Date Generated: Monday, June 19, 2017 2:02:25 PM
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ID: IRB#17-000182 View: NEW 1.1 - Study Title and Key Personnel

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Study Title and Key Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 ***Full Title of the Submission:**
Establishing Responsive Linkages between Voters and Local Politicians in Pakistan

- 1.1
- **Protocol Version Date and/or Number:**

2.0 ***Working or Lay Title:**
Responsive Linkages in Pakistan

3.0 **Principal Investigator:**

- 3.1
- ***Name:** MIRIAM GOLDEN
- **Degree(s):** If degrees are not shown here, please add them to the next section, Section 1.1a/Item 1.0, which will then update the Principal Investigator's webIRB account information.
  PhD
- 3.2
- **UCLA Title:**
- 3.3
- ***Will the Principal Investigator conduct the informed consent process with potential study participants?**
  - (●) Yes
  - ( ) No
  - ( ) Not Applicable
- 3.4
- ***Is the Principal Investigator an undergraduate student, graduate student, post-doctoral fellow, or resident physician?**
  ( ) Yes (●) **No**
  - 3.4.1
  - **If you answered "yes" to the above question, indicate the Faculty Sponsor for this study.**
- 3.5
- **UCLA Policy 900 defines types of UCLA employees who may be eligible to serve as a Principal Investigator. Check the policy to see if the Principal Investigator for this study needs an exception to the eligibility requirements.**

  If an exception is needed, either attach the letter of exception here, or indicate a Faculty Sponsor in the above item.

Document Name	Document Version #
There are no items to display	

4.0 **Study Contact Person: Indicate the person, in addition to the Principal Investigator, who should receive all of the study correspondence.**
LUKE SONNET

5.0 **List the key personnel and study staff below.**

Note: All personnel listed below are required to complete CITI training courses. HIPAA training is also required if personnel will be accessing protected health information.
Please make sure to have all key personnel update their webIRB profile, contact information.
Instructions on how to update the webIRB profile: Click here.

Name	Department	Role	Other Role (if applicable)	Will Obtain Consent?	Manage device accountability?	Access to personally identifiable info?	Access to code key?

There are no items to display

ID: IRB#17-000182 View: NEW 1.1a - Other Personnel

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Other Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 Principal Investigator

- 1.1
- **Name:** MIRIAM GOLDEN
  ***Please type the Degree(s):** PhD
- 1.2
- **Principal Investigator's UCLA Department:** POLITICAL SCIENCE
- 1.3
- ***Protocol's UCLA Home Department:** POLITICAL SCIENCE
- This response defaults to the PI's payroll department. If you wish to affiliate this protocol with another department, please select the department from the list above.
-
- **For tips on effective search, please see guidance to the right.**

2.0 If there will be other types of personnel working directly under the PI's supervision on aspects of the study, provide their name, title and institution, indicate their responsibilities, training and qualifications and complete Item 2.1.

Please also indicate, if applicable, whether that person will obtain consent, manage device accountability, have access to personally identifiable information and/or have access to the code key.

Please use a new entry to add each individual unless describing a class of individuals who rotate through the study team (see guidance area to the right).

Note: If there will not be other types of personnel go to Item 3.0.

	Name, title, institution	Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc.
View	Muhammad Parvez, Mr.	Will hire and supervise enumerators, conduct interviews, recruit participants, obtain consent, review data collection procedures. Mr. Parvez has experience working for Pakistani NGOs, including with vulnerable populations. Has received numerous trainings by poverty and development organizations. C.V. is included with these document.
View	Saad Gulzar, Assistant Professor of Political Science, Stanford University	Has participated in survey design, and aided in finding staff partners, such as Mr. Muhammad Parvez. Will participate in data analysis and write up of the final project. Will also have access to personally identifiable information.

-
-

For existing protocols: Item 2.0 has been modified and this item cannot be edited. When submitting an amendment please use the information found in the text box below to complete Item 2.0 above.
Briefly describe the other study personnel.

- 2.1
- **Indicate the human subjects research training these personnel have or will receive. If training is required in a language other than English or if research is occurring in a location where research personnel do not have access to the internet (e.g., rural community without internet capability), please describe how human subjects training requirements will be fulfilled.**
-
- **Check all that apply:**

☑	CITI Training
☐	UC HIPAA Training
☑	Other

- 2.2
- **If you indicated "Other" to item 2.1, describe:**
  Saad Gulzar has received CITI training. Certification is included with these documents.

  Luke Sonnet will provide human subjects training to Mr. Parvez and the enumerators that he hires at a training session in Islamabad. Training material is included with these documents.

  Enumerators will be instructed not to share phone numbers with anyone. Information, including phone numbers, will be recorded electronically and transmitted immediately to VOTO. Enumerators will not have continuing access to identifiable information with this technology.

3.0 ***Will any of the study procedures or analyses be contracted to a consultant or an organization?**

◉ **Yes** ○ No

- 3.1
- **If yes, specify the consultant(s) and/or organization(s) and the work that they will do for the study.**
  VOTO Mobile (www.votomobile.org) will provide the technology that makes cell phone calls to respondents using the cell phone numbers they have provided us.

ID: IRB#17-000182 View: NEW 1.1b - Type of Study Review

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Type of Study Review

1.0 ***Indicate the level of risk involved with this study.**

(if there are multiple groups or phases associated with this study, select the highest level of risk.)

◉ Minimal risk or no known risks - Click here for the OHRPP tip sheet on minimal risk.

○ Greater than minimal risk

2.0 ***Indicate the type of review that you are requesting for this study.**

◉ IRB Review: Expedited or Full Board

○ Certification of Exemption from IRB Review

- 2.1
- **If you indicated "IRB Review: Expedited or Full Board" as the type of review in item 2.0, select the IRB that you think best matches your research.**

Name	Description

○	Medical Institutional Review Board 1	MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.
○	Medical Institutional Review Board 2	MIRB2 reviews oncology and hematology research.
○	Medical Institutional Review Board 3	MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse and dental research.
◉	North General Institutional Review Board	NGIRB reviews research from the College of Letters & Science and the Professional Schools.
○	South General Institutional Review Board	SGIRB reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine.

***Please note*: The above requests are for initial routing purposes only. The final decision as to committee assignment and type of review, rests with OHRPP and/or the IRBs.**

ID: IRB#17-000182 View: NEW 1.2 - Conflict of Interest Information

Warning: Save your work at least every 15 minutes by clicking ﷺSave﷽ or ﷺContinue.﷽

Conflict of Interest Information

1.0 * **Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have a financial interest in the sponsor (profit, non-for-profit) of the research?**

○ Yes ◉ **No**

- 1.1
- **If yes, attach a completed copy of the Financial Interests Form for each person who indicates a financial or related interest:**

Document Name	Document Version #
There are no items to display	

2.0 * **Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have any financial interests related to the research sponsored by a government agency?**

○ Yes ◉ **No**

- 2.1
- **If yes, attach a completed copy of the Financial Interests Form:**

Document Name	Document Version #
There are no items to display	

3.0 * **Indicate whether any of these financial interests have been submitted to or reviewed by the UCLA campus Conflict of Interest Review Committee (CIRC):**

○ Yes ◉ **No**

- 3.1
- **If you have received a response from CIRC, attach it here:**

Document Name	Document Version #
There are no items to display	

ID: IRB#17-000182 View: NEW 1.3 - Study Locations

Warning: Save your work at least every 15 minutes by clicking ﷺSave﷽ or ﷺContinue.﷽

Study Locations

1.0 ***Indicate the locations where any research activities will be performed by the UCLA research team with participants and/or private information obtained.**

Check all that apply:

- [x] a. UCLA Sites or UCLA Health System Sites
- [ ] b. Off Campus (in California)
- [ ] c. Outside California (in the U.S.)
- [x] d. Outside the United States ***See note at right**
- [ ] e. Internet

- 1.1
- **If you selected b, c or d above, please provide your assurance that documentation of each site's permission to conduct the research at the site(s) will be obtained and maintained by the UCLA PI as applicable:**

  Agree [x]

2.0 ***Is this a multi-institutional study (i.e., a collaborative project with other sites that have their own IRBs or principal investigators)?**
(Includes but not limited to UC MOU and CTSI MOU collaborations where UCLA IRB review is requested.)

(•) **Yes** ( ) No

If no, please skip directly to the next page, do not complete the questions below.
If yes, please answer items 2.1-2.3:

- 2.1
- **Will UCLA be responsible for the overall direction of the study at the other institutions?**

  (•) **Yes** ( ) No

  - 2.1.1
  - **Indicate the measures that will be taken to assure regulatory compliance at each site and that the following types of information will be communicated to the other sites: study procedures; modifications to the protocol and related documents; and safety updates, interim results and other information that may impact risks to study participants.**
  - **Check all that apply:**

    - [x] Conference calls or meetings with minutes distributed to each site
    - [x] Timely e-mail communications
    - [ ] Postings on the study website
    - [ ] Other

      - 2.1.1.1
      - **If you chose "other", describe.**

  - 2.1.2
  - **If you answered "yes" to item 2.1 above, please provide your assurance that the current IRB approval for each site(s) will be obtained and maintained by the UCLA PI as applicable:**

    Agree [x]

- 2.2
- **Will the UCLA principal investigator specified on this application be responsible for the data coordinating center?**
  Yes

- 2.3
- **Indicate the anticipated total number of study participants that will be enrolled across all of the institutions.**

20,000

ID: IRB#17-000182 View: NEW 1.5 - Other Sites and/or Collaborators • Multi-Institutional Research

Warning: Save your work at least every 15 minutes by clicking •Save• or •Continue.•

Other Sites and/or Collaborators • Multi-Institutional Research

Use Section 1.5/item 1.0 to list off-campus locations where research activities will be performed by the UCLA research team. If UCLA is the lead institution or responsible for the oversight of the collaborators, please also list these collaborators below.

1.0 ***List the research sites or collaborating institutions (including UC/CTSI institutions).**

	Name of Site	Site(s) Information

View Stanford University

Name or description of the site or collaborating institution:	Stanford University
Name of contact person and address or general location of the site or collaborating institution, as applicable:	Professor Saad Gulzar, Department of Political Science, Stanford University
Country	United States
If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.	This item is not applicable to this study
If you indicated "Other", describe:	*No Value Entered*
Indicate the activities that will be conducted by employees of this institution/entity	☐ (a)Obtain informed consent ☑ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes. ☐ (c)None of the above or not applicable to this study.
If you checked (a) or (b) in response to item above, check the applicable item:	The site or collaborator is requesting that UCLA serve as the IRB of record. Please also complete the required application form and submit by email to OHRPP to make a formal request.

	Name of Site	Site(s) Information
View	220 village locations in Khyber Pakhtunkhwa province, Pakistan	

Name or description of the site or collaborating institution:	220 village locations in Khyber Pakhtunkhwa province, Pakistan
Name of contact person and address or general location of the site or collaborating institution, as applicable:	220 village locations in Khyber Pakhtunkhwa province, Pakistan
Country	Pakistan
If the research procedures at this site are greater than minimal risk, indicate the resources applicable to handle research-related emergencies.	This item is not applicable to this study
If you indicated "Other", describe:	*No Value Entered*
Indicate the activities that will be conducted by employees of this institution/entity	☐ (a)Obtain informed consent ☐ (b)Perform research procedures, or obtain identifiable information or specimens for other than commercial purposes. ☑ (c)None of the above or not applicable to this study.
If you checked (a) or (b) in response to item above, check the applicable item:	

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Project Identification Information

1.0 ***Type of Submission (Select one)**

- ◉ Research Study
- ○ Application for Approval of "Research Participant Pool" or recruitment database only

2.0 ***Type of Submission (Select one)**
For Amendments, do not undo the response below. Undoing the response may remove sections of the original application.

- ◉ New Submission
- ○ Transfer of Ongoing Research from Another Site from Investigator moving to UCLA. Please complete Item 2.1.

- 2.1
- **If you selected "Transfer of Ongoing Research" in Item 2.0 indicate the current status of the study and a brief summary of the work to date.**
-

3.0 ***Who developed this study?**

Check all that apply:

- ☑ UCLA investigator
- ☑ Investigator from another institution
- ☐ Industry/Pharmaceutical Company
- ☐ Cooperative Group (e.g., Children's Oncology Group, AIDS Clinical Trial Group)
- ☐ Other

- 3.1
- **If other, specify.**

4.0 Review For and Reliance Upon External IRBs.

***Indicate if one of the following applies to this study. (Select one)**

- ○ None of the options apply.
- ◉ UCLA IRB to serve as IRB of record for another institution.
- ○ UCLA to RELY on another IRB.
  This includes reliance using UC MOU, CTSI, NCI, RAND, and Western IRBs.

5.0 ***Is this study cancer related,** including the recruitment of individuals with cancer, collection of cancer human biological samples, specimens or data, or the recruitment of individuals because they are cancer survivors or at risk of developing cancer and/or involves gene therapy?

○ Yes ◉ **No**

Note: If you answered "Yes", you must submit an application to the Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC). Click here for instructions for submitting to the ISPRC. The ISPRC approval notice or letter of exemption should be attached in Section 2.1/Item 7.2 of the webIRB application.

6.0 ***Nurse Involvement:** Does this study involve any nursing time, effort, and/or resources at UCLA Health System sites, including as subjects, investigators, clinical care providers or data or specimen collectors?

○ Yes ◉ **No**

Note: If you answer "Yes", please submit an application to the Nursing Practice Research Council (NPRC). For contact information or for more information about NPRC and how to apply, click here. ***IRB approval is not contingent on NPRC approval and you do not need to upload documentation of approval from the NPRC into webIRB.***

7.0 ***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. See http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific_Review.pdf for additional details.**

Do you want the IRB to consider external scientific or scholarly review?

○ Yes ◉ **No**

- 7.1
- **If yes, indicate the source of scientific or scholarly review for the study.**
-
- **Check all that apply.**

☐ National Institutes of Health (NIH)

☐ The funding agency (other than NIH)

☐ Faculty Sponsor

☐ JCCC ◆ Internal Scientific Peer Review Committee (ISPRC)

☐ Clinical Translational Research Center (CTRC)

☐ UCLA Department

☐ Other

  - 7.1.1
  - **If you checked "other", describe.**

- 7.2
- **Attach a copy of the scientific or scholarly review, if applicable.**

Document Name	Document Version #
There are no items to display	

ID: IRB#17-000182 View: NEW 2.2 - Lay Summary and Keywords

Warning: Save your work at least every 15 minutes by clicking ◆Save◆ or ◆Continue.◆

Lay Summary and Keywords

Please provide the following information about your study.

1.0 ***Provide a brief lay summary describing this study. (limit 500 words).**

This study pre-tests an intervention to improve service delivery and political accountability for rural residents in one province in Pakistan. In partnership with a democratically elected member of the Provincial Assembly in Khyber Pakhtunkhwa
Province, Pakistan, we will collect cell phone numbers from a random sample of approximately 200 male adults. During the collection of cell phone numbers, informed consent will be collected. Some basic demographic and political information will be collected at this stage.

Using an appropriate vendor (VOTO Mobile), we will then send pre-recorded messages to some of these respondents from either the assemblyman or from the top civil servant in his area (the District Official) regarding upcoming public infrastructure improvements and public policy priorities. We will allow a selection of respondents to provide feedback about their preferences using Interactive Voice Technology (IVR).

We will then aggregate and present the aggregated preference information to the public officials. Finally, we will send another pre-recorded cell phone message to respondents informing them of the public investment that they should expect in their area, and when it is likely to occur.

Following this, we will collect end-line data and debrief respondents to understand their experiences with the IVR and with the opportunity to use their cell phones to communicate with their elected (or appointed) representative.

2.0 ***List three to five keywords describing this study (separate the words with commas). The keywords may be used for identifying certain types of studies.**

Pakistan, political accountability, information

3.0 ***Is this study conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Control and Prevention, etc.)?**

○ Yes ◉ **No**

4.0 ***Is this study regulated by the Food and Drug Administration (FDA)?**

○ Yes ◉ **No**

- 4.1
- **If yes, check all that apply:**

☐	Human Drugs
☐	Medical Devices
☐	Biological Products
☐	Food Additives
☐	Color Additives
☐	Other

  - 4.1.1
  - **If Other, describe:**

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Methods/Procedures - Descriptors

Note: The items listed below are not an inclusive list of methods and procedures that may be used in research studies. The list only includes items that will trigger additional questions related to the research or are needed for the review process

1.0 ***Indicate all that apply to this study.**

☑	Audio, Visual or Digital Recordings
☐	Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)
☐	Certificate of Confidentiality
☐	Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention
☐	Community Based Research
☐	Controlled Substances (Schedule I or II)
☐	Deception or Partial Disclosure

- [ ] Devices/Diagnostics (including Humanitarian Devices - HUD)
- [ ] Drugs/Biologics/Dietary Supplements
- [ ] Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)
- [ ] Genetic Analyses/Genotyping
- [ ] Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells
- [ ] Human Gene Transfer/ Recombinant DNA
- [ ] Infectious Agents
- [ ] Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.
- [ ] Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)
- [ ] Substance Abuse Research (with Medication)
- [ ] Treatment in an Emergency Setting (with request to waive consent)
- [ ] **None of the above**

2.0 ***Will the study require services or resources owned/rented/operated or provided by the UCLA Health System (e.g. clinic and/or hospital visit(s), professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.)?**

Please direct any questions about this to the Clinical Trials Administration Office at coverageanalysis@mednet.ucla.edu.

○ Yes ◉ **No**

ID: IRB#17-000182 View: NEW 3.1 - UCLA IRB Review or Reliance

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

UCLA IRB Review or Reliance

1.0 ***Please incidate the type of reliance (check all that apply):**

- [ ] UC MOU
  Online registration is ALSO required at the UC IRB Reliance Registry.
- [ ] UCLA/RAND Health Services MOU
  UCLA/RAND Request registration form.
- [ ] CTSI MOU
  CTSI protocol registration form.
- [ ] NCI CIRB
- [ ] Western IRB
- [ ] Quorum IRB
- [x] Other IRB(s) not listed above

Note:

- Please be sure that you have indicated in section 1.3 of this application that this is a multi-institutional study and whether UCLA is responsible for the overall direction of the study at the other institution(s).
- Regardless of your selection above, please list the collaborating site(s) in section 1.5 (or lead site institution in section 1.6) of this application.
- If you are requesting UCLA to serve as IRB of record for collaborator(s), please also ***complete the required application form*** and submit by email to OHRPP to make a formal request.
- See Reliance of UCLA Investigators on External IRBs for information about existing UCLA agreements and contact OHRPP for assistance.

- 1.1
- **If you selected UC MOU above, please select all involved:**
-
  - [ ] UC Berkeley
  - [ ] UC Davis
  - [ ] UC Irvine

- [ ] UC Merced
- [ ] UC Riverside
- [ ] UC San Diego
- [ ] UC San Francisco
- [ ] UC Santa Barbara
- [ ] UC Santa Cruz

- 1.2
- **If you selected CTSI MOU above, please check all the collaborating institutions:**

- [ ] Cedars-Sinai Medical Center (CSMC)
- [ ] LA BioMed
- [ ] Charles R. Drew University
- [ ] USC

- 1.3
- **Documentation Required for UCLA to Serve as Reviewing IRB for CTSI or UCLA/RAND MOUs**
  See Reliance of UCLA Investigators on External IRBs for instructions.

Document Name	Document Version #
There are no items to display	

ID: IRB#17-000182 View: NEW 6.1 - Funding and Other Study Characteristics

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Funding and Other Study Characteristics

1.0 ***Indicate the funding status for this study**.

- (•) Funded
- ( ) Application for funding is pending
- ( ) Departmental funding / Self funding / No funding

2.0 ***Check all that apply**:

- [ ] The research will be conducted through the UCLA Clinical and Translational Research Center (CTRC)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Defense (DOD)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Energy (DOE)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Justice (DOJ)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Education (ED)
- [ ] The study will be supported by or conducted in collaboration with the U.S. Department of Protection Agency (EPA)
- [x] **None of the above**

- 2.1
- **If you selected DOD, DOE, DOJ, ED, and/or EPA support/collaboration, please provide your assurances that you will review the additional requirements for research supported by the relevant federal agency.**
- **Agree** [ ]
- **Note**: Please refer to the Federally-Supported Research section of the OHRPP guidance document: Funding Considerations for Federally-Funded and Industry-Sponsored Human Research.

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Funding - Description

Based on the response to section 6.1/item1, this study is or will be funded. Please provide the following information.

The Office of Contract and Grant Administration (OCGA) provides the list of funding sources used by webIRB in this section. Please check your OCGA paperwork to find the correct name of the funding source(s) for this study. Identifying the right funding source is important because:

? webIRB will auto-populate the designated funding source name on the approval letter for the study. Many funding sources require an accurate identification of their name on the IRB approval letter before they will release funding;
? The Office of Research Administration uses data from webIRB to generate funding reports.

Click here for tips on how to find the funding source name in webIRB.

1.0 Identify the funding source(s).
If a specific funding source has ended, do not delete it, instead please click Update next to the funding entry and **revise item 1.9**.

	Funding Source	Funding Source Information

View Other

Name of the Funding Source	Other
If other, specify	International Growth Center, London School of Economics and Political Science and Oxford University Governance Initiative of the Abdul Latif Jameel Poverty Action Lab, MIT
UCLA PI named on the grant, contract, subcontract or gift:	MIRIAM GOLDEN
Indicate the type of award:	Grant
Indicate the Grant Title:	Establishing Responsive Linkages between Politicians and Voters in Pakistan
Indicate the Award Number assigned by the funding source:	VCG-VPAK-VXXXX-37412
Indicate the description that applies to the source of funding named in the above item. If this is a subcontract, indicate the original source of funding:	Private/Not-for-Profit
If Other, specify	*No Value Entered*
Attach a copy of the funding proposal, subcontract, or scope of work.	**Document Name**: Annex 1- IGC Project Proposal Form 1-VCG-VPAK-VXXXX-37412.pdf **Document Version #**: 0.01 **Document Name**: Responsive Linkages **Document Version #**: 0.01 **Document Name**: SubContract for Signature CDPR 37412.pdf **Document Version #**: 0.01
Does the content of this IRB application differ from the activities described in the attached funding proposal, subcontract, or scope of work?	Yes
If yes, describe:	Co-PI Saad Gulzar moving to Stanford University as Assistant Professor
Check this box to indicate that this specific funding has ended	No

ID: IRB#17-000182 View: NEW 8.1 - Study Design

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Study Design

1.0 ***Check all that apply to the study design.**

- [x] **Direct subject contact ONLY** The research activities involve direct contact with study participants (e.g., collection of data or specimens in person or via internet, phone, mail, etc.)
- [ ] **No direct subject contact** None of the research activities involve direct contact with study participants and include only analyses of data, records and/or human biological specimens (e.g., medical record or other record review, study of specimens left over from clinical procedures).
- [ ] **BOTH Direct subject contact AND No direct subject contact** Some of the research activities involve direct contact with study participants and some of the research activities involve analyses of data, records and/or human specimens obtained without contact with participants.

ID: IRB#17-000182 View: NEW 8.8 - Audio, Visual or Digital Recordings

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Audio, Visual or Digital Recordings

You indicated that this study includes recordings (audio or visual) (section 2.3/item 1.0). Please provide the following information.

1.0 ***Who will transcribe the research tapes/recordings?**

Check as many as apply:

- [x] Members of the research team
- [x] Persons outside the research team

2.0 ***Is the use of recordings an optional part of the research?**

○ Yes ◉ **No**

3.0 ***Will individual study participants be able to review, edit, and erase the tapes/recordings of their research participation?**

○ Yes ◉ **No**

- 3.1
- **If no, provide an ethical and scientific justification for NOT allowing study participants to review, edit, and erase the tapes of their research participation.**
  Respondents will be asked to respond to pre-recorded queries by their Member of the Provincial Assembly or their District Official using Interactive Voice Technology on their cell phone keypads. The questions will be about priorities for public investments and other preferred government priorities. Respondents will be asked to use their keypads to indicate their preferences. Respondents may also be offered the option of leaving a voice message. The data collected will be aggregated and analyzed in an effort to provide to public officials information about what their voters prefer for public spending decisions and use of official time. It will not be feasible for respondents to review their answers after the fact. The electronic records contain only information in direct response to very specific questions.

4.0 **Transcription of Research Tapes/Recordings**

- 4.1
- ***Type of media (Check as many as apply):**
  - [ ] CD ROM
  - [ ] DVD
  - [x] Digital Files

- [ ] VHS tape
- [ ] Cassette or microcassette
- [ ] Handwritten files
- [ ] Other

- 4.2
- * **Method of transmission (Check as many as apply):**

- [ ] Courier or mail with delivery confirmation
- [x] Posted to a secure website
- [ ] Email
- [ ] Other
- [ ] **Not Applicable**

- 4.3
- * **Transcription Service (Check as many as apply):**

- [ ] Transcription service secures tapes in a secure locked area
- [x] Transcription(s) sign confidentiality agreements
- [x] Transmission of voice files and text files is encrypted and password protected
- [ ] Other
- [ ] **Not Applicable**

  - 4.3.1
  - **If you selected "other" for any/all of the above items, describe.**

ID: IRB#17-000182 View: NEW 9.2 - Information about Study Data

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Information about Study Data

This information is needed to determine how you will best protect the confidentiality of data.

1.0 ***Indicate all that apply to the study data.**

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
- [x] **None of the above**

2.0 ***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?**

( ) Yes (•) **No**

- 2.1
- **If yes, explain below and include a discussion of the reporting requirements in the consent document:**

3.0 ***Indicate if any of the following are being obtained and used without any direct contact with study participants.**

- [ ] Records (Not medical)
- [ ] Human biological specimens
- [x] **None of the Above**

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

- [x] Names

- [x] Dates
- [ ] Age (if over 89 years)
- [x] Postal Address
- [x] Phone Numbers
- [ ] Fax Numbers
- [ ] E-Mail Address
- [ ] Social Security Number
- [ ] Medical Record Number
- [ ] Health Plan Numbers
- [ ] Account Numbers
- [ ] License/Certificate Numbers
- [ ] Vehicle ID Numbers
- [ ] Device Identifiers/Serial 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**

- 4.1
- **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.**

5.0 ***Select all that apply:**

- [x] The data and/or specimens will be directly labeled with personal identifying information when acquired by the investigator for this research
- [x] The data and/or specimens will be labeled with a code that the research team can link to personal identifying information when acquired by the investigator for this research
- [ ] The data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information when acquired by the investigator for this research
- [ ] The data are restricted use data (A term used in Social-Behavioral research. See guidance on the right.)

- 5.1
- **Indicate how the data will be used when this study is completed.**

Check all that apply:

- [x] Use for this study
- [x] Use for possible future research
- [ ] Use to create a bank or repository at UCLA
- [ ] Add to existing repository
- [ ] Other

  - 5.1.1
  - **If Other, specify:**

Privacy and Confidentiality

Important Notes:

- **Privacy is about people.** Privacy refers to a person's wish to control the access of others to themselves.
- **Confidentiality is about data.** Confidentiality refers to the researcher's plan to handle, manage, and disseminate the participant's identifiable private information.

See OHRPP Quick Guide: Protecting Privacy and Maintaining Confidentiality

1.0 ***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, or conducting medical procedures in an examination room, or behind a curtain in an emergency room).**

Interviews will be conducted in the household only if the household member grants entry to the enumerator. Within the household, there is no expectation of privacy regarding the questions asked in the cultural context in which we work.

2.0 ***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.**

Note: Other sections of the application (e.g., Sections 9.3, 9.3a, 9.4, 9.5, and 15.3) will request specifications such as identification of persons who will have access to code keys or measures to comply with HIPAA requirements.

The research team will store the data on a server, and password access will only be available to authorized researchers. Phone numbers will be stored in this server and will not be downloaded to our computers without encryption. They will be downloaded, encrypted, and stored on a removable disk and not in any cloud storage.

The numbers in this encrypted format will be handed to the VOTO Mobile team who will make the recorded calls, but they will have no other metadata about the respondents, only the phone numbers.

The data will be aggregated to the level of the village for dissemination to the assemblyman and the district official, and thus individually identifying information will not be made available to them, to respondents, or to other residents of the area.

ID: IRB#17-000182 View: NEW 9.3 - Data Security

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Data Security

You indicated that the study team will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items.

1.0 ***Do you agree to follow the OHRPP Data Security in Research guidance and procedures?**

- (●) Yes
- ( ) I have an alternate equally effective plan (*Note: The plan must be attached to item #2.1*)

2.0 ***Do you have a data security plan for this study?** *(Note: a plan is not required for all studies; it may be recommended in some instance).*

( ) Yes (●) **No**

- 2.1
- **If yes, attach it here:**
-

Document Name	Document Version #
There are no items to display	

3.0 ***Indicate all that apply to personally identifiable information or codes during conduct of the study:**

- [ ] The data and/or specimens will be coded
- [ ] The personal identifying information will be removed and destroyed
- [x] Personally identifying information will be maintained with the data and/or specimens

- 3.1

- **If you indicated that the personal identifying information will be removed or destroyed or that the data/specimens will be coded, provide the following information:**
    - **The process for removing and destroying the personal identifying information or for coding the information, and**
    - **Indicate who will perform the task**
-

4.0 ***Will coded or personally identifiable data be collected, transmitted or stored via the internet?**

(•) **Yes** ( ) No

- 4.1
- **If yes, indicate all that apply:**

☐	A mechanism such as Survey Monkey, Zoomerang, or an e-mail anonymizing service will be used to strip off the IP addresses for data submitted via e-mail.
☑	The data will be encrypted.
☑	A firewall will be used to protect the research computer from unauthorized access.
☐	Controlled access privileges will be used on the hardware storing the data.
☐	Other.

-
-
    - 4.1.1
    - **If you indicated "Other", describe:**

5.0 ***Provide your assurances that if there is a data security breach for this study, the PI will notify the IRB and your department's IT Compliance Coordinator.**

Agree ☑

ID: IRB#17-000182 View: NEW 9.3a - Data Security - Identifiable Data

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Data Security - Identifiable Data

You indicated that personally identifiable information will be maintained with the study data and/or specimens during conduct of the study (Section 9.3/item 3). Please complete the following items.

1.0 ***Will any personally identifiable data be stored on portable devices (e.g., laptops, PDAs, iPods, external hard drives)?**

(•) **Yes** ( ) No

- 1.1
- **If yes, provide the rationale for keeping personally identifiable information on a portable device(s):**
- Researcher's laptops who will be moving in the field.

2.0 **Indicate how the information will be handled and stored to assure confidentiality.**

- 2.1
- ***Electronic Data:**
-

☑	Encryption or password protection software will be used
☐	Secure network server will be used to store data
☐	Stand alone desktop computer will be used to store data (not connected to server/internet)
☐	A contracted outside vendor will store the code key. The vendor will have a business associate agreement with UCLA.
☐	Other
☐	**Not Applicable**

- 2.2
- ***Hardcopy Data, Recordings and Specimens:**
-

☐	Locked file cabinet or locked room with limited access by authorized personnel
☐	Locked lab/refrigerator/freezer with limited access by authorized personnel
☐	Other
☑	**Not Applicable**

- 2.3
- **If you indicated "Other" in item 2.1 or 2.2 above, describe here:**
-

3.0 ***By checking this box, I provide my assurance that all the person(s) who will have access to the personally identifiable information have been identified in section 1.1 or section 1.1a.**

Agree ☑

ID: IRB#17-000182 View: NEW 9.5 - Data Security Plan

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Data Security Plan

You indicated that the study will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items:

1.0 ***After the study is completed**, indicate how the data codes and/or personal identifying information will be handled.

Check all that apply:

☑	All data files will be stripped of personal identifiers and/or the key to the code destroyed.
☐	All specimens will be stripped of personal identifiers and/or the key to the code destroyed.
☐	Personal identifiers and/or codes linking the data and/or specimens to personal identifiers will be maintained for future research.
☑	Audio or Video recordings will be transcribed and then destroyed or modified to eliminate the possibility that study participants could be identified.
☐	Photos or Images will be modified to eliminate the possibility that study participants could be identified.
☐	Restricted use data will be destroyed or returned to the source.

- 1.1
- **If you indicated that personal identifiers will be maintained for future research, provide the following information:**
- **a) How the information will be securely handled and stored**
- **b) assure confidentiality, and**
- **c) who will have access to the identifiers and/or codes.**
-

2.0 **Describe any additional steps, if any, to be taken to assure that the subjects' identities and any personal identifying information are kept confidential.**

ID: IRB#17-000182 View: NEW 9.8 - Data and/or Specimens for Possible Future Use

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Data and/or Specimens for Possible Future Use

You indicated that prospectively collected data and/or specimens would be stored for future use (Section 9.2/item 5.1). Please provide the following information.

1.0 ***Specify what information directly or indirectly linked to the subject will be provided with data and/or specimens to other investigators.**

Check all that apply:

☑	No subject identifiers (The data/specimens are anonymous; no one including the investigator could identify the person from whom the materials were gathered.)

- [ ] The data will be coded (A code links the data/specimens to the study participants. A key to the code exists.)
- [ ] Personal Identifying Information
- [ ] **Not applicable, the data will not be shared outside the study team.**

2.0 Distribution Rules: 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):
Academic researchers.

ID: IRB#17-000182 View: NEW 10.1 - Study Summary - Research Study

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Study Summary - Research Study

1.0 Study Materials: As applicable to this study, attach the following:

- **Protocol, Dissertation Proposal or Study Plan**
- **Preliminary Data**
- **Surveys, Questionnaires or other instruments to be used with study participants**
- **References**

Document Name	Document Version #
Baseline survey instrument	0.02
Enumerator training document	0.01
Mr. Muhammad Parvez, c.v.	0.01
Recorded message and IVR questions	0.01

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

The aims of this research are:

(1) to assess if respondents will provide cell phone numbers;
(2) to assess if respondents will answer questions using IVR technology when called with a pre-recorded message and set of questions from their Member of the Legislative Assembly or District Officer;
(3) to assess the policy priorities of respondents;
(4) to inform respondents of the decisions made by their Member of the Legislative Assembly based on the answers to the questions (item 2).

3.0 *Background and Significance: Provide a summary of the background for this study and explain how it will contribute to existing knowledge.

For greater than minimal risk biomedical studies, include preliminary data. If necessary, attach in Item 1.0 graphs or tables used to convey information. If there no preliminary data are available, briefly indicate why this proposed study is a reasonable starting point.

This study aims to provide public officials with new technological tools with which to communicate with the public. In less developed settings, where opinion polls are unavailable, public officials often have no way to know what policies voters prefer. We will help public officials gather this information. Likewise, we will allow ordinary people to express their views to their public officials on matters that are immediate, of high importance, and actionable. We thus hope to built durable feed-back links between voters, elected officials, and bureaucrats that are helpful to all.

4.0 *Research Design and Methods: Describe in detail the design and methodology of the study.

We are partnering with 20 Members of the Provincial Assembly (MPA) in KP province, Pakistan. We will select 11 villages for each MPA and then randomly sample 100 respondents in each using geographic sampling and random walks.

We will collect cell phone numbers from male heads of households using face-to-face household interviews that will be organized and supervised by Mr. Muhammad Parvez. These interviews will contain a few other baseline questions. This baseline survey will occur in fall 2017.

Then we send and SMS message to respondents encouraging them to participate in the program and be attentive for the MPA call that is forthcoming.

Then we send pre-recorded messages to respondents who have provided valid cell phone numbers from their MPA through a platform known as VOTO Mobile. VOTO receives only the phone numbers and no other metadata about respondents. In the call, we solicit views on specific policy questions and randomize which, if any, questions respondents hear. Then we present aggregated information about responses to the MPA. Finally, we will send

another pre-recorded cell phone message to respondents from the MPA informing them of the public investment that they should expect in their area, and when it is likely to occur.

Finally, we will collect end-line data using telephonic surveys or in person with the same respondents and debrief them to understand their experiences with the IVR and with the opportunity to use their cell phones to communicate with their elected (or appointed) representative.

- 4.1
- * **Will you be providing results of any experimental tests that are performed for the study?**
-
  - ○ Yes - Complete Items 4.1.1 and 4.1.2
  - ○ No
  - ◉ Not Applicable
-
  - 4.1.1
  - **You indicated in Item 4.1 that the research involves experimental tests. Please describe the tests, provide a rationale for providing participants with the experimental test results and explain what, how and by whom participants and their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.**
  -
  -
  - 4.1.2
  - **Will tests be performed by a Clinical Laboratory Improvement Amendments (CLIA) approved lab?**
  - ○ Yes ○ No

5.0 ***Indicate how much time will be required of the subjects, per visit or contact, and in total for the study.**

10 minutes for initial survey; 2-5 minutes for cell phone calls and IVR; 2 minutes for follow-up cell phone call; 10 minutes for follow up debriefing by enumerators.

6.0 ***Statistics and Data Analysis: Describe the proposed statistical procedures or descriptive analyses for the study. If applicable, indicate how the sample size was determined.**

We will analyze percentage of respondents providing cell phone numbers. We will compare percentages of respondents who utilize IVR to answer questions according to whether the questions are asked by the MPA or the District Officer, and according to the specific questions asked. We will analyze whether respondents then listen to the full follow-up pre-recorded message.

Sample size determined on the basis of expectations about IVR take-up rates.

ID: IRB#17-000182 View: NEW 11.1 - Characteristics of the Study Population

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Characteristics of the Study Population

1.0 ***Is this an observational or ethnographic study for which the number of participants observed or interviewed cannot be determined in advance.**

○ Yes ◉ **No**

2.0 **If you answered "no" to item 1.0, indicate the maximum number of study participants you hope to enroll:**
20000

3.0 **How many participants do you expect you will need to recruit, consent and/or screen to meet the target number above?**
20000

4.0 ***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.
Male head of household of voting age.

We are seeking only men because in Pakistan, we would have to send out female enumerators to be able to enroll women. In that culture, it is not appropriate for a male enumerator to ask to interview a woman. We do not have access to female staff.

5.0 ***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.**
Women are excluded, as described above.

6.0 ***How (chart review, additional tests/exams for study purposes, etc.), when and by whom will eligibility be determined?**
Eligibility will be determined by enumerators by asking household members who is the male head of household.

ID: IRB#17-000182 View: NEW 11.2 - Characteristics of Study Population

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Characteristics of Study Population

1.0 ***Indicate the age range of the study participants.**

Check all that apply:

- [ ] 0 to 6 years
- [ ] 7 to 11 years
- [ ] 12 to 17 years
- [ ] 17 or younger **in California** who can consent for themselves - see note below
- [ ] 17 or younger **outside California** who can consent for themselves - see note below
- [x] 18 years or older

NOTE:

- For additional information on minors **in California** who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians
- For additional information on minors **outside of California** who are permitted to consent for themselves please refer to the section "Exceptions Outside of California" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians

2.0 ***Indicate if any of the following populations/specimens will be specifically recruited/obtained for the study.**

- [x] Adults who are competent to give informed consent
- [ ] Adults unable to give informed consent
- [ ] Adults with diminished capacity to consent
- [ ] Fetal Tissue
- [ ] Neonates
- [x] Participants Unable to Read, Speak, or understand English
- [ ] Pregnant Women/Fetuses
- [ ] Prisoners
- [ ] UCLA Faculty/Staff
- [ ] UCLA Students
- [ ] Wards
- [ ] **Unknown/Not Applicable**

3.0 ***Is it possible that there may be non-English speakers enrolled in this study or children whose parents are non-English speaking?**

(•) **Yes** ( ) No

ID: IRB#17-000182 View: NEW 14.1 - Risks & Benefits

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Risks & Benefits

Risks & Benefits

Benefits

1.0 ***Are there any potential direct benefits (physical, psychological, social or other) to study participants?**

(●) **Yes** ( ) No

- 1.1
- **If yes, describe.**
- Study participants, if placed into treatment, will receive direct communication about policy decisions by their Member of the Provincial Assembly or their District Officer.

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

Our study will provide a new way for government to collect actionable information allowing it to be more responsive to public needs and preferences. This will make government more responsible and more accountable, and may reduce public tolerance for political extremism.

Risks

3.0 ***Indicate the potential risks/discomforts, if any, associated with each intervention or research procedure.**

Additionally discuss any measures that will be taken to minimize risks. If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility. The information provided should be reflected in risks section of the informed consent documents.

If this is an exempt study and there are no risks, indicate N/A. Otherwise, please see the help text. Participants may not wish to reveal their political or other views to strangers. They may decline to participate, or cease participation at any time.

Risk/Benefit Analysis

4.0 ***RISKS/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 are minimal because respondents can cease participation if they do not wish to answer a question. The potential benefits to participants and to society are much greater than the risks.

Alternatives

5.0 ***Indicate the alternatives to participating in this study.**

Check all that apply.

☑	All types of studies - Choose not to participate in the study
☐	Clinical/Intervention Studies - Receive standard of care instead of participating in the study
☐	Clinical/Intervention Studies - Medication, device, or other treatment is available off study
☐	Item is Not Applicable (e.g., study of existing data)
☐	Other

- 5.1
- **If "other" was selected, specify.**
-

- 5.2
- **If this is a clinical/intervention study:**

  Describe the standard of care or activities at UCLA (or study site) that are available to prospective participants who do not enroll in this study. If not applicable to your study, state not applicable (N/A).

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Data & Safety Monitoring Plan

1.0 ***Is a Data and Safety Monitoring Plan (DSMP) required by the funding agency or other entity?**

( ) Yes (●) **No**

Payment, Costs, and Injury

1.0 ***Indicate what the participants will receive for their participation in the study.**

Check all that apply.

- [x] No payment will be provided
- [ ] University check
- [ ] Course Credit
- [ ] Cash
- [ ] Gift Cards/Bruincard Deposit
- [ ] Non-Monetary Gifts or Services
- [ ] Other (including vouchers for parking)

- 1.1
- **If you selected Non-Monetary Gifts or Services or Other, describe:**
-

- 1.2
- **If you selected *Cash* and/or *Gift Cards/Bruincard Deposit* please specify the estimated total amount of money you will require to pay all participants during the length of the entire study. This information is required by UCLA Business and Finance Services (BFS), the office that will provide the cash/gift cards for payment.**
-

2.0 **If study participants will receive financial or other payment for their participation in the study, please provide the following information:**

- If applicable, the amount each participant will receive and the payment schedule to be followed including whether partial payment will be provided when the participant does not complete the study.
- If there are different plans for different populations or sub-studies, specify the groups and describe the plans.
- If families or children will be involved in the research, clarify how the payments, items or services will be apportioned.

3.0 ***Will subjects** incur **any financial obligations from participation in the study?**

- ( ) Yes (•) **No**

- 3.1
- **If yes, describe:**
-

4.0 ***Indicate below that you are familiar with UCLA policy related to treatment and compensation for injury and that you will use in the consent form for this study the appropriate UC required statement describing "Treatment and Compensation for Injury." Click here to access the UCLA policy: Treatment and Compensation for Research Related Injury.**

Note: Select **Not Applicable** if study is minimal risk.

- ( ) Agree
- (•) Not Applicable

Identification/Recruitment Methods

1.0 ***How will you identify and/or recruit participants for this study.**

Check all that apply:

- [ ] Advertisements/Flyers/Information Sheet/Internet Postings
- [x] Direct recruitment of potential study participants (e.g., physicians talking with their own or clinic patients about the study, contact between the study team and potential subjects in person, on the phone or on the internet, etc.)
- [x] Random or Other Probability Sampling
- [ ] Recruitment Letters/Emails
- [ ] Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)
- [ ] Review of medical records to identify potential research participants
- [ ] Review of publicly available records
- [ ] Review of other records
- [ ] Participant pool for which potential research participants have given permission for future contact
- [ ] Potential Study Participants are identified from another IRB approved study or IRB approved screening protocol
- [ ] Other

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Recruitment Methods

1.0 **Please upload copies of your recruitment materials below. This includes advertisements, flyers, internet postings, recruitment scripts and letters/emails.**

Document Name	Document Version #
There are no items to display	

Ads/Flyers/Info Sheets/Internet Postings

2.0 **If you have indicated that study participants will be recruited with advertisements/flyers (Section 18.1/Item 1.0), please indicate the type of media that will be used (e.g., newspaper, radio, internet, etc.) and/or where information will be posted or distributed.**

Direct Recruitment

3.0 **If you have indicated that participants will be recruited through direct contact (Section 18.1/Item 1.0), please provide the following information:**

- A description of how, when, and where initial contact would be made (e.g. in a public setting, in a waiting room, via a phone call, via a letter, via the internet, etc.)
- If applicable to the study, indicate how the potential research participant's privacy will be maintained.
- Who will make the contact (e.g. the investigator, a patient's physician, etc.)

Initial contact will be made at the home. Contact will be made by trained enumerators hired for this study. Surveys will be conducted inside the home, where privacy from other household members is not expected.

- 3.1
- **If you will be directly recruiting potential participants who are your patients, students, laboratory workers or any 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.**

Recruitment Letters/Emails

4.0 **If you have indicated that recruitment letters will be distributed to participants (Section 18.1/item 1.0), please indicate who will send out the recruitment letter (i.e. will it be the investigator or other persons who have authorized access to the information), how inquiries will be handled, and if there will be follow-up contacts.**

Referrals

5.0 **If you have indicated that study participants will be identified from referrals (Section 18.1/item 1.0), please indicate the source of the referral (e.g., friends, other participants, healthcare providers) and how the referral will be elicited.**

Research Participant Pools/Recruitment Databases

6.0 **If you have indicated that subjects will be identified and recruited from a subject pool(s) or recruitment database, (Section 18.1/item 1.0), please indicate the name of the Pool or Recruitment Database and UCLA Department. If the Pool or Recruitment Database is not at UCLA, identify the location.**

ID: IRB#17-000182 View: NEW 18.3 - Identification Methods

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Identification Methods

Random or Other Probability Sampling

1.0 **If you have indicated that probability sampling will be used to identify potential study participants (Section 18.1/Item 1.0), please indicate the specific technique(s) and how it will be used in this study.**

Random walk within villages.

Review of Publicly Available Records

2.0 **If you have indicated that publicly available records will be used to identify potential participants for the study (Section 18.1/item 1.0), please indicate the type(s) of records to be used.**

Review of Other Records

3.0 **If you have indicated that other records will be used to identify potential study participants (Section 18.1/item 1.0), please indicate the type(s) of records to be used.**

- 3.1
- **If applicable, indicate the permissions that you have received to review the records.**

Another IRB Approved Study or Screening Protocol

4.0 **If you have indicated that potential subjects are identified from another study or from a screening protocol (Section 18.1/item 1.0), please provide the IRB# for the study.**

- 4.1
- **If you do not have the IRB#, please provide the title of the study.**
-

Identification/Recruitment - Other

5.0 **If you have indicated that "other" ways will be used to identify or recruit study participants (Section 18.1/item 1.0), please describe.**

ID: IRB#17-000182 View: NEW 19.1 - Eligibility Screening

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Eligibility Screening

1.0 ***Will you be conducting a preliminary assessment with potential research participants to determine study eligibility during the recruitment process?**

○ Yes ◉ **No**

ID: IRB#17-000182 View: NEW 20.1 - Informed Consent Process

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Informed Consent Process

You indicated that adults (and/or minors who are permitted to consent for themselves) are participating in the study (Section 11.2/item 1.0 or Section 12.2/item 1.0).

For additional information on minors who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians.

1.0 ***Indicate your plans for obtaining informed consent for this study.**

Check all that apply:

☐ **Signed consent** will be obtained from the research participant or Legally Authorized Representative.

- Signed consent means research participants will be asked to **sign and date** a written consent form.

☑ **A waiver of signed consent is requested for the entire study.** One of the following procedures will be conducted:

- **A written information sheet will** be used. Signed consent will not be obtained from research participants.
- **Oral consent** will be obtained from the research participant or Legally Authorized Representative (LAR)
- This option should be selected if the study involves consenting participants via the internet.

☐ A **waiver of consent** is being requested.

- Research participants will **not** be asked to sign a consent form or give oral consent

☐ Consent will be obtained by a collaborating institution.

- 1.1
- **- If you checked more than one plan above, list the study groups and the plan that you will use for each.**
- **- If you checked "Consent will be obtained by a collaborating institution", explain the consent process and upload a copy of the most recent approved consent document in item 1.2.**

- 1.2

- **If applicable, attach the consent document(s) from collaborating institution(s).**

Document Name	Document Version #
There are no items to display	

ID: IRB#17-000182 View: NEW 20.2 - Waiver of Signed Informed Consent (Consent Without a Signature)

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Waiver of Signed Informed Consent (Consent Without a Signature)

You indicated that you are obtaining oral consent for the study (Section 20.1/item 1). Please provide the following information.

1.0 ***Indicate the reason that you are requesting to conduct an oral consent process instead of obtaining signed consent.**

◉ The research is minimal risk and does not involve any procedures for which written consent is normally required outside the research setting (e.g., in everyday life written consent is not needed for minimal risk surveys, non-invasive health measurements, etc.) (45 CFR 46.117 c2)

○ The only record linking the participants and the research would be the consent document, and the main risk of research would be a breach of confidentiality (45 CFR 46.117 c1).

e.g., Participants could suffer from social stigma, embarrassment, or other harms if it became known that they participated in research that identified them as having issues including, but not limited to, risky sexual behaviors, HIV, or mental health problems.

If you indicated that the **main risk is a breach of confidentiality**, answer 1.1, if appppropriate.

- 1.1

- **According to DHHS regulations at 45 CFR 46.117 (c1) when the main risk of the research would be a breach of confidentiality and an oral consent process is used, each subject should be asked whether he/she wants**

documentation linking the subject with the research and the subject's wishes will govern.

Check here if you want the IRB to consider allowing a waiver of this regulation so that you do not need to ask each subject if he/she wishes documentation.

☐ Request to waive documentation linking the participant with the research

2.0 If the oral consent process applies only to certain parts of the study (e.g., specific procedures or populations), explain.

ID: IRB#17-000182 View: NEW 20.3 - Description of the Consent Process

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Description of the Consent Process

1.0 *Indicate the type of setting(s) in which the consent process will be conducted.

Check all that apply.

- ☑ In a private home
- ☐ In a private room
- ☐ In a waiting room
- ☐ In a public setting
- ☐ In a group setting
- ☐ On the internet
- ☐ Over the telephone
- ☐ Other

- 1.1
- **If you checked more than one response, or indicated other, describe.**
-
- 1.2
- **If the setting is not private, describe the measures to protect confidentiality or indicate "not applicable."**
-

2.0 *Indicate the measures that will be taken to provide prospective research participants with sufficient opportunity to consider whether or not to participate in the study.

Check all that apply.

- ☑ Member(s) of the study staff will meet with the prospective participants/families to review the consent document(s) and/or provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study.
- ☐ Prospective participants/families will have the opportunity to take the consent form(s) home and may discuss the documents with others prior to deciding whether or not to participate in the study.
- ☐ Prospective participants will self-administer the consent and send it back if they decide to participate in the study.
- ☐ Other

- 2.1
- **If you indicated other, describe.**

3.0 *Indicate the length of time subjects are given to decide whether they wish to participate in the study.
As long as desired, but we expect they will typically take less than five minutes.

4.0 *How will you assess whether subjects understand the information conveyed during the consent process?

Check all that apply.

- [ ] Use the Subject Comprehension Tool form for research
- [x] Investigator or study team member will evaluate during the consent process
- [ ] Other
- [ ] Not Applicable

- 4.1
- **If you indicated other, describe.**
-

5.0 ***Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.**

Document Name	Document Version #
Informed Consent English Only.pdf	0.01

ID: IRB#17-000182 View: NEW 22.1 - Cultural Considerations

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Cultural Considerations

The following items are designed to acquaint the IRB with cultural features of the population that you are studying that may require procedures to ensure truly informed consent.

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

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

- 1.1
- **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.**
- Enumerators will recruit only male heads of households, so that more vulnerable populations are not recruited. Enumerators will be trained to be sensitive to respondents, to answer questions frankly, to be tactful, and to allow respondents to withdraw from the study at any time.

ID: IRB#17-000182 View: NEW 22.2 - Non-English Speaking Study Participants

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Non-English Speaking Study Participants

You indicated that you would involve non-English speaking participants in the study (Section 11.2/Item 2.0) and/or that there is a possibility that non-English speaking participants may be enrolled in the study (Section 11.2/Item 3.0). Please provide the following information.

1.0 ***Indicate the method that you use to conduct the consent process[1] with participants who do not speak English.**

Check all that apply.

- [x] The consent form and other study documents will be available in the participants' primary language. Study personnel (or qualified translators) able to discuss the participation in the patients' language will be present for the consent process.
- [x] Study staff or qualified translators will discuss the study in the participants' language.
- [x] An oral consent process will be used. Study personnel (or qualified translators) able to discuss the participation in the participants' language will be present for the consent process.
- [ ] The short form or another method will be used to conduct the consent process.

Important Note: The short form may be used in very limited circumstances. For additional information please refer to the " 'Short Form' Method" section of the OHRPP guidance document, Research Involving Non-English Speaking Research Participants.

- 1.1
- **If you checked "short form or another method", provide additional details.**

2.0 ***How will you maintain the ability to communicate with non-English speakers throughout their participation in the study?**
Indicate "N/A" if not applicable to your study.
Enumerators will be fluent in Pashto, the language of our respondents.

3.0 ***If you are conducting research for which there is a real or foreseeable risk of biomedical harm in the state of California, indicate your agreement that you will provide the participants who do not read, speak, or understand English a copy of the Research Participants Bill of Rights in a language in which they are fluent. Translations into the most common languages in the greater Los Angeles area are available for download on the OHRPP website.**

- ( ) Agree
- (•) Not Applicable

[1] *If minors are involved in the study, this would also include the processes of obtaining parental permission and assent, as applicable.*

ID: IRB#17-000182 View: NEW 24.0 - Additional Information and/or Attachments

Warning: Save your work at least every 15 minutes by clicking Save or Continue.

Additional Information and/or Attachments

1.0 **Attach any other documents that have not been specifically requested in previous items, but are needed for IRB Review.**

Document Name	Document Version #
SMS Messages after Consent/Baseline	0.01

2.0 **If there is any additional information that you want to communicate about this study, include it in the area provided. Note: this section should not be used instead of the standard application items.**

Enumerators will explain to potential respondents that the study is undertaken by their Member of the Provincial Assembly, working with researchers at the Center for Economic Research in Pakistan (CERP). The P.I. is a Political Economy Fellow of CERP. Enumerators will be instructed to answer all questions honestly, but will not initially disclose that the research team is based in the U.S. Revealing an American affiliation will provoke fear. This is because clandestine United States government operatives masqueraded as polio vaccination workers going door to door in Pakistan in the search for Bin Laden. As a result, respondents might incorrectly assume that enumerators are clandestine operatives of the United States government if any US affiliation is disclosed. A US affiliation could put enumerators in danger and could generate unnecessary fear in the villages where we work.

ID: IRB#17-000182 View: NEW 100.0 - Instructions for Study Submission

Instructions for Study Submission

You have completed your application, **but it has *not yet been submitted*.**

FOLLOW THESE STEPS TO SUBMIT THE APPLICATION TO THE IRB FOR REVIEW:

1. Click the **Finish** button to return to exit the SmartForm and return to the study workspace.
2. Use the **View SmartForm Progress** function to make sure that the application is complete.
3. If you are the PI or PI Proxy, click **Submit Study** under **My Activities**. If you are a member of the study team, you can let the PI know that the study is ready to submit by

clicking **Send Ready Notification.**

4. Once the study is submitted, the state indicator at the top of the page will no longer display **Pre-Submission.**
5. After submission of the study, the **PI Assurances** activity will immediately become available under **My Activities**. The PI should provide his/her assurances at that time. If the PI is not available, the study can be submitted by a PI Proxy and the assurances provided at a later time. The study will be reviewed by the IRB while the **PI Assurances** are pending; however, it will not be approved until the **PI assurances** are completed.
6. ***If there is a Faculty Sponsor for the study***: The study can not be submitted to the IRB until the Faculty Sponsor provides his/her assurances through **FS Assurances** activity.

ID: IRB#17-000182 View: Display - Method Description

Audio, Visual or Digital Recordings

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Certificate of Confidentiality

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. The project does not need to be funded by NIH to obtain a Certificate of Confidentiality. For additional information see http://grants.nih.gov/grants/policy/coc/

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention

A clinical trial is a research study designed to answer specific questions about medical or behavioral treatments. The trial may be interventional or observational. Interventional studies are those in which the research participants are assigned by the investigator to a treatment or other intervention, and the outcomes measured. Observational studies are those in which individuals are observed and the outcomes are measured by the investigators.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Community Based Research

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Controlled Substances (Schedule I or II)

Check here only if you are using a Schedule I or II Controlled substance in this study. Research using Schedule I or Schedule II controlled Substances must be submitted to the Research Advisory Panel of California for review and approval prior to initiation. Research using Schedule III, IV, or V Controlled Substances as a study drug do not require review by the Research Advisory Panel. For further information see: http://ag.ca.gov/research/guide.php o Schedule I Controlled Substances are drugs or substances with a high potential for abuse, that have no currently accepted medical use in treatment in the United States. Examples of Schedule I Controlled Substances are: heroin, lysergic acid diethylamide (LSD), methylenedioxy-methamphetamine (MDMA), marijuana, and psilocybin. o Schedule II Controlled Substances are drugs or substances with a high potential for abuse, that have a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions. Examples of Schedule II Controlled Substances are: fentanyl, methadone, methylphenidate, morphine, and oxycodone. For further information see: http://www.deadiversion.usdoj.gov/schedules/index.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Deception or Partial Disclosure

Deception includes withholding information about the real purpose of the study or purposely giving subjects false information about some aspect of the research to prevent bias. Some professions, such as the American Psychological Association (APA) have ethical codes regarding the use of deception in research. (See sections 8.07 and 8.08 at http://www.apa.org/ethics/code/index.aspx#807) If deception is included in the study, you must also apply for approval of a waiver of the informed consent process (Section 20.1) in addition to selecting the other consent procedures planned for the study (e.g., written or oral consent).

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

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Devices/Diagnostics (including Humanitarian Devices - HUD)

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy. For further information see: http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000182 View: Display - Method Description

Drugs/Biologics/Dietary Supplements

- Drug: The term "drug" means: articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.
- Biologics vs. Drugs: Most drugs consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination. This requires sterile processes to be applied from initial manufacturing steps. For more information see: http://www.fda.gov/consumer/updates/biologics062608.html#drugs
- Dietary Supplements are products that are intended to supplement the diet and have one of the following ingredients:
    - ? A vitamin
    - ? A mineral
    - ? An herb or other botanical
    - ? An amino acid

? A dietary substance for use by man to supplement the diet by increasing the total daily intake
? A concentrate, metabolite, constituents, or an extract of combinations of these ingredients.

For additional information see: http://www.foodsafety.gov/~dms/supplmnt.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Genetic Analyses/Genotyping

Genetic analyses/genotyping include, but are not limited to, studies of inheritable conditions or traits, gene markers or mutations, and pedigrees.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells

Research with human embryonic stem cells (hESC) and related lines requires IRB review under the following conditions: o Clinical research in which human subjects are given hESCs or related products. o When the UCLA research team will have a research related direct interaction or intervention with the cell donors, including donation of blastocysts or gametes for the purpose of creating hESCs,. o Cells provided to the UCLA research team that have identifiers or codes that can be linked back to the donor. Research involving hESC requires review and approval by the ESCRO Committee. For further information see: http://www.stemcell.ucla.edu/research

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Human Gene Transfer/ Recombinant DNA

Studies involving gene transfer and/or recombinant DNA require approval of the UCLA Institutional Biosafety Committee (IBC) and the NIH Recombinant DNA Advisory Committee (RAC) . Human gene transfer is an investigational method for correcting defective genes responsible for disease development through one of the following techniques: o A normal gene may be inserted into a nonspecific location within the genome to replace a nonfunctional gene. o An abnormal gene could be swapped for a normal gene. o The abnormal gene could be repaired through selective reverse mutation, which returns the gene to its normal function. o The regulation of a particular gene could be altered. Recombinant DNA molecules, according to the NIH Guidelines, are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Infectious Agents

Studies involving the use of Risk Group 2 or 3 infectious agents (such as bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) require approval of the UCLA Institutional Biosafety Committee (IBC).

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.

Clinical Engineering is responsible for completing incoming inspections on investigational devices that are used to diagnose, treat or monitor a patient and that are used in the patient care area on site at UCLA, but *not* in other hospitals such as Cedars Sinai, CHLA, or Drew. If a device is FDA and/or testing - laboratory approved for the purpose it was designed, then evaluation is not required of the device. If you have a copy of an inspection report from Clinical Engineering, please attach here. As appropriate, please contact Clinical Engineering at 310-267-9000 to arrange an inspection.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Substance Abuse Research (with Medication)

Research for the treatment of controlled substance addiction or abuse that uses any drug (scheduled or not) as treatment, requires the review and approval of the Research Advisory Panel of California prior to initiation. For further information see: For further information see: http://ag.ca.gov/research/guide.php

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

Treatment in an Emergency Setting (with request to waive consent)

Federal regulations allow certain research activities to be conducted in emergency settings with waiver of informed consent - in the interest of facilitating potentially life-saving and life-enhancing research with protecting the rights and welfare of participants. For further information see: o OHRP Guidance: http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm o FDA Guidance: http://www.fda.gov/oc/ohrt/irbs/except.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.
ID: IRB#17-000182 View: Display - Method Description

None of the above

Click "OK" below to return to the SmartForm page where you can select the appropriate response.