provider Recruitment Script). If providers are unavailable to speak after the clinic visit, we will approach providers using encrypted email within 1 week after the clinic visit (Appendix B.4. Recruitment Materials: Provider Recruitment Email) and invite them complete an interview. We are requesting a waiver of informed consent to inquire providers if they had used the CKM Jumpstart Tool during their visit and the primary reason for not using the Tool to determine providers' eligibility to participate in the study.

5.3 Informed Consent Procedures

Patients

We will provide potential patients a *Patient Study Information Document* (Appendix B.5 Recruitment Materials: Patient Study Information Document) either by mail or a link to an online version of the *Patient Study Information Document* for them to review and download (https://redcap.link/CKMjumpstart). The *Patient Study Information Document* describes the study procedures, risks, and benefits, and information on what to do and expect if they decide not to participate. We will provide this link verbally over the phone and read aloud the study information document. A copy of the *Patient Study Information Document* can also be downloaded from the webpage. For those who prefer to first review a mailed a paper copy of the *Patient Study Information Document* before deciding whether to participate, we will follow-up by phone in about 1 week after the mailing.

The *Patient Study Information Document* will be hosted on UW REDCap, however UW REDCap will not be used for the storage or analysis of any VA data, and no VA data will be shared with UW REDCap. The only use of UW REDCap in this study is to use the provided link to disseminate an information sheet that does not require patients to enter any information or to provide their electronic consent.

Because the study procedures and intervention poses minimal risk to patients, and many patients prefer to complete study procedures remotely, we are requesting a waiver of written informed consent from patients to participate in the study. To ensure informed consent, we will use a "*Teach-back Method"* (see Appendix B.6. Recruitment Materials: Patient Teach-back Exercises) in which, after reviewing the study, we will ask patients a series of true/false questions about key aspects of the study aims, procedures and potential risks and benefits. Any responses that are incorrect or incomplete will be reviewed with patients, and they will be asked for responses to missed statements for a second time. We will repeat this teach-back approach a second time if there are aspects of the study that are still not understood by patients. Patients whose responses to statements are still incorrect after three responses would be considered to have inadequate understanding of the study and to be ineligible to participate.

Patients will be informed that participation is fully voluntary and that their decision regarding participation will in no way affect their access to services or the quality of care they receive at the VA, and that their identifiable information will not, at any time, be linked to the digitally recorded interview or the subsequent transcript.

Providers

Because the study procedures and intervention pose minimal risk to providers and that intervention is intended to promote standard of care (i.e. discussion of available treatment options for advanced CKD with patients), we are requesting a waiver of written informed consent from providers to participate in study interviews. We will review the study with providers using a standard script (Appendix B.7. Recruitment Materials: Provider Consent Script), which will cover the aims of the study, study procedures, and potential risks and benefits. They will also receive a study information document (Appendix B.8: Provider Study Information Document) when they are provided the CKM JumpStart tool in an encrypted email.

5.4 Inclusion/Exclusion Criteria

<u>Patients</u>

Inclusion:

- Adults aged ≥75 years
- Advanced CKD as defined as having at least 2 outpatient measures of eGFR <25 ml/min/1.73m^2 separated by >90 days in the prior year and with at least 1 eGFR measure <20.
- English-speaking
- Receive care from a provider at UW Medicine or VAPSHCS
- Open to discussing their values and treatment options for kidney disease with their provider.

Exclusion:

- Unable to complete the informed consent process
- Currently receiving maintenance dialysis

Providers

Inclusion

- Their patient is a participant in the study.
- Are a UW Medicine or VAPSHCS provider or trainee.

Exclusion

- None

5.5 Study Evaluations

Patients

The date of study enrollment will be the date that a patient's consent is obtained. Patients will be followed through patient's death, date of study withdrawal, or study completion, whichever is earliest.

Patients will complete the following surveys and interviews at enrollment (T1), within 2 weeks of their following clinic visit with their provider (T2), and about 3 months after this clinic visit (T3). All study procedures will be conducted by phone. Each phone call will take a total of 15 to 30 minutes. We will give participants a $20 gift card for each study visit that they complete. Gift cards will be mailed within five business days of a completed call.

Demographic survey (Appendix C.1): At T1, patients will be asked their gender, age, race, prior education, total annual household income, current employment status, and self-rated overall health.

EuroQol 5D (Appendix C.2): At T1, patients will be asked to complete a 5-item survey inquiring different domains of quality of life, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, on a 5-point scale.[24]

Control Preferences Scale (Appendix C.3): At T1, using a single question, patients will be asked to rate on a 5-point scale their preference in taking lead in medical decision-making.

Healthcare values (Appendix C.4): At T1, using a single validated question, we will ask patients about their preference for either extending life or preserving comfort. Patients will also have the option of indicating that they are uncertain about which they prefer. We will also ask whether they perceive that their provider provides care that is mostly directed at extending life or preserving comfort or are unsure. Patients will be considered as receiving goal concordant care if they perceive the care that they receive matches the care that they value.

Quality of communication (Appendix C.5)*:* At T1, T2 and T3, patients will be asked to rate the quality of serious illness communication with their providers using the 13-item subscale of the Quality of Communication Questionnaire.[25-27]

Discussion of treatment options (Appendix C.6): At T1, patients will be asked if they had ever discussed CKM and dialysis with their provider. At T2 and T3, patients will again be asked if they had discussed these topics since the last study visit.

Decisional conflict (Appendix C.7): At T1, T2 and T3, patients will be asked to complete the 4-item SURE Test to assess their preference for dialysis vs. CKM and the decisional conflict they have about their options.[28,29]

Post-clinic patient interview (Appendix C.8): At T2, patients assigned to the intervention will be invited to answer 4 open-ended questions about their clinical encounter with their provider. Questions will pertain to topics discussed during the encounter with their clinician, whether their provider asked them about their values, whether CKM was discussed, and their perception of CKM based on the conversation. Interviews will be audio-recorded then transcribed. We estimate that an interview will take 10-15 minutes to complete.

Documentation of discussion of CKM with patients: At T2 and T3, we will review each patient's recent nephrology clinic notes to determine whether providers documented a discussion with patients about CKM. Documentation will be transcribed into a Word document without personal identifiers.

<u>Providers</u>

Demographic information: From publicly available directories, we will ascertain providers' gender, race, and years since completing their medical degree.

Use of the CKM Jumpstart Tool (part of Appendix B.3)*:* For providers whose patients were assigned to the intervention, we will ask them after their visit with their enrolled patient (T2) whether they had used the CKM Jumpstart Tool during their visit, and if not their reasons for not using the Tool.

Post-clinic provider interview (Appendix C.9): For providers who used the CKM Jumpstart Tool, we will ask 4 open-ended questions about their clinical encounter with the patient and their experience using the CKM JumpStart Tool. Clinician responses will be recorded in writing, then transcribed into a Word document. We estimate that an interview will take 5 minutes to complete. Interviews will be conducted by phone or in-person in a private clinic room or office of the provider, per the provider's preference. Providers will be offered a $10 gift card for their participation.

5.6 Data Analysis

Feasibility and acceptability: As our primary outcome, and measure of feasibility, we will compare the proportion of patients in each study arm who reported having discussed CKM with their provider at T2 and T3. Based on prior work, the rate of patient-reported discussion of CKM with their health care providers in usual care settings is approximately 3%. The target sample size (n=76) is estimated to provide 80% power (two tailed, α=0.05) to detect an absolute difference of 25% or more in rates of patient-provider discussion of CKM between the intervention and control groups assuming a 30% attrition rate. We will also evaluate the proportion of patients in each arm who has documentation in their nephrology clinic notes that CKM was discussed with the patient at T2 and T3.

As a measure of acceptability, we collect attrition rates at T2 and T3. We will further assess user experience of the CKM JumpStart by performing a qualitative analysis of post-intervention interviews with patients and providers, coding for themes elucidating pros, cons and other considerations with using the CKM JumpStart Tool and discussion about CKM.

Exploratory outcomes: We will assess change (i.e., T3-T1 and T2-T1) in decision conflict about treatment decisions for advanced CKD and quality of communication scores. We will also assess change in the proportion of patients who reported receiving goal concordant care at each study time point based on patients.

5.7 Withdrawal of Subjects

Subjects will be informed during the consent process and at each study visit that they can choose to withdraw from the study at any point in time.

There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent. There are no anticipated consequences of a subject's decision to withdraw from the research. During data collection, study interviewers will assure participants that they can, at any time during the interview, refuse to answer any questions asked of them and may at any time elect to withdraw from the study. If a participant elects to withdraw during the phone call, the interviewer will immediately end the interview or questionnaires.

5.0 Reporting

We do not anticipate any adverse events that might occur. However, any and all unanticipated problems, serious adverse events and protocol deviations will be recorded and reported immediately to the study Principal Investigator. Any serious adverse events and/or serious problems will be reported to the IRB within 5 business days. Additionally, the ISO and Privacy Officer will be notified within one hour of any improper use or disclosure of study data. The Principal Investigator will be the monitoring entity responsible for ensuring that all measures related to data security and protection of subject privacy and confidentiality are being followed.

Subjects will be informed to contact the PI for all urgent and non-urgent questions and concerns at the following: Susan Wong, Phone: 206-277-4376.

6.0 Privacy and Confidentiality

The proposed work will use protected health information. All study personnel who will have access to protected health information and/or will be involved in obtaining subject consent will be required to complete all necessary training in the protection of human subjects and privacy

through the Department of Veterans Affairs (VA) Learning University Talent Management System (TMS). All study personnel who have access to study and patient data have been approved by both the UW and VAPS.

All subjects will be given a unique study ID, and data collected for this study will be associated with study IDs only. A separate crosswalk file linking study IDs with personal identifiers will be kept separate from data analysis files. Data analysis files will not contain personal identifiers. Chart passages containing information about discussion of CKM will be transcribed without personal identifiers. All interviews will be transcribed and purged of any personal identifiers by the transcriptionist. Data analysis will be conducted using only the de-identified transcripts. Patient responses during interviews will also be kept confidential from their providers and close persons. Likewise, information shared by close persons will not be shared with patients.

Study data will be aggregated for presentations or publications related to the study in order to conceal the identities of subjects.

7.0 Communication Plan

The Head of the Division of Nephrology at each medical center will be notified of any adverse events or changes to the study protocol.

9.0 Information Security and Data Storage/Movement

UW patient data, including recruitment information, audio-recordings of interviews, interview transcripts, patient tracking information, and survey responses will be stored at the KRI in secure study folders. After recruitment and data collection, deidentified UW patient data will be moved to VAPS for final pooled analysis. All analysis will take place at VAPS.

The data flow for UW data is:
UW patient > VA and UW approved staff > UW servers > deidentified data into VA servers.

VA patient data, including recruitment information, audio-recordings of interviews, interview transcripts, patient tracking information, and survey responses, will be stored at VAPS in a secure J-drive study folder. No VA patient data will be shared with the UW, and all analysis will take place at VAPS.

The data flow for VA data is:
VA patient > VA and UW approved staff > VA servers

For both UW and VA data, interviews will be digitally audio-recorded and downloaded from recording devices to secure study folders using a USB fire cable. After audio-recordings have been saved, audio files will be erased from audio-recorders. Audio files of interviews will be labeled with study IDs and date of the interview only and will be accessible to the transcriptionist through the secure study folder. Transcripts of audio files will be saved as Microsoft Word format directly to secure study folders. The transcriptionist will not be permitted to save copies of audio files or transcripts onto personal computers or devices.

Survey study data will be assembled using structured forms designed in Microsoft Excel and saved in secure study folders. Data will be associated with study IDs only.

After deidentified UW data is moved to VAPS, all data collected at UW Medicine and VAPS will be stored on VACOIN access-protected servers on the J: drive. No VA data will be shared with the UW. Please note that although UW protocol is referenced here for informational purposes, this protocol only covers VA research activities. UW research activities are covered by UW IRB.

Only VA **and** UW approved study team members will be authorized to access the study folders on the VACOIN secure server. The server is located at:

VA Puget Sound Health Care System
Office of Information and Technology
1660 S. Columbian Way
Building 1, Rm B70
Seattle, WA 98108

All research records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration (NARA) and are published in VHA's Records Control Schedule (RCS 10-1). (VHA Handbook 1200.05).

After all data are analyzed and manuscripts summarizing study findings are published (estimated 2029), all identifiable and crosswalk files will be destroyed.

Data Sharing Plan:

Partial restrictions to the data and/or materials apply: anonymized data for the study will be made available to interested parties upon written request and submission of a formal written research proposal that has undergone human subjects review.

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