Study Title: SMART Pilot Trial of Glycemic Screening Outreach

NCT Number: 06915194

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INSTRUCTIONS

- This application is intended for behavioral, health services, epidemiological, social science, and education research involving human subjects.

- The UCLA IRB/OHRPP uses this application for all levels of review – Certification of Exemption from IRB review, IRB review using Expedited Review Procedures, and IRB review by the Convened Board. This form should also be used for requests for the UCLA IRB/OHRPP to confirm that IRB review is not required.

- This template identifies supplemental applications that may be required to provide additional information for IRB review of research involving vulnerable populations and/or requiring waivers and alterations of informed consent. The supplements include:

Adults not able to consent for themselves
Children (minors)
Pregnant individuals, fetuses, and/or neonates
Prisoners
Wards
Waivers, waiver of documentation, and alteration of consent, assent, and/or parental permission
HIPAA-covered research

- Additional information that should be appended to the BruinIRB application to support the IRB/OHRPP review of this protocol includes:
    - Recruitment and consent scripts and documents
    - Data collection instruments (surveys, interview protocols, etc.)
    - Federal funding proposals or subcontracts
    - External reviews of project proposals
    - Other supporting documentation as requested by the IRB/OHRPP

- ***Answer all questions***. If a question is not applicable to the research, indicate "n/a".

For questions about how to complete this form, contact the OHRPP staff at gcirb@research.ucla.edu
For email addresses for individual NGIRB or SGIRB staff, see https://ohrpp.research.ucla.edu/staff-directory/

OVERVIEW

Title of Study. This should match the study title provided in the BruinIRB application.

SMART Pilot Trial of Glycemic Outreach

Specific Aims. Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed.

Implement a pilot/feasibility study engaging individuals aged 35-70 with obesity and a family history of T2D who are unscreened for prediabetes or T2D, in a feasibility trial of a SMART design to deliver a random sequence of messages encouraging glycemic screening uptake.

Background and Significance. Provide a summary of the background for this study and explain how it will contribute to existing knowledge. State concisely the importance and relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Include citations to relevant scientific or scholarly literature as appropriate. References can be attached to the BruinIRB application.

Approximately 130 million Americans have prediabetes or type 2 diabetes (T2D) but remain unscreened and/or unaware of their diagnosis. While prediabetes/T2D screening, also known as glycemic screening, is endorsed in national guidelines, there is almost no research on how to increase screening rates, or evaluations of interventions testing the effectiveness of screening promotion strategies. The American Medical Association has published prediabetes quality measures that apply to UCLA Health as well as all other health systems, specifically tracking the percentage of adult patients with risk factors for T2D due for glycemic screening for whom the screening process was initiated. However, there is no current systemic effort underway at UCLA, or most other health systems, to encourage glycemic screening. We are proposing a pilot trial of the first SMART (Sequential Multiple Assignment Randomized Trial) for glycemic screening. Our SMART experiment will provide preliminary feasibility and acceptability data for a larger, multisite trial that will provide vital guidance to optimize screening approaches for a growing number of screening-eligible patients so that they may seek earlier detection, treatment, and/or access to lifestyle programs and interventions for T2D or prediabetes.

Scientific or Scholarly Review. Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review. Click here for additional details. If you want the IRB to consider external scientific or scholarly review, explain the source of the external review, and attach a copy of the review to your BruinIRB application, if applicable.

The pilot project has not been externally reviewed.

CHARACTERISTICS OF THE STUDY POPULATION

Number of subjects. State the total number of subjects planned for the study and how many you expect to recruit to obtain this sample size. If research involves multiple groups of participants, specify the number for each (e.g., 50 interview participants, 1,000 survey participants), and the number you would need to recruit for each group.

We plan to randomize 105 patients, and expect reaching out to primary care providers about 110 patients to identify these 105 patients who are ultimately randomized.

Inclusion criteria. Indicate the specific inclusion criteria for enrollment of each of the groups of research participants in this study. If there are any inclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken,* explain the nature of and scientific rationale for the inclusions.

Patients will be eligible if they are aged 35-70, obese, have a family history of type 2 diabetes, have not received glycemic screening in the prior three years, and have contact information in CareConnect for all three potential outreach modalities (patient portal/MyChart account, cell phone, address).

UCLA students or staff as participants. If either (a) you will have grading or supervisory responsibility for some or all students recruited for the study, or (b) you plan to recruit staff or faculty from your own lab or office, provide justification for recruiting your students/staff. If not applicable, indicate "n/a".

N/A

Exclusion criteria. Indicate the specific exclusion criteria for each of the groups of research participants in this study. If there are any exclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken,* explain the nature of and scientific rationale for the exclusions.

We will exclude patients with a history of type 2 diabetes. We will also exclude patients who have expressed to UCLA Health that they have opted out of text messages, and we will obtain information for this exclusion criterion from OHIA. Finally, we will exclude patients who do not have a PCP listed in CareConnect.

Eligibility. How (screening survey, chart review, etc.), when and by whom will eligibility be determined?

Chart review by the PI and Jessica Harwood (analyst on this IRB application)

Vulnerable Participant Populations requiring submission of additional regulatory supplement(s).
Check all that apply and **attach completed supplement(s) to BruinIRB application.**

☐	Adults not able to consent for themselves
☐	Children (minors)
☐	Fetuses, fetal tissue, and/or neonates
☐	Pregnant individuals
☐	Prisoners
☐	Wards

STUDY DESIGN

☐ **ATTACHMENTS REQUESTED**

Attach your study instruments to your BruinIRB application.

- Include interview protocols/outlines, focus group protocols, survey instruments, intervention materials.
- Ensure that names of your documents (e.g., Parent interview) match your description below.
- For complex study designs, develop a flow chart of study procedures.

Study methods and procedures. Describe in chronological order how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures.

- Explain who will conduct the procedures, where and when they will take place.
- Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.
- State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).
- If your research involves participant observation, explain where the observations will occur, including whether locations are public/private, indicate who and what you are proposing to observe, describe the information that will be recorded in the research records (indicate whether data will include personally identifiable information), and outline the procedures for collecting data (written notes, audio/video recording).
- Describe alternatives to participation, if any.
- Use sub-headings to organize and describe separate procedures if applicable to subsets of the study population.

(describe study methods and procedures)

This research study will use data from the UCLA EHR (CareConnect) to track patient eligibility and assess outcomes. All data was collected as part of routine care and will be accessible only to study team members and be stored behind existing firewalls. We will submit a Service Now ticket to obtain the necessary baseline data from the UCLA CTSI to identify patients eligible for inclusion and randomization and will submit a New Project Report through the UCLA Office of Health Information and Analytics (OHIA) for their assistance in study protocol administration. The team will randomize 75 eligible patients to outreach or usual care, and we will work with OHIA to deliver the appropriate intervention at the first randomization point. The documents for the 50 patients randomized to outreach are attached to this IRB application. We will inform primary care physicians (PCPs) of the 75 patients that were included in the pilot study, including those randomized to usual care, so that they are aware of their patient's involvement. The PI, who is a practicing UCLA PCP, will also place A1c laboratory orders for these 75 patients in CareConnect, which are valid for 12 months. Our team will track A1c testing in CareConnect, re-randomize those patients who were unscreened, and work with OHIA to deliver the appropriate intervention at the second time point (4 weeks). Finally, our team will send letters at the third timepoint (8 weeks) to any individuals in the treatment arm who remain unscreened, and track A1c testing over the following 4 weeks. At the conclusion of the study, patients will receive a 5-item Qualtrics survey to assess the acceptability of the messages, and also receive an email with debriefing about the study.

Collaborative Research. If non-UCLA-affiliated personnel or institutions are collaborating in the research describe the nature of the collaboration. If UCLA will serve as reviewing IRB (aka Single IRB or "SIRB"), explain.

After submission of your BruinIRB application, the UCLA IRB/OHRPP will provide instructions – when applicable - for how to provide the information required for UCLA to formalize the necessary reliance agreements and to complete IRB review for the relying sites. Click here for more information about UCLA serving as reviewing IRB.

N/A

Deception or Withholding of Information. Reference: OHRPP Guidance Deception or Incomplete Disclosure,
If the study will involve any type of deception or incomplete disclosure to participants, respond below to provide the requested information.

- Describe the information that will be withheld from, or misinformation that will be provided to participants.
- Explain why it is necessary to involve deception in the research.

- Describe plans for de-briefing participants after study participation or explain and justify why no de-briefing will be provided.
- Explain why the research could not practicably be carried out without the alteration of consent.
- Attach your debriefing script to your BruinIRB application.

If your research does not involve deception or incomplete disclosure, indicate "n/a".

We are planning to withhold from participants the information that our research goal is to determine the best modality or sequence of modalities for diabetes screening outreach (text, MyChart, etc.). We are proposing to sequentially randomize the participants to different study arms with different messages and track the outcome of interest (hemoglobin A1c blood draws). As our goal is to assess spontaneous behavior in response to the different message modalities, we are concerned that providing information about the goal of the research up front will as an unintended consequence influence behavior. As this is a minimal risk study, we do not anticipate that this necessary withholding of information will cause harm or create adverse participant reactions. We will send a debriefing letter (attached to the IRB application) to all participants after the conclusion of the 90-day study.

Existing data/specimens. If the proposed research includes use of existing data/specimens, describe how data/specimens will be acquired. Specify the source of the data/specimens, explain what personally identifying information (PII) is included with the data/specimens. Explain if data are publicly available.

- Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective.
- Describe the data and/or specimens and indicate the original collection dates.
- Indicate the approximate number of data records and/or specimens to be collected.
- Attach to your BruinIRB application any data abstraction tools or lists with the data elements to be collected.

If your research does not involve use of existing data/specimens, indicate "n/a".

N/A

Statistical plan. Describe the proposed statistical procedures or descriptive analyses for the study. If applicable, indicate how the sample size was determined. For qualitative research, briefly describe how qualitative data will be analyzed.

(describe statistical plan)

The data analysis for this pilot study will be entirely descriptive. We will track feasibility measures, specifically the dates on which outreach messages are sent to the 75 patients included in the study sample, including messages after re-randomization for patients who have not obtained an A1c screening test. These feasibility measures include the following: 1) successful delivery of all messages at baseline, 2) successful delivery of messages at 4 weeks only to individuals without an A1c in the EHR, 3) successful mailing to letters at 8 weeks to all individuals without an A1c in the HER, 4) how many participants open the patient portal messages. We will not be able to track opening of text messages since many individuals do not enable the read receipt option.

IDENTIFICATION, RECRUITMENT, AND SCREENING

☐ **ATTACHMENTS REQUESTED**

Attach your recruitment and screening documents to your BruinIRB application, including flyers, letters, email text, scripts. **Click here for UCLA guidance on recruitment materials** .

Recruitment methods. Check all that apply to identify your recruitment methods.

- ☐ Recruitment letters, emails, or text messaging
- ☐ Direct recruitment (e.g., contact between study team and potential subjects in person, by phone or internet)
- ☐ Advertisements, flyers, internet posting
- ☐ Online platform such as mTurk, Prolific, Dynata, Cloud Research, etc.
- ☐ Review of publicly available records *(indicate the source below)*
- ☒ Review of medical records
- ☐ Review of other records *(indicate the source below)*
- ☐ Participant pool for which potential research participants have agreed to future contact.*
- ☐ Potential study participants are identified from another IRB approved study or screening protocol.*
- ☒ Referrals (e.g., referrals from non-investigator healthcare providers, participants referring other persons, etc.)
- ☐ Other

Indicate the source of records and/or the related IRB number(s) for the recruitment methods selected above.

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Description of recruitment and screening. Explain below how subjects will be identified, recruited, and screened.

- Include information about **how, when, where, and in what setting** these processes will occur.
- Identify who (by position or role, not name) will approach and recruit subjects, and who (by position or role, not name) will screen them for eligibility.
- If existing records will be accessed or obtained for recruiting and screening procedures prior to enrollment, describe the source and contents of the records used and whether it will be retained as part of the study data.
- Note: If screening questions will be used to determine eligibility, they should be limited to those required to confirm eligibility.
- If you will be directly recruiting potential participants who are your patients, students, laboratory workers or others with whom you have a **relationship of authority or unequal power,** describe what measures you will put in place to avoid those approached from feeling pressured or unduly influenced to participate in the study.
- If consent will be obtained for any of the screening procedures, explain.
- If the research involves physicians/clinicians recruiting their own patients, avoid conflating the research with clinical care/services.

(describe recruitment and screening)

Our team will identify potentially eligible patients from the EHR and reach out to the PCPs of these patients to ask if they are appropriate for this screening pilot, which is implementing USPSTF national guidelines. We will also share the recruitment message to be sent by portal/text/letter (attached elsewhere in this application) and confirm that the PCP is OK with including their name in the document. We will not include patients if the PCP objects to their participation or objects to including the PCPs name in the recruitment materials but will consider them eligible otherwise.

CONSENT FOR STUDY PARTICIPATION

☐ **ATTACHMENTS REQUESTED**
Attach your consent documents to your BruinIRB application.
Click here for UCLA template consent documents and standard language .

Method(s) of Informed Consent. Select the consent methods you will use. Check all that apply.

☐ Obtain signed consent (Participant or Legally Authorized Representative)
☐ Obtain consent online* (Waive written documentation of consent)
☐ Obtain verbal consent* (Waive written documentation of consent)
☐ Obtain signed parental permission
☐ Obtain signed assent from children/adolescents
☐ Obtain verbal assent from children/adolescents or adults unable to consent
☒ Waive consent and/or parental permission*
☐ Waive assent / Assent is not appropriate*

**If selected, complete and attach to your BruinIRB application the applicable supplement to provide information to justify the waiver(s): Supplement: Waiver of Documentation of Consent or Waiver of Informed Consent*

If different groups of participants will have different consent methods, explain.

N/A

Consent Process Description. Provide a step-by-step description of the consent process, including:

- Outline the personnel involved, and the methods to be used.
- Indicate the type of setting(s) in which the consent process will be conducted – if the setting is not private, describe the measures to protect confidentiality.
- Describe the measures that will be taken to provide prospective research participants with sufficient opportunity to consider whether or not to participate in the study.
- Specify the length of time subjects are given to decide whether they wish to participate in the study.
- Explain how you will assess whether subjects understand the information conveyed during the consent process.
- If applicable, explain if permission will be obtained from individuals other than parents, and if so, how you will determine that the individual providing permission has the authority to do so.

N/A

Parent Permission and Child/Adolescent Assent Processes. If research involves minors, provide a step-by-step description of the processes for obtaining parent permission and child/adolescent assent.

If research does not involve minors, indicate "n/a".

N/A

Cultural Considerations. Check all that apply to the population(s) with which this study will be conducted.

- ☐ Participants may be illiterate or insufficiently literate to be able to comprehend a conventional written informed consent form.
- ☐ The participants may be reluctant or unwilling to sign a written informed consent form.
- ☐ The husbands make decisions for their wives.
- ☐ Elders make decisions for younger adult family members.
- ☐ Elders make decisions for their community.
- ☐ It is considered impolite to refuse a request.
- ☐ People are fearful of refusing requests that they regard as coming from authorities.
- ☒ **None of the above are applicable to this study.**

If any of the above items are applicable to this study, indicate the steps that you will take to ensure voluntary participation after providing the study information, and if applicable, any planned involvement with the community regarding the consent process.

Click or tap here to enter text.

INFORMATION ABOUT THE STUDY DATA

Data related to health or mental health care. Check all that apply.

☒ Obtained from a medical or clinical record.*
☐ Created or collected as part of health or mental health care.*
☐ Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals.*
☐ Research data will be entered into the participants' medical or clinical record.*
☐ None of the above.

Responses with * require completion of the HIPAA-COVERED RESEARCH SUPPLEMENT

Indicate all identifiers that may be **accessed or included in the research records** for the study:

- ☒ Names
- ☒ Dates
- ☐ Age (if over 89 years)
- ☒ Postal Address
- ☒ Phone Numbers
- ☐ Fax Numbers
- ☒ Email Address
- ☐ Social Security Number*
- ☒ Medical Record Number
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☐ License/Certificate Numbers
- ☐ Web URLS
- ☐ IP Address Numbers
- ☐ Biometric Identifiers (including finger and voice prints)
- ☐ Facial Photos/Images
- ☐ Any Other Unique Identifier (this does not include the code assigned by the investigator to identify the data)

None of the above ☐

***If social security numbers will be collected** explain why they are necessary, how they will be used, how they will be protected and how long they will be retained.

N/A

DATA SECURITY

Data security plan. Describe your data security plan by either providing a narrative response or attaching a document that addresses the following:

- Indicate **how data will be stored and secured** including paper records, electronic files, audio/video tapes, specimens, etc. Specify how the **code key** will be securely maintained, as applicable.
- **Data on portable devices (e.g., laptops, external hard drives)**: Specify whether personal or private identifiable data will be stored on portable devices. If so, **provide the rationale** for storing the identifiers on the device. Note: only the minimum data necessary should be stored on portable devices.
- Describe **any additional steps** taken to assure that identities of participants and any personal or private information are kept confidential.
- If personal identifying information will be removed or destroyed or the data/specimens will be coded, describe the process for removing and destroying the personal identifying information or for coding the information, and indicate who will perform the task.
- **If video or audio recordings will be made as part of the study,** disposition of these recordings should be addressed here and in the consent document(s).
- **Internet research:** If data will be collected, transmitted, and/or stored via the internet, indicate the measures that will be taken to ensure security of data transmitted over the internet.
- **If you have a data security plan, attach it to your BruinIRB application.**

The data will be maintained in ULEAD, and will not be stored on any portable devices. The analyst doing the randomization will not include PHI in that process. All patients will be given a post-randomization study ID (e.g., Intervention 1, Control 2) for within-team communication, and the code key for this linkage will be maintained on the password-protected hard drive of the PI, in his locked office.

☒ **In event of data security breach.** Provide your assurance that if there is a data security breach for this study, you will notify the IRB and your department's IT Compliance Coordinator. See UCLA Policy 420 for more info.

FUTURE USE OF DATA AND/OR SPECIMENS

Future use. Indicate if the data will be stored for future use after this study is completed. Check all that apply.

- ☐ Stored for possible future research
- ☐ Add to existing repository
- ☒ Not applicable, data will not be stored for future use
- ☐ Use to create a bank or repository at UCLA. *If you will create a bank or repository, attach to your BruinIRB application your Standard Operating Procedures (SOPs). Click here to review related UCLA IRB/OHRPP guidance and requirements.

Retention of personal or private information after the study is completed. If personal or private information will either be kept with the data and/or specimens, or data or specimens will be coded, provide the following information.

- Describe how and where data and/or specimens will be stored, including the security measures for preventing un-authorized access.
- If personal or private information and/or codes will be maintained, explain how the information will be securely handled and stored, how will you assure confidentiality, and who will have access to the identifiers and/or codes.
- Explain whether the materials will be de-identified, and if so, when, how and by whom.
- If data include audio or video recordings, explain whether transcriptions include identifiers and explain whether recordings will be destroyed or modified to eliminate the possibility that study participants could be identified.

N/A

Distribution Rules. If data and/or specimens will be shared for future research, describe the criteria used to determine the adequacy of requests to obtain data and/or specimens (e.g., the type of researchers that will be eligible to receive data and/or specimens).

N/A

PRIVACY AND CONFIDENTIALITY

Privacy. How will the investigator maintain privacy in the research setting(s)? (e.g., interviewing participant in a room or area where conversations cannot be overheard by others).

All study-related communication with providers and patients will be done electronically, in order to maintain privacy.

Confidentiality: If the protocol will collect and maintain identifiable data, explain how the planned safeguards to maintain confidentiality of identifiable data and data security are appropriate to the degree of risk from disclosure.

While the study involves identifiable data, the PHI including names, etc. will only be used in direct messaging to providers or patients themselves. All communication between the study team will use the coded post-randomization study ID described above.

State mandated reporting. Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse), ethically requires action (e.g., suicidal ideation) or is a reportable disease? ☒ No ☐ Yes

If yes, explain below and include a discussion of the reporting requirements in the consent document. For more information see UCLA OHRPP Guidance: Reporting Suspected Abuse or Neglect of Children, Elderly Individuals, and Dependent Adults, Reporting of Diseases and Conditions Identified in the Course of Research, and Research Protocols and Risk of Suicide

N/A

☐ **Certificate of Confidentiality.**
Check here if you plan to apply for a Certificate of Confidentiality for non-federally funded research. For more information see https://ora.research.ucla.edu/OHRPP/Documents/Policy/6/COC_NonFederallyFunded.pdf .

RISK/BENEFIT ASSESSMENT

Risk Assessment. Indicate the level of risk involved with this study. If there are multiple groups or phases involved with this study indicate the highest level of risk.

☒ **Minimal risk.** Click here for OHRPP tip sheet on Minimal Risk.
Minimal risk is defined *as the probability and magnitude of harm anticipated in the research are not greater than those encountered in daily life (i.e., daily lives of the general population) or during performance of routine physical or psychological examinations or tests.*

☐ **Greater than minimal risk.**

Benefits to participants. Describe any potential **direct** benefits (psychological, social or other) to study participants. If participants will not directly benefit from their participation, state this. *Note that payment for participation is not considered a benefit.*

The participants will be encouraged to seek glycemic screening, which is standard of care for these individuals.

Benefits to society. Describe the potential benefits to society including the importance of the knowledge to be gained.

This pilot study will demonstrate the ability of the team to conduct a SMART trial, which will support revision of a previously submitted multicenter R01 that may identify the best outreach approaches for glycemic screening, both overall and for key subgroups.

Potential risks/discomforts. Indicate potential risks/discomforts, if any, associated with each intervention or research procedure, and discuss any measure that will be taken to minimize risks.

- A risk/discomfort is a potential harm associated with the research that a reasonable person would consider important in deciding whether to participate in the research.
- Risks can generally be categorized as physical, psychological, sociological, economic, and legal.
- The information provided should be reflected in risks section of the informed consent documents.
- *If there are no anticipated risks or discomforts, indicate n/a.*

There are no appreciable risks, other than potential loss of confidentiality for participants, regarding their risk of diabetes.

Risk/Benefit Analysis: Indicate how the *risks to the participants are reasonable in relation to anticipated benefits,* if any, to participants and the importance of the knowledge that may reasonably be expected to result from the study.

The risks to participants are quite limited, and there is the potential for this work to lead to information on preferred messaging for glycemic screening outreach.

FINANCIAL CONSIDERATIONS FOR PARTICIPANTS

Payment. Describe method and amount of any payments or remuneration (e.g., course credit) made to participants. If there are multiple study visits for which participants are paid, indicate if payments are pro-rated and when payment will be made.

None

Costs. Describe any research-related costs for which participants may be responsible.

None, because glycemic screening is a covered benefit for patients at risk of diabetes as per the inclusion criteria.

ADDITIONAL INFORMATION

If there is any additional information that you want to communicate about the study, provide that information here.

Click or tap here to enter text.