

IRB Office use only
Date submitted _____
FB _____ **Exp.** _____

BU Charles River IRB
Application Form (Full Board and Expedited Review)

SECTION A: PROTOCOL AND CONTACT INFORMATION

| | |
|---|--|
| Protocol Number (To be assigned by IRB Office): | |
| Protocol Title: | An Evaluation of the Relative Efficacy and Effectiveness of Written and Verbal Contracts: Lessons from a Field Experiment in Urban Malawi |
| Principal Investigator (Name, degrees, licenses, etc.): <input checked="" type="checkbox"/> Mr. <input type="checkbox"/> Ms. | Mahesh Karra, B.A., M.Sc., Sc.D. |
| Department/School: | Frederick S. Pardee School of Global Studies |
| BU Mailing Address: | 152 Bay State Road, Room G04C Boston, MA 02215 |
| Email: | mvkarra@bu.edu |
| Telephone: | +1-617-358-0197 |
| Additional Contact Person: | Thomas Gautier |
| Email: | tgautier@bu.edu |
| Telephone: | +1-857-222-3094 |
| <input type="checkbox"/> YES (REQUIRED) | I confirm that I qualify to serve as the Principal Investigator of this study and am in compliance with the following policies: • http://www.bu.edu/researchsupport/compliance/human-subjects/ |

SECTION B: FUNDING

Provide information regarding **ALL** funding sources in this section. This includes **ANY EXISTING FUNDING, PENDING FUNDING, OR FUNDING THAT HAS BEEN APPLIED FOR TO SUPPORT THIS RESEARCH.**

| Please check all that apply: | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | This research is funded Have you received Just In Time (JIT) Notification? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| <input type="checkbox"/> | Funding has been requested Have you received Just In Time (JIT) Notification? <input type="checkbox"/> Yes <input type="checkbox"/> No |

| | |
|--------------------------|---|
| | NOTE: Once the funding has been awarded, submit an amendment to the IRB to add the funding source |
| <input type="checkbox"/> | Research is not funded |

If the research is funded or funding has been requested, it is REQUIRED that you complete the box below. The Sponsor Award # must be included in the box below. If you don't have an award #, please state that in the box below. If you have multiple funding sources, add additional boxes as necessary.

| | | |
|---|-------------------------------------|--|
| Sponsor Name | | Hariri Institute Research Incubation Award |
| Title of Grant/Proposal | | "Can I get that in writing?" Lessons from a Contracting Field Experiment in Urban Malawi |
| Sponsor Award # (REQUIRED)* *If Award # is pending, put pending. Once the funding has been awarded, submit an amendment to the IRB to add the funding source | | BU Hariri Institute of Computing Research Award Award ID: 2019-03-003 |
| | | |
| YES | NO | |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Is Boston University the Prime Awardee of the grant? |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Is Boston University receiving a sub-award? Name of Prime Recipient: |

***NOTE:** Provide a copy of the grant application, funding proposal, scope of work, or sub-award agreement. The University is required to verify that all funding proposals and grants have been reviewed by the IRB before funds are awarded.

If this research study is for your dissertation, provide a copy of your prospectus (if available).

SECTION C: CONFLICT OF INTEREST

| | |
|--|--|
| <input checked="" type="checkbox"/> YES (REQUIRED) | I confirm that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms, submitted them to the COI office, and completed training as dictated at: http://www.bu.edu/researchsupport/compliance/conflicts-of-interest/ , and as provided under the <u>Boston University Policy on Investigator's Conflicts of Interest</u> . |
| Of the financial interest disclosure forms submitted, has anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form? <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No | |

***If anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

SECTION D: TYPE OF REVIEW

For Guidance regarding Type of Review please refer to the following website:

<http://www.bu.edu/researchsupport/compliance/human-subjects/submitting-an-irb-protocol/>

I. FULL BOARD ☐

Please refer to the IRB website for Full Board submission deadlines and meeting dates:

<http://www.bu.edu/researchsupport/compliance/human-subjects/dates-and-timing-of-the-irb-committee/>

II. EXPEDITED ☒

In order to qualify for expedited review, the study must be no more than minimal risk* **AND** must fall into one of the categories below. Check all that apply:

1. ☐ Clinical studies of drugs and medical devices only when an investigational new drug application (IND) or investigational device exemption application (IDE) is not required
2. ☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn

may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings, saliva or cheek swabs, sweat, etc.
4. ☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

Examples:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
 2. Weighing or testing sensory acuity
 3. Magnetic resonance imaging
 4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
 5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
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5. ☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
 6. ☐ Collection of data from voice, video, digital, or image recordings made for research purposes.
 7. ☒ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: The IRB will make the final determination on the Type of Review

***Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

SECTION E: STUDY STAFF AND HUMAN SUBJECTS TRAINING

List **ALL** current members of the research team in the table below. Add more rows as necessary.

STUDENT RESEARCH:

The Faculty Advisor must be listed as a co-investigator in this section and must complete the Human Subjects training requirements. Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student's human subjects research. Faculty Advisors must sign this Application prior to it being submitted to the IRB.

BU CHARLES RIVER CAMPUS (CRC) INVESTIGATORS/STUDY STAFF

Note: Boston University Medical Campus (BUMC) investigators/study staff should be listed in the NON-BU INVESTIGATOR/STUDY STAFF section

| Name, Degree, & Department/School | Study Role (e.g. co-investigator, research coordinator, research assistant, project manager, lab manager) | Human Subjects Training* |
|---|--|--|
| Mahesh Karra, Sc.D., Frederick S. Pardee School of Global Studies | Principal Investigator | <input checked="" type="checkbox"/> CITI <input type="checkbox"/> Other**: _____ Most Recent Date Completed: _____ |
| Thomas Gautier, Ph.D., Economics, Graduate School of Arts and Sciences | Co-Investigator | <input checked="" type="checkbox"/> CITI <input type="checkbox"/> Other**: _____ Most Recent Date Completed: _____ |
| | | <input type="checkbox"/> CITI <input type="checkbox"/> Other**: _____ Most Recent Date Completed: _____ |

*For more information regarding the Human Subjects Training Policy, refer to the 'Training' section of the Policies & Guidance section IRB website:

<http://www.bu.edu/researchsupport/training-how-to/human-subjects-training/>. This site includes a Study Personnel Training List. You can search this list by name to obtain the completion and expiration dates of training for investigators and study staff.

**If the investigator/study staff did not complete CITI, you must submit a copy of his/her training certificate.

NON-BU INVESTIGATORS/STUDY STAFF*☒ **N/A**

Note: BUMC and BMC staff are considered to be non-BU staff and should be listed in this section. Add more rows as necessary. All the columns in the box below must be completed. In addition, you must complete the box that follows with a description of the activities for each staff member.

| Name, Degree, & Affiliate Institution | Study Role | Staff Information | Will IRB Approval be Obtained from Affiliate? |
|---------------------------------------|------------|---|--|
| | | <p>1. Will this staff interact with subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Will this staff have access to identifiable information? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>3. Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> | <p><input type="checkbox"/> Yes: Provide copy of IRB approval letter when available: <input type="checkbox"/> No (provide reason): _____</p> |
| | | <p>1. Will this staff interact with subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Will this staff have access to identifiable information? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>3. Is the work that the staff will complete related to his/her role or coursework at</p> | <p><input type="checkbox"/> Yes: Provide copy of IRB approval letter when available: <input type="checkbox"/> No (provide reason): _____</p> |

| | | | |
|--|--|---|--|
| | | his/her affiliate institution.? <input type="checkbox"/> Yes <input type="checkbox"/> No | |
|--|--|---|--|

*If IRB approval will be obtained from the affiliate site, only list the lead investigator from the affiliate on this form.

The box below must be completed. Include a summary for each staff listed in the above box. If any of the investigators listed on this form are not affiliated with BU, provide a summary of the study activities that he/she will conduct. If IRB approval is not being obtained at the affiliate institution, provide an explanation. **NOTE: Non-BU staff may be required to complete an Individual Investigator Agreement (IIA). The IRB will notify you if this form is required.**

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| N/A |
|-----|

REQUIRED GOOD CLINICAL PRACTICE TRAINING FOR NIH-FUNDED CLINICAL TRIALS

| YES* | NO | NIH-FUNDED CLINICAL TRIALS |
|--------------------------|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Is your study NIH-Funded AND meet the definition of a clinical trial as defined below:</p> <p>Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those intervention on health-related biomedical or behavioral outcomes. This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g. behavioral interventions.</p> <p>Of note, this requirement for GCP training applies to both biomedical and behavioral clinical trials funded by the NIH.</p> <p>On January 1, 2017, a new policy of the National Institutes of Health (NIH) goes into effect that requires all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP).</p> |

| | | |
|--|--|---|
| | | <p>The policy applies to all active grants and contracts, no matter what point they are in the life cycle of the trial.</p> <p>Currently, there is a GCP course available in our CITI training program (https://www.citiprogram.org/). This current course does have a focus on FDA-regulated research. Please note that online social-behavioral GCP courses are under development and we expect to have a social-behavioral focused GCP course available in the near future.</p> <p>If this study meets the definition, all staff must complete GCP training.</p> <p>For more information on this policy please refer to:</p> <ul style="list-style-type: none"> • NIH definition of a Clinical Trial: http://osp.od.nih.gov/sites/default/files/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf • Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html • Frequently Asked Questions: http://osp.od.nih.gov/sites/default/files/FAQs_on_NIH_GCP_Policy.pdf |
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SECTION F: LOCATION OF THE RESEARCH

| YES* | NO | |
|-------------------------------------|--------------------------|---|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <p>Will this research take place at sites/locations other than Boston University?</p> <p>Note: If the research will take place at Boston University, state the location (Building and Room number):</p> |

*If **YES**, please complete the boxes below

NOTE: You are responsible for obtaining permission/letters of support for research conducted off-site. This may include locations such as schools, workplaces, community organizations, etc. You must submit the letters/documentation of support with this application.

| Institution Name and Address (if known) | Describe Involvement (recruiting, consenting, data analysis, etc.) of the site. If the site or the site staff is not involved (engaged) ¹ in research procedures, state NONE. | IRB/Ethics Approval/Site Permission Attached? If no ² , explain the plan to obtain this approval. If the site is not engaged in the |
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| | | |

| | | research, you do not need to complete the box. |
|--|---|--|
| <p>Innovations for Poverty Action (IPA) 101 Whitney Ave, 2nd Fl. New Haven, CT 06510</p> <p>IPA Malawi Area 47, Sector 3, Plot 249 PO Box 31093, Lilongwe 3 Lilongwe, Malawi Phone: +265 1762424 Country Representative: Suleiman Asman sasman@poverty-action.org</p> | <p>1) hiring, training, and management of the local field staff; 2) data collection, monitoring, and evaluation; 3) implementation of the intervention; and 4) assisting the investigators with the dissemination of results in Malawi.</p> | <p>All study materials and protocols will be submitted to the local scientific and ethics committee, the National Committee On Research In The Social Sciences And Humanities (NCRSH), for review and approval. All materials will be submitted by 15 October 2020 and the NCRSH has informed us that they will require approximately one month to review the study. If approved, we will receive a letter of approval from the NCRSH as a confirmation and will submit this letter to the BU IRB.</p> <p>We will also obtain a letter of approval from the Lilongwe District Council that allows us to conduct our study. The police Officer-in- Charge of Lilongwe district will be informed of the study as required. Copies of the letters of approval will be provided as attachments.</p> <p>The ethical roles of the local institution, IPA Malawi, will be covered by the NCRSH.</p> |
| <p>¹Guidance on Engagement of Institutions in Human Subjects Research: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html</p> <p>²If IRB approval will not be obtained at the site, describe the IRB oversight arrangements here:</p> | | |

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| YES* | NO | |
|--------------------------|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Is the off-site location requesting that the Boston University IRB review the protocol in place of local IRB review?</p> <p>*If YES, complete the Single IRB Review Form “Boston University is Institution A”: http://www.bu.edu/researchsupport/compliance/human-subjects/.</p> |

| YES* | NO | |
|--|--------------------------|---|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <p>Is the BU PI the lead investigator OR is BU the lead site for this research?</p> <p>Note: This box only needs to be completed if the off-site location is engaged in the research.</p> |
| <p>*If YES, provide the following information in this box:</p> <ul style="list-style-type: none"> The plan for collection and management of data from all the sites <p>All data (baseline, follow-up, intervention tracking, monitoring) will be administered in an electronic Computer-assisted personal interview (CAPI) format using the CommCare survey management system. CommCare is an open-source mobile health (mHealth) platform designed for data collection, client management, decision support, and behavior change communication. CommCare consists of two main technology components: CommCare Mobile and CommCareHQ. The mobile application is used by client-facing enumerators in visits as a data collection and educational tool and includes optional audio, image, and video prompts. Users access the application-building platform through the website http://www.commcarehq.org which Dimagi operates on a cloud-based server. CommCare supports J2ME feature phones, Android phones, and Android tablets and can capture photos and GPS readings. CommCare supports multi-languages and non-roman character scripts as well as the integration of multimedia (image, audio, and video). CommCare mobile versions allow applications to run offline and collected data can be transmitted to CommCareHQ when wireless (GPRS) or Internet (WI-FI) connectivity becomes available. Further information about the CommCare system can be found at www.commcarehq.org.</p> <p>To effectively monitor firms and participants over the study period, identifiable data on and firms characteristics will be collected, as well as firms contact information (addresses, phone numbers, e-mails, and GPS locations). In addition, photographs of the firms be taken to facilitate identification at follow-up. Minimal risk data on employees’ demographic background (age, sex), years of experience in the printing industry, and previous training (educational attainment) will also be collected. All identifiable data collected from surveys (both baseline and follow-up) and from the intervention will be administered in an electronic Computer-assisted personal interview (CAPI) format using the CommCare survey management system. Electronic survey data will be collected by interviewers on Android-based tablets, and data will be securely transferred from the Android tablets onto a CommCare-supported secure cloud server at the end of each working day. All Android tablets will be used for data collection only, and tablets settings will be adjusted so that field staff are blocked from accessing applications that are not</p> | | |

applicable for data collection (e.g. internet browsing, social media, email). The CommCare cloud server will be HIPAA-compliant and will meet all the necessary security requirements for storing Level 4 identifiable data. Once the data has been securely transferred to the cloud server, the survey record on the Android tablet will be immediately erased. A technical overview of the CommCare system, including descriptions of the data transfer process and the HIPAA-compliant storage system, can be found at [https://confluence.dimagi.com/display/commcarepublic/CommCare +Technical+Over-view](https://confluence.dimagi.com/display/commcarepublic/CommCare+Technical+Over-view), and an electronic version of the CommCare Terms of Use / End User License Agreement (EULA) can be found at <https://www.commcarehq.org/eula/>.

All data uploaded to the CommCare cloud server will be encrypted and password-protected in accordance to the Level 4 data security and storage regulations. For each collected data case, which will consist of a firm data record, all personal identifiable data will be separated from the other non-identifiable data. The de-identified data will then be uploaded to an encrypted password-protected FTP site on a daily or weekly basis and will be circulated to the project PIs for analysis purposes for the duration of the study. Identified data will be stored separately from the de-identified data on the CommCare secure encrypted server for the duration of the study. Identified data will only be accessed for the purpose of revisiting the firms during follow-up. After the study ends, the IPA Malawi research site will maintain the identified data in an encrypted file on a secure server. Only de-identified datasets will remain available for analysis purposes after the end of the study.

Every effort will be made to be sure that participation in this study, and all records about participation, will remain confidential. As previously stated, all confidential identifiable data will be secured by trained study personnel upon collection. Data will be collected by trained staff and fully de-identified as soon as possible. We will set up a data management system that meets the following requirements:

1. Raw electronic survey data will be immediately transferred once it has been collected on the Android-based tablets using a secure data transfer to the CommCare secure cloud server. Following the transfer, the data from the Android tablets will be automatically erased.
2. All identifying information will be separated from the raw electronic survey data immediately after collection and secure transfer to the cloud server, and a unique ID number will be assigned to each case. Coded, de-identified data files will be stored separately from the code list and identified data files to maintain confidentiality. Only Mr. Gautier, and Dr. Karra, the overall PI, will have access to the linkages to the underlying identifiable files. Identifiable electronic data will be encrypted, password-protected, and securely stored on the CommCare protected cloud server and one copy of the data will be stored on a password-protected computer, which will be designated as the Target Computer. De- identified data will be encrypted, password-protected, and securely stored separately from the identifiable data on the CommCare protected cloud server and on an encrypted password- protected FTP site.
3. Restrictions will be placed on non-authorized users from accessing certain data or features by assigning them permission levels. This includes restricting access to any identifying data that would violate HIPAA or other privacy standards. Each study team member will be assigned one

of three permission levels, which will provide them with varying levels of access, from no access (Level 0) to full access (Level 2).

Identifiable hard-copy data, including signed consent forms, will be stored in locked cabinets in access-limited rooms at the IPA Malawi office. All study computers that are used for descriptive analysis of the de-identified data will be password protected and only study staff who are cleared to view the data will have the password. All study data and linking keys will be password protected at all times. All electronic data, both on the CommCare secure cloud server and on any study computers, will be encrypted and password-protected. The information will only be accessible to the research team.

With specific regard to the dissemination of identifiable data, policies are in place to limit data dissemination beyond the immediate research team (comprising of the PI and Co-Investigator, and project manager, Mr. Asman). If there is any need to transmit identifiable data in electronic form, it will be done via secured connections. Team members have received training on the proper handling and storage of such data (e.g. never to store files on computers accessible outside the team). As is indicated, de-identified data may be shared more widely among the wider research team; even with de-identified data, all feasible precautions will be taken to limit access to those members of the research team who require such access.

All staff members of the study will be required to sign a data confidentiality agreement. The data will be stored in a relational database. Usernames and passwords are required to access the data. A security policy is used to ensure these passwords are updated on a regular basis.

Data sharing of de-identified data between Dr. Mahesh Karra and Mr. Thomas Gautier will be conducted in person – a USB key will be used to transfer the de-identified data from one secure hard drive to the next, and data will then be deleted from the USB key. The USB key will be used only for storing and transferring research material between the research team members mentioned above and will not be used for storing or transferring other files that are unrelated to the study. Two sets of de-identified data will be stored, one for each Dr. Karra and Mr. Gautier. De-identified data will be transmitted from Malawi to BU via secure file transfer (through the BU system). Colleagues in Malawi will be offered ‘guest access’ in order to transfer the data. All hard copy data and electronic data will be retained for seven years after study closure, after which it will be destroyed (shredding hard copies and permanently deleting all electronic files). Following the completion of the analysis, data will be stored on the BU network and will be deleted from all authors’ hard drives.

Field staff will have access to the primary data for a short period of time, given the nature of their responsibilities. Surveyors will have access to the primary data until the data has been cleared by either a field manager or the project manager, Mr. Asman, after which the data will be erased from their Android tablets. Field managers and the project manager will have access to the de-identified data and have been fully trained in managing this information in a confidential manner and they have completed the training for data security measures. Only the study investigators who will be directly analyzing the data (Dr. Karra and Mr. Gautier) will have permission to access the raw data. All individuals with access to data have been indicated in the IRB applications on the study team.

Following our own use and analysis of the data (a minimum 1-year time period), we hope to open access to de-identified baseline and follow-up survey data at no cost to authorized users. Only de-identified data will be available for download through a secure website, through which authorized users can download de-identified survey data files for legitimate academic research. To access the data, prospective users must first register on the secure website and must then create a new research project request. The request must include a project title and a description of the analysis that the user proposes to perform with the data. The requested data should only be used for research or study purposes. To request the same data for another purpose, a new research project request needs to be submitted. Requests for data access will then be reviewed by the PI, who can then grant or deny access to the user. All publications that users produce from the dataset must appropriately acknowledge the data source and project from which the data was collected. Once downloaded, the datasets must not be passed on to other researchers without the written consent of the PI. All reports and publications based on the requested data must be sent via e-mail to the PI in a Portable Document Format (pdf) or as a printed hard copy.

- The plan for reporting and evaluating:
 - Unanticipated problems
 - Serious and/or continuing non-compliance
 - Suspensions and terminations of research
 - Interim results
 - Protocol modifications

Unanticipated Problems, Non-Compliance, and Suspension of Research

We do not anticipate that there will be any reportable events in this minimal risk study; however, any communicating of reportable events of the data will be reported to the IRB at BU and to the NCRSH in Malawi immediately by us. The local project manager at IPA Malawi, Mr. Asman, and the Principal Investigator, Dr. Karra, will review all adverse events and protocol deviations. This information will then be reported to the IRB at BU and to the NCRSH in writing within 5 business days, as per the BU IRB's reportable new information policies. As per our stated reporting protocols, we will also inform local community leaders of any adverse events that relate to participant safety.

Breach of confidentiality is a risk of this study. We will take every step to make sure that participants' information is kept confidential by study staff, but there is a small chance that there is unintentional disclosure of information to those not trained as study staff members. However, our study staff members will be trained to make sure that collected information is kept private and will not be shared with others. In the event that we find out through the study that participants are at risk of harm or there is a risk of harm to others, we will need to break confidentiality in order to provide an active referral for services and/or report this risk to the relevant authorities (BU IRB and NCRSH included).

The information that will be collected in this study will neither place participants at risk of criminal or civil liability nor be damaging to the participants' financial standing or

All risk of harm cases will be discussed with the local project manager, Mr. Asman, and will be reported to the PI and Co-Investigators, who will then report it to the BU IRB and NCRSH. A standardized form for reporting risk of harm cases will be designed and all study team members

will be trained in its application. These forms will be securely stored at the IPA Malawi office. Dr. Mahesh Karra and Suleiman Asman will be the immediate supervisors of study staff in the field (research assistants). They will meet with the study staff on a weekly basis and will make sure that the study protocol and IRB regulations are being followed. On-site supervision will allow Dr. Karra and Mr. Asman to provide support for staff as well as quality assurance and confidentiality of study data. In addition, the local team and Boston-based team will be in regular contact via email in the interim to discuss the progress for the study protocol procedures. Dr. Karra and Mr. Gautier will travel regularly to Malawi over the course of the study period and particularly during the data collection phases to monitor field activities. All regulatory documentation will be maintained for 7 years after IRB study closure.

The study Principal Investigator, Dr. Mahesh Karra, will be assume overall responsibility for the safety, monitoring, and review of the data. He and Mr. Gautier will oversee the weekly review of all data collected in the study and will be present during the administration of the baseline and follow-up surveys. He and the co-investigators of the study will ensure that the data is treated as confidential and is stored in a secure location, as is detailed above. For the proposed research, the local project manager at IPA Malawi, Suleiman Asman and the Principal Investigator, Dr. Karra, will review adverse events and protocol deviations. This information will then be provided to the Institutional Review Boards at BU and the NCRSH in Lilongwe. Unanticipated adverse events and protocol deviations will be immediately reported to both the BU IRB and the NCRSH in writing within 5 business days.

Conflict of Interest Statement

All study investigators have read and understood the BU IRB and NCRSH policies on the declaration of competing interests, and we declare that we have no conflict of interest, financial or otherwise, other than the normal scholarly gains from taking part in this study.

Interim Results

Interim results and study progress reports, which will include completed interviews, project activities, and intervention progress will be submitted to the BU IRB and NCRSH on a six-month basis. A final progress report will be submitted to both ethics committees at the end of data collection.

Protocol Modifications

All protocol modifications will be submitted in writing to both the BU IRB and the NCRSH. The protocol modification will be updated on the official protocol that is submitted and will be highlighted for the committee's review. No protocol modifications will be implemented until both the BU IRB and the NCRSH have approved the changes.

- The name of the Principal Investigator from each site

The overall Principal Investigator of the study is Dr. Mahesh Karra (BU). The local Principal Investigator of the study site in Malawi is Suleiman Asman (IPA Malawi).

- If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site

All study materials and protocols will be submitted to the local scientific and ethics committee in Malawi, the National Committee On Research In The Social Sciences And Humanities

(NCRSH), for review and approval. All materials will be submitted by 15 October 2020, and the NCRSH has informed us that they will require approximately one month to review the study. If approved, we will receive a letter of approval from the NCRSH as a confirmation and will submit this letter to the BU IRB.

We will also obtain a letter of approval from the Lilongwe District Council that allows us to conduct our study. The police Officer-in-Charge of Lilongwe district will be informed of the study as required. Copies of the letters of approval will be provided as attachments. We will inform local community leaders (village heads, chiefs) in the areas of the study that the study will be conducted in their communities. We will also inform local community leaders of any adverse events that relate to participant safety.

The ethical roles of the local institution, IPA Malawi will be covered by the NCRSH.

- If IRB approval will be obtained at the site, confirmation that the site IRB has a federalwide assurance (FWA)

The National Committee On Research In The Social Sciences And Humanities (NCRSH) was established by the National Commission for Science and Technology under section 11 of the S&T Act No.16 of 2003 in Malawi and is registered with the USA Office for Human Research Protections (OHRP) as an International IRB (IRB Number IRB00003905, FWA Number FWA00005976).

| YES* | NO | |
|-------------------------------------|--------------------------|--|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Will this research be conducted outside of the United States?* |

*If **YES**, complete the International Research Form at <http://www.bu.edu/researchsupport/compliance/human-subjects/>

SECTION G: STUDY SUMMARY

Summarize the study in lay language (do not copy from the grant/scope of work/proposal, etc.). This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information.

Note: Do not include a list of citations in this section. Please limit this section to no more than 300 words.

Designing and enforcing the optimal contract is complicated and tedious, particularly in settings where formal contracts are not the norm. In many low- and middle-income countries, for example, transactions between customers (buyers) and firms (sellers) are often conducted informally to the extent that written receipts or other types of documentation are often not provided when purchasing goods in a market, negotiating prices for services, or disputing the receipt or quality of

previous purchases. While much of the empirical research has focused on contract enforcement and the evaluation of unforeseen contingencies, less work has been conducted to understand the costs and benefits associated with writing a complete contract or, more generally, having a written contract at all. The introduction of a transparent agreement (either written or verbal) in informal settings could serve to mitigate unforeseen contingencies, limit the uncertainty on transaction outcomes, settle disputes over transactions between buyers and sellers, improve performance standards and accountability, and raise productivity. At the same time, however, a formal contract may limit the scope for renegotiation over the price of the good in future periods, particularly as reputation between buyers and sellers is built over repeated interactions. To this end, it may be harder to renegotiate or to provide benefits to loyal customers if the contract explicitly fixes all terms of the transaction. It is therefore not clear as to whether the costs of implementing and enforcing contracts in informal settings would necessarily be outweighed by the benefits from introducing such a formal mechanism.

In this study, we propose to conduct a field experiment in which we test the relative effects of introducing and enforcing task-oriented contracting structures on outcomes related to contract compliance, levels of effort exerted by contracted agents, and service quality. The study will be conducted among a sample of 100 print shops, kiosks, and firms in Lilongwe, Malawi. We particularly are interested in testing the extent to which introducing certain imposing conditions (e.g. tight completion deadlines, strict printing specifications, etc.) along with a formal contract impact firm performance. Preliminary scoping work has been conducted to inform the design and implementation of the intervention, test survey instruments, establish the field site, and identify the local partnerships for the study.

Following a baseline survey, all printing firms that participate in the study will be randomized in one of three treatment groups: a control group, a “loose contract” group, and a “tight contract” group. Print firms that are assigned to the control group will be asked to complete a task (up to four print orders), and no formal contract will be given to the firm along with each order. Firms assigned to the loose contract group will be given a written contract along with each print order, and the contract will be structured without any strictly imposing conditions (e.g. tight deadlines). Firms assigned to the tight contract group will be given a contract with a specific tight condition (a short deadline) along with each order. A follow-up survey will be conducted with firms upon completion of the print orders. This experiment serves to test two hypothesis. First, we want to understand whether formal contracts have an impact on quality in the printing industry in Lilongwe. Second, we want to better understand the conditions under which formal contracts may be useful to increase output quality.

SECTION H: RESEARCH METHODS AND ACTIVITIES (Check all that apply)

| | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Collection of audio, video, digital, or image recordings |
| <input type="checkbox"/> | Biological samples → Complete Biological Samples Form: http://www.bu.edu/researchsupport/compliance/human-subjects/ Examples: blood, hair, cheek swab, urine, tears, saliva, etc. |

| | |
|-------------------------------------|--|
| <input type="checkbox"/> | Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. Examples: Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc. |
| <input type="checkbox"/> | Coordinating Center/Lead Site |
| <input type="checkbox"/> | Deception |
| <input type="checkbox"/> | Devices → Complete Devices Form: http://www.bu.edu/researchsupport/compliance/human-subjects/ |
| <input type="checkbox"/> | Drugs → Complete Drugs Form: http://www.bu.edu/researchsupport/compliance/human-subjects/ |
| <input checked="" type="checkbox"/> | Ethnographic: The study of people in their own environment through the use of methods such as participant observation and face-to-face interviewing |
| <input type="checkbox"/> | Focus Groups |
| <input type="checkbox"/> | Genetics Testing → Complete Genetics Form: http://www.bu.edu/researchsupport/compliance/human-subjects/ |
| <input type="checkbox"/> | MRI |
| <input type="checkbox"/> | Placebo |
| <input type="checkbox"/> | Pregnancy Testing |
| <input checked="" type="checkbox"/> | Randomization |
| <input checked="" type="checkbox"/> | Surveys, interviews, questionnaires |
| <input type="checkbox"/> | Secondary Data Analysis |
| <input type="checkbox"/> | Other (please describe): |

SECTION I: SUBJECT POPULATION

| | |
|--|---|
| Number of Subjects to be Enrolled: | 100 print shops |
| If you have sub-groups or more than one arm, please separate out these enrollment numbers. | Control group (40 print shops): receive up to 4 print |

| | |
|---|---|
| <p>Note: Please account for subjects who may drop out or be withdrawn from the study. Any subject who signs a consent form is considered to be enrolled regardless of whether they complete any study procedures</p> | <p>orders without formal contract.</p> <p>“Loose contract” group (30 print shops): receive up to 4 print orders with a formal contract without any “tight” constraint.</p> <p>“Tight contract” group (30 print shops): receive up to 4 print orders with a formal contract with a “tight” binding constraint.</p> |
|---|---|

| Check all categories that apply to your target population: | |
|--|------------------------------|
| <input checked="" type="checkbox"/> | Adults |
| <input type="checkbox"/> | Children (< 18 years of age) |
| <input type="checkbox"/> | Cognitively-Impaired Adults |
| <input checked="" type="checkbox"/> | Non-English Speaking |
| <input type="checkbox"/> | Prisoners |
| <input type="checkbox"/> | BU Employees |
| <input type="checkbox"/> | BU Students |
| <input type="checkbox"/> | Wards of the state |
| <input type="checkbox"/> | Other (please describe): |

| If Categories other than ‘Adult’ are checked, describe the additional safeguards that have been put in place to protect that subject population. For Cognitively-Impaired Subjects, provide the rationale for including this population in this research study. |
|---|
| |

Eligibility Criteria

Inclusion Criteria:

For this pilot study, we will select 100 printing firms in accordance with the following criteria:

1. The firm is located in Lilongwe
2. The firm is registered as a printing and/or stationery firm (shops, kiosks, centers) with the Malawi Stationery and Printers Association
3. The firm provide printing, photocopying, and other related services for profit

Exclusion Criteria (exclusion criteria are the specific criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria):

Any firm that may be misclassified as a print shop during the scoping and recruitment phase will be excluded from the study

SECTION J: RECRUITMENT

Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified

Note: Submit any recruitment materials such as advertisements, brochures, flyers, letters/e-mails, scripts, etc. Please submit these materials as separate documents in either Word or PDF format.

We shall travel to Lilongwe in December 2020 to initiate the study and complete preparations for the baseline survey and intervention. We will hire field staff, which include 5 surveyors who will be responsible for administering the baseline and follow-up survey to the firms; and 1 field manager who will supervise the survey enumerators, monitor and spot-check the data for quality issues, and oversee administration of the intervention.

With the support of IPA Malawi, we will then train surveyors to administer a baseline survey using the interviewer training manual. We will train the field manager to monitor surveyors and oversee field activities using the supervisor training manual. Enumerators will visit up to 100 potentially eligible print shops in Lilongwe that were identified during a preliminary scoping exercise that was completed by IPA Malawi in 2018. Firms will be recruited to participate in a complete baseline survey. The baseline survey will be administered either to the firm owner or, in the case where the owner is unavailable, an employee of the firm who is present at the time of the screening and recruitment visit. The baseline survey will be comprised of modules that collect background information related to firm activity, firm operations, and firm capacity. Minimal risk data on employees' demographic background (age, sex), years of experience in the printing industry, and previous training (educational attainment) will also be collected. Finally, data capturing the firm's range of services provided along with price data will be collected. In order to minimize observation biases that may arise, whereby firms and employees who are aware of being monitored as part of a research study may behave differently than they

otherwise may have, enumerators will introduce the baseline survey to the firm respondent as a vendor scoping exercise on behalf of IPA Malawi. To effectively monitor participants over the study period, the names and the geographic coordinates of the print shops will be collected. We will also collect the names of the employee who answered the baseline survey in order to conduct follow-up activities. The training of enumerators will occur in early January 2021, and enumerators will visit the print shops for recruitment in the middle of January 2021.

SECTION K: CONSENT AND ASSENT

NOTE: Please refer to the consent and assent form templates on the IRB website when creating your consent/assent documents. The templates include the required elements of consent and will help to ensure that your consent/assent form meets the requirements of the federal regulations and the BU CRC IRB. The consent templates can be located at:
<http://www.bu.edu/researchsupport/compliance/human-subjects/>.

Note: STUDENT RESEARCHERS must: 1) indicate in the consent form/information sheet/script that he/she is a student and 2) list the Faculty Advisor as a contact in the form/sheet/script.

Provide a summary of the consent process, including who will consent, and when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant and obtaining consent, that the prospective participant or the legally authorized representative has sufficient opportunity to consider whether to participate, and steps taken to minimize coercion or undue influence.

Note: Submit copies of all consent forms and scripts. Please submit these materials as separate documents in Word format.

Indicate the consent and/or assent process and document(s) to be used in this study. Check all that apply

| | | |
|--|--------------------------------|-------------------------------------|
| Consent: Adults (≥ 18 years of age) | | N/A <input type="checkbox"/> |
| One of the following MUST apply | | |
| <input type="checkbox"/> | Consent Form/Information Sheet | |
| <input type="checkbox"/> | Verbal Consent (Script) | |

| | |
|-------------------------------------|--|
| | Note: If written consent will not be obtained, complete the ‘Waiver of Written Documentation Consent’ box (Box 1) located further down in this section |
| <input checked="" type="checkbox"/> | <p>Consent will not be obtained</p> <p>Note: If consent will not be obtained, complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section</p> |

| | | |
|---|--|------------------------------|
| Assent of Children (≤ 18 years of age) | | N/A <input type="checkbox"/> |
| One of the following MUST apply | | |
| <input type="checkbox"/> | Assent Form OR Parent Consent Form/Information Sheet (older children may sign the parent consent form along with their parents as long as the consent form is written at the grade level of the subjects) | |
| <input type="checkbox"/> | Verbal Assent (Script) | |
| <input type="checkbox"/> | <p>Assent will not be obtained</p> <p>If assent will not be obtained, one of the following conditions must exist:</p> <ol style="list-style-type: none"> <input type="checkbox"/> The capability of some or all of the children is so limited that they cannot reasonably be consulted <input type="checkbox"/> The children are too young to provide assent <input type="checkbox"/> The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research <input type="checkbox"/> The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. (Complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section) <p>*45 CFR 46.116(d): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</p> | |
| Guidance on age requirements for obtaining assent: <ul style="list-style-type: none"> • Parental Permission for minors under 6 years of age • Verbal assent for minors 6-11 years of age | | |

| | |
|---|---|
| <ul style="list-style-type: none"> • Written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects) | |
| Parental Permission N/A <input type="checkbox"/> | |
| One of the following MUST apply | |
| <input type="checkbox"/> | Parental Consent Form |
| <input type="checkbox"/> | Parental Verbal Consent (Script) Note: If written consent will not be obtained, complete the ‘Waiver of Written Documentation of Consent’ box (Box 1) located further down in this section |
| <input type="checkbox"/> | Parental permission will not be obtained If parental permission will not be obtained, one of the following conditions must exist: <ol style="list-style-type: none"> 1. <input type="checkbox"/> The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). 2. <input type="checkbox"/> The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. (Complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section) <p>*45 CFR 46.116(d): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</p> |

| | |
|--|--|
| Consent: Cognitively Impaired Adults (≥18 years of age) | N/A <input checked="" type="checkbox"/> |
| Describe the process for the consent and/or assent process for enrolling cognitively impaired adult subjects including how capacity to consent is determined and if there is continual assessment of capacity | |
| | |

| | |
|---|--|
| Assent will be obtained from: | |
| <input type="checkbox"/> All Subjects <input type="checkbox"/> Some Subjects, specify: <input type="checkbox"/> No Subjects | |
| <input type="checkbox"/> | Consent will be obtained from the subject's Legally Authorized Representative (REQUIRED) |

| | |
|--|------------------------------|
| CONSENT OF NON-ENGLISH SPEAKING SUBJECTS | N/A <input type="checkbox"/> |
| Describe the process for obtaining consent from non-English speaking subjects. List the individual who will serve as the interpreter and his/her qualifications. | |
| NOTE: A copy of the translated consent along with the Attestation Form for Translation of Consent must be submitted. The Attestation Form can be located at: http://www.bu.edu/researchsupport/compliance/human-subjects/ . | |
| | |

BOX 1—WAIVER OF WRITTEN DOCUMENTATION OF CONSENT

| WAIVER OF WRITTEN DOCUMENTATION OF CONSENT N/A <input checked="" type="checkbox"/> | Yes | No |
|---|--------------------------|--------------------------|
| Either Criteria 1 or 2 must be met in order to qualify | | |
| <input type="checkbox"/> Criteria 1 | | |
| The research is NOT FDA Regulated | <input type="checkbox"/> | <input type="checkbox"/> |
| The only record linking the subject and the research would be the consent document | <input type="checkbox"/> | <input type="checkbox"/> |
| The principal risk would be potential harm resulting from a breach of confidentiality | <input type="checkbox"/> | <input type="checkbox"/> |
| Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject's wishes will govern | <input type="checkbox"/> | <input type="checkbox"/> |
| A written statement/information sheet will be provided to subjects. If NO , provide rationale for not providing this information | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Criteria 2 | | |
| The research is NOT FDA Regulated | <input type="checkbox"/> | <input type="checkbox"/> |
| The research presents no more than minimal risk of harm to subjects | <input type="checkbox"/> | <input type="checkbox"/> |

| | | |
|---|--------------------------|--------------------------|
| The research involves no procedures for which written consent is normally required outside of the research context | <input type="checkbox"/> | <input type="checkbox"/> |
| A written statement/information sheet will be provided to subjects. If NO , provide rationale for not providing this information | <input type="checkbox"/> | <input type="checkbox"/> |

BOX 2—WAIVE OR ALTERATION OF CONSENT

| WAIVER OR ALTERATION OF CONSENT | N/A <input type="checkbox"/> | Yes | No |
|---|-------------------------------------|-------------------------------------|--------------------------|
| All of the criteria below must be met in order to qualify | | | |
| The research is NOT FDA Regulated | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The research involves no more than minimal risk to the subjects | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| The research could not practicably be carried out without the waiver or alteration | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation. If NO , provide rationale for not providing this information: | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <p>Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):</p> <p>This minimal risk study that aims to examine firm behavior meets the above criteria for waiving consent for the following reasons:</p> <ol style="list-style-type: none"> 1. The study involves no more than minimal risk to subjects, who are mainly providing information about the print firm where they are employed. Information on firm capacity, firm activities, and outputs are all classified as non-human subjects data. Only employee names and background data (age, sex, years of employment and experience, and training background) will be collected for follow-up purposes. 2. Given that the main aim of the study is to observe firm responses to different contracting structures, it is essential to maintain an environment where any interactions with the firm are as devoid of appearance that a research study is being conducted so as not to introduce any observation biases that would contaminate any scope for inference. In order to minimize observation biases that may arise from research-related interactions, whereby firms and employees who are aware of being monitored as part of a research study may behave differently than they otherwise may have, enumerators will introduce the baseline survey to the firm respondent as a vendor scoping exercise on behalf of IPA Malawi. This excludes any firm behavior that may be induced as a response to specified intervention-related interactions (i.e. introduction of contracts). <p>Additional information, particularly information that concerns privacy and confidentiality, will be provided to participating firms and employees as needed.</p> | | | |

SECTION L: STUDY PROCEDURES

In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes versus which procedures are part of standard of care, if applicable. Be sure to include the following information:

- **Methods of data collection**
- **Details regarding research activities/procedures/interventions**
- **Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)**
- **Time required from each subject**
- **Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.***

***Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit Appendix C: Device Form.**

Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study. Please submit these materials as separate documents in either Word or PDF format.

Note: If subjects will have standard of care procedures in addition to research procedures, clearly state which procedures are standard of care and which are for research purposes only.

Timeline

This study is a three-armed randomized controlled trial that consists of a baseline survey followed by implementation of our print order intervention immediately following completion of the baseline. A follow-up survey will be conducted one week after completion of the final order, at the time when the order will be picked up at the print firm.

The study will span a total of 6 months, from October 2020 to March 2021. Months 1 to 3 (October 2020 to December 2020) will consist of finalizing local and BU IRB approvals, finalizing the electronic version of the survey instruments, preparing the orders, and other intervention materials for the study. The first half of month 4 (January 2021) will consist of hiring surveyors, other field staff (field managers) and working with local partners. Training of intervention staff, field staff, and surveyor will be administered in the third week of month 4 (January 2021) and will last less than 5 workdays.

During the last week of month 4, eligible print shops that participate in the study will receive a baseline survey. Immediately following completion of the baseline survey, print shops will be randomized on site to either the control arm or one of the two intervention arms. Following randomization, print shops will receive their first print order for completion.

During the first week of month 5 (February 2021), 7 days after the first visit to a print shop, enumerators will return to the print shop, collect the submitted orders for evaluation, and administer another print order. Each firm will receive up to 4 print orders over the next month (months 5 and 6). Upon completion of the final print order, a follow-up survey will be conducted with the firm. Analysis of data and write-up of the study findings will begin in the second half of month 6 and will continue through month 6 (February to March 2021).

Dr. Karra and the co-investigator, Thomas Gautier, will oversee all study activities over the full study duration. Mr. Gautier will be present in Malawi in March to oversee the setting up of the study, the training of surveyors, and administration of the baseline survey. In addition, he will provide local on-site support in Lilongwe and will primarily be involved in setting up the study, supervising the field team, and locally managing day-to-day field activities. Dr. Karra will be present in Malawi in the month of December 2020 and will return to Lilongwe over the course of the study to monitor the data collection process and to supervise the administration of the intervention. Dr. Karra and Mr. Gautier will conduct the analysis of the results following fieldwork and data collection after the experiment is completed from December 2020 to March 2021.

Initial Preparations and Training of Field Staff

We shall travel to Lilongwe in December 2020 to initiate the study and complete preparations for the baseline survey and interventions. We will meet with our partner organization, IPA Malawi in order to:

1. Hire field staff. Field staff include: 5 surveyors who will be responsible for administering the baseline, collect orders, and administering the follow-up surveys to the the print shops; and 1 field manager who will supervise the survey enumerators, monitor and spot-check the data for quality issues, and oversee administration of the treatment to the respective intervention arms.
2. Confirm transportation logistics (hiring of vehicles for field staff transport to and from study sites) and other related issues (mobile credit, internet, ...) for field staff.

With the support of IPA Malawi, we will then train surveyors to administer the baseline survey using the interviewer training manual. We will train field managers to monitor surveyors and oversee field activities using the supervisor training manual.

Sample Identification and Selection

For this pilot study, we will recruit firms that:

1. Are located in Lilongwe
2. Are registered as printing and/or stationery firms (shops, kiosks, centers) with the Malawi Stationery and Printers Association
3. Provide printing, photocopying, and other related services for profit

Printing firms that successfully meet these criteria will be recruited to participate in a comprehensive baseline survey. The baseline survey will be administered either to the firm owner or, in the case where the owner is unavailable, an employee of the firm who is present at the time of the screening and recruitment visit. The baseline survey will be comprised of modules that collect background information related to firm activity, firm operations, and firm capacity. Data on employee experience, training, and capacity will also be collected. Finally, data capturing the

firm's range of services provided along with price data will be collected.

Baseline Survey

Print shops that are identified as eligible and that participate in the study will receive a baseline survey. Surveys (both baseline and follow-up) will be administered in an electronic Computer-assisted personal interview (CAPI) format using the CommCare survey management system. Survey responses will be collected on Android-based tablets and will be securely transferred to the CommCare-supported server. All data on Android tablets will be encrypted, and the tablets themselves will be password protected. Refer above for additional details on data storage and security measures.

The baseline survey instrument will be comprised of questions from the Enterprise Survey (World Bank) as well as a few additional questions about experience with written contracts.

The survey will include questions about:

1. General information (ownership of the firm, opening year of the establishment, number of employees)
2. Sales and supplies (main activities, capacities, annual sales)
3. Degree of competition (practices of competitors)
4. Innovation
5. Finance (investments in new materials, credits)
6. Labor (number of permanent and temporary employees, education of employees)
7. Business environment (biggest obstacles faced by establishment)
8. Contracts (previous exposure to written contracts)

Prior to administering the survey, we will explain clearly the purpose of the study to respondents. If possible, baseline surveys will be administered in a private room in the shop and will last approximately 30 minutes. Breaks will be taken at the request of the participant and at other scheduled times (e.g. mealtime, picking children up from school, etc.) as needed. Surveys will be conducted in Chichewa, the local language, and will follow the format of the survey questionnaire, which will be electronically programmed into Android tablets. In order to successfully track the participating firms over time, we will be collecting identifiable data, including names and contact information for each of the survey respondents (the owner or the employee), the firm's address, contact phone numbers and e-mails, and GPS coordinates of the firm. For the purposes of minimizing loss to follow-up, we will also be taking photographs of the firm. To protect participant privacy and ensure confidentiality, all identifiable data will be appropriately stored and secured in accordance with the data security measures that are further described above. Photographs will be taken through the CommCare survey management system using Android tablets. Once the survey data is securely synced to the CommCare server, all photographs will be erased from enumerators' tablets. Each photograph will be securely stored on the CommCare server along with the survey data that is collected for each respondent.

Randomization

Following the baseline survey, firms will be randomized into one of three experimental arms:

1. A control group (T0). The firm will receive an order without formal contracts. All the instruction will be given orally.

Following the baseline interview, the enumerator will ask the print shop to complete an order in less than 7 days for a given price. The order will consist of printing a given set of documents or photocopying and collating a set of documents that have already been printed, or both. The

complexity of the printing and photocopying order will depend on the firm's printing and photocopying capacity, which will be determined over the course of the baseline interview. The enumerator will ask the print shop employee to complete the order at a stated agreed-upon price (to be paid seven days later, upon successful completion of the order) with the print shop.

If the print shop accepts the order, the enumerator will return within seven days after the first visit. If the print shop completes the order (even partially), the enumerator will pay the agreed-upon price and bring back the copies to IPA's office in Lilongwe, where an enumerator will evaluate the quality of the order for completeness, quality, and timeliness. If the print shop was unable to complete the task for any reason, the enumerator will withdraw the order. The enumerator will then administer the next order, for a total of up to four (4) print orders per firm.

2. A treatment group (T1) where the firm will receive an order with a written formal contract. In this arm, the print shop will receive exactly the same order as in the control group. However, the enumerator will give a written contract to the employee. The contract will specify the number of copies to be made, a description of the expected quality, a deadline (7 days after the order), and the price to be paid by the enumerator if the contract is respected. If the print shop accepts the task and accepts to sign the contract, the enumerator will come back 7 days later to collect the copies. The remainder of the intervention sequence (order assessment, etc.) will remain the same as has been described for the control group.

3. A treatment group (T2) where the firm will receive an order with a written formal contract specifying a shorter deadline (2 days) for completion. In addition, the enumerator will informally inform the shop owner that the deadline is not a binding constraint as long as the quality of the realized order is adequate.

In this treatment arm, the contract given to the print shop will specify a tighter deadline (two days). However, the enumerator will informally add that the deadline can be extended up to seven days if the quality of the completed job is high.

If the print shop accepts the order and accepts to sign the contract, the enumerator will return after two days to collect the order. If the order has not been completed yet, the enumerator will return after seven days to collect the order. The remainder of the intervention sequence (order assessment, etc.) will remain the same as has been described for the control group.

Each shop in each treatment group will receive up to 4 print orders, which will be administered as specified within their respective group assignments, over a one month intervention period.

Follow-Up Survey

After having collected the final print order (up to seven days after the disbursement of the fourth and final order), the enumerator will administer a short follow-up survey that will take between 5 to 10 minutes with a shop employee. The survey will document the experiences of the firm with receiving a formal contract and will document reasons as to why orders may or may not have been completed as per the specifications that were outlined when they were initially submitted.

Outcome Measurement

For each order of a given complexity that was submitted to a print shop, we will construct a series

of variables that aim to capture order quality as follows:

1. Did the shop accept the task?
2. Did the shop deliver the task before the (informal) deadline?
3. Did the shop deliver the task before the formal deadline (if any)?
4. How many copies did the shop deliver? The correct amount?
5. Number of copies that were correctly printed by the print shop.

For each task, we will check the number of copies that were correctly completed by the print shop. We will then create indexes of order quality for each order that a shop received.

SECTION M: RISKS

Describe any expected risks to subjects. Consider physical, psychological, social, political, legal, economic, or other risks that are related to the study.

We do not foresee any considerable physical, psychological, social, political, legal, or economic risks to firms, their employees, or any other human subjects who may be related to or involved in this minimal risk study.

Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.

As this is a minimal risk study where the unit of observation and assessment is the print firm, we do not foresee any risks that participating respondents may incur. With this said, any communicating of reportable events of the data will be reported to the IRB at BU and to the NCRSH in Malawi immediately by us. The local project manager at IPA Malawi, Mr. Asman, and the Principal Investigator, Dr. Karra, will review all adverse events and protocol deviations. This information will then be reported to the IRB at BU and to the NCRSH in writing within 5 business days, as per the BU IRB's reportable new information policies. We will inform local community leaders (village heads, chiefs) in the areas of the study that the study will be conducted in their communities. We will also inform local community leaders of any adverse events that relate to participant safety. As per our stated reporting protocols, we will also inform local community leaders of any adverse events that relate to participant safety.

SECTION N: BENEFITS

Describe the potential benefits to subjects related to the study. State if there are no direct benefits.

NOTE: Compensation and/or course credit are not considered benefits.

Firms that participate in the study will receive additional revenue in the form of payments for successfully completed print orders. For each order, firms will receive the market value of the services (printing, photocopying, etc.) that are provided as part of that order.

Describe the potential benefits to society and/or others related to the study

Our study findings will explore new approaches to investigating firm productivity and behavior as they relate to the introduction and implementation of contracts in informal settings and will generate new data and evidence on contracting mechanisms in low-income countries. Policymakers may use our findings to identify if and how contracting may serve to improve transparency and accountability, which in turn may have positive effects on productivity, quality, and output. Our findings may motivate the introduction of contracting in sectors where informal agreements are still the norm (e.g. health, agriculture, education, public services). Evidence from this study will be disseminated through local partnerships with the World Bank, the Economics Association of Malawi (ECAMA), and the Malawi Ministry of Finance. The team will work with these organizations to adapt the lessons learned to other contexts.

SECTION O: COSTS/PAYMENTS

| YES* | NO | |
|-------------------------------------|-------------------------------------|--|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Are there any costs to subjects as a result of participating in this study? *If YES, provide a description of the costs: |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Will subjects be compensated for participating in the study? Compensation may include cash, checks, gift cards, lotteries, course credit, etc. *If YES, provide a description of the compensation: Firms that participate in the study will receive additional revenue in the form of payments for successfully completed print orders. For each order, firms will receive the market value of the services (printing, photocopying, etc.) that are provided as part of that order. NOTE: Payments should be prorated to compensate subjects for time and procedures completed |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Will identifiable information be sent to Central University departments (Accounts Payable, Post Award Financial Operations, etc.) for payment purposes? *If YES, this information must be disclosed in the consent form. |

SECTION P: CONFIDENTIALITY OF DATA

Describe how data will be stored (e.g. paper, electronic database, etc.)

Identified data will be stored separately from the de-identified data on the CommCare secure encrypted server for the duration of the study (electronic database). Refer to previous sections and additional descriptions of our data storage and management system below.

Per Boston University (BU) Record Retention Policy, records concerning human subjects must be retained for 7 years. Please refer to the policy at: <http://www.bu.edu/policies/finance/record-retention/>. As the investigator, you must also adhere to all applicable requirements as defined by regulatory agencies (e.g. FDA, etc.) or Sponsors.

| YES* | NO | |
|--|--------------------------|--|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | <p>Will you collect identifiable information? (e.g. names, social security numbers, addresses, telephone numbers, etc.)</p> <p>*If YES, complete the box below</p> |
| <p>Describe the coding system* that will be used to protect the information including who will have access to the code</p> <p>*Coding system: Coding systems are used to: 1) protect the confidentiality of the research data and 2) allow the investigator to link subjects to their responses. Each subject is assigned a unique study ID at the beginning of the study. A separate document (key) should be maintained that links the names of the subjects to the study ID numbers.</p> | | |
| <p>To effectively monitor participants over the study period, identifiable data on participants' demographic backgrounds and personal contact information (firm addresses, phone numbers, e-mails, and GPS locations) will be collected. In addition, photographs of the firms will be taken to facilitate identification at follow-up. All identifiable data collected from surveys (both baseline and follow-up) and from the intervention will be administered in an electronic Computer-assisted personal interview (CAPI) format using the CommCare survey management system. Electronic survey data will be collected by interviewers on Android-based tablets, and data will be securely transferred from the Android tablets onto a CommCare-supported secure cloud server at the end of each working day. All Android tablets will be used for data collection only, and tablets settings will be adjusted so that field staff are blocked from accessing applications that are not applicable for data collection (e.g. internet browsing, social media, email). The CommCare cloud server will be HIPAA-compliant and will meet all the necessary security requirements for storing Level 4 identifiable data. Once the data has been securely transferred to the cloud server, the survey record on the Android tablet will be immediately erased. A technical overview of the CommCare system, including descriptions of the data transfer process and the HIPAA-compliant storage system, can be found at https://confluence.dimagi.com/display/commcarepublic/CommCare+Technical+Over-view, and an electronic version of the CommCare Terms of Use / End User License Agreement</p> | | |

(EULA) can be found at <https://www.commcarehq.org/eula/>.

All data uploaded to the CommCare cloud server will be encrypted and password-protected in accordance to the Level 4 data security and storage regulations. For each collected data case, which will consist of a woman data record, and sometimes a husband data record, all personal identifiable data will be separated from the other non-identifiable data. The de-identified data will then be uploaded to an encrypted password-protected FTP site on a daily or weekly basis and will be circulated to the project PIs for analysis purposes for the duration of the study. Identified data will be stored separately from the de-identified data on the CommCare secure encrypted server for the duration of the study. Identified data will only be accessed for the purpose of revisiting the firms for follow-up. After the study ends, the IPA Malawi research site will maintain the identified data in an encrypted file on a secure server. Only de-identified datasets will remain available for analysis purposes after the end of the study.

| YES* | NO | |
|-------------------------------------|--------------------------|--|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Will you share data with others outside of the study? *If YES, complete the box below |

Describe how data will be transferred and how confidentiality will be maintained (e.g. identifying information will not be sent outside, etc.)

With specific regard to the dissemination of identifiable data, policies are in place to limit data dissemination beyond the immediate research team (comprising of the PI and Co- Investigators, and project manager, Mr. Asman). If there is any need to transmit identifiable data in electronic form, it will be done via secured connections. Team members have received training on the proper handling and storage of such data (e.g. never to store files on computers accessible outside the team). As is indicated, de-identified data may be shared more widely among the wider research team; even with de-identified data, all feasible precautions will be taken to limit access to those members of the research team who require such access.

All staff members of the study will be required to sign a data confidentiality agreement. The data will be stored in a relational database. Usernames and passwords are required to access the data. A security policy is used to ensure these passwords are updated on a regular basis.

Field staff will have access to the primary data for a short period of time, given the nature of their responsibilities. Surveyors will have access to the primary data until the data has been cleared by either a field manager or the project manager, Mr. Asman, after which the data will be erased from their Android tablets. Field managers and the project manager will have access to the de-identified data and have been fully trained in managing this information in a confidential manner and they have completed the training for data security measures. Only the study investigators who will be directly analyzing the data (Dr. Karra, and Mr. Gautier) will have permission to access the raw data. All individuals with access to data have been indicated in the IRB applications on the study team.

Following our own use and analysis of the data (a minimum one-year time period), we hope to open access to de-identified baseline and follow-up survey data at no cost to authorized users.

Only de-identified data will be available for download through a secure website, through which authorized users can download de-identified survey data files for legitimate academic research. To access the data, prospective users must first register on the secure website and must then create a new research project request. The request must include a project title and a description of the analysis that the user proposes to perform with the data. The requested data should only be used for research or study purposes. To request the same data for another purpose, a new research project request needs to be submitted. Requests for data access will then be reviewed by the PI, who can then grant or deny access to the user. All publications that users produce from the dataset must appropriately acknowledge the data source and project from which the data was collected. Once downloaded, the datasets must not be passed on to other researchers without the written consent of the PI. All reports and publications based on the requested data must be sent via e-mail to the PI in a Portable Document Format (pdf) or as a printed hard copy.

Describe how you will maintain the confidentiality of the data (e.g. locked cabinet, password-protected files, encryption, etc.)

Note: Confidentiality refers to the researcher's agreement with the participant about how the subject's identifiable private information will be handled, managed, and disseminated

For further assistance and/or access to resources regarding information security, please refer to the BU Information Security website: <http://www.bu.edu/tech/security/>

Identifiable hard-copy data, including signed consent forms, will be stored in locked cabinets in access-limited rooms at the IPA Malawi office. All study computers that are used for descriptive analysis of the de-identified data will be password protected and only study staff who are cleared to view the data will have the password. All study data and linking keys will be password protected at all times. All electronic data, both on the CommCare secure cloud server and on any study computers, will be encrypted and password-protected. The information will only be accessible to the research team.

Every effort will be made to be sure that participation in this study, and all records about participation, will remain confidential. As previously stated, all confidential identifiable data will be secured by trained study personnel upon collection. Data will be collected by trained staff and fully de-identified as soon as possible. We will work with Dimagi to set up a data management system that meets the following requirements:

1. Raw electronic survey data will be immediately transferred once it has been collected on the Android-based tablets using a secure data transfer to the CommCare secure cloud server. Following the transfer, the data from the Android tablets will be automatically erased.
2. All identifying information will be separated from the raw electronic survey data immediately after collection and secure transfer to the cloud server, and a unique ID number will be assigned to each case. Coded, de-identified data files will be stored separately from the code list and identified data files to maintain confidentiality. Only Dr. Karra and Mr. Gautier will have access to the linkages to the underlying identifiable files. Identifiable electronic data will be encrypted, password-protected, and securely stored on the CommCare protected cloud server and one copy of the data will be stored on a password-protected computer, which will be designated as the

Target Computer. De-identified data will be encrypted, password- protected, and securely stored separately from the identifiable data on the CommCare protected cloud server and on an encrypted password-protected FTP site.

3. Restrictions will be placed on non-authorized users from accessing certain data or features by assigning them permission levels. This includes restricting access to any identifying data that would violate HIPAA or other privacy standards. Each study team member will be assigned one of three permission levels, which will provide them with varying levels of access, from no access (Level 0) to full access (Level 2).

| YES | NO | |
|--------------------------|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Will you obtain a Certificate of Confidentiality?</p> <p>Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.</p> <p>For more information about a Certificate of Confidentiality, please review the NIH website at: http://grants.nih.gov/grants/policy/coc/</p> |

SECTION Q: PRIVACY

Describe how you will protect the privacy of subjects. Include the following information: location of data storage, who will have access to study information, and location of study visits

Note: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others

Participants' privacy and confidentiality of their responses will be explicitly outlined in their consent forms and will also be verbally explained to them prior to enrollment. All surveys and administration of the intervention will be conducted in a private room. Informed consent procedures will also be performed in private rooms. Staff members will ensure that participants will feel that they can refuse to answer any question or stop participating in the study at any time. Staff members will also ensure that participants understand that maintaining confidentiality is a requirement of participation and will ask that they do not share what is discussed with those outside of the interview. Staff members will be trained to assess the comfort of participants with the level of privacy during all research activities, and will ensure that participants' concerns about privacy are suitably addressed before proceeding.

Data Storage: Identifiable electronic data will be encrypted, password-protected, and securely stored on the CommCare protected cloud server and one copy of the data will be stored on a password-protected computer, which will be designated as the Target Computer. De-identified data will be encrypted, password-protected, and securely stored separately from the identifiable data on the CommCare protected cloud server and on an encrypted password-protected FTP site.

Who Will Access to Study Information: All identifying information will be separated from the raw electronic survey data immediately after collection and secure transfer to the cloud server, and a unique ID number will be assigned to each case. Coded, de-identified data files will be stored separately from the code list and identified data files to maintain confidentiality. Only Dr. Karra and Mr. Gautier will have access to the linkages to the underlying identifiable files. Restrictions will be placed on non-authorized users from accessing certain data or features by assigning them permission levels. This includes restricting access to any identifying data that would violate HIPAA or other privacy standards. Each study team member will be assigned one of three permission levels, which will provide them with varying levels of access, from no access (Level 0) to full access (Level 2).

Field staff will have access to the primary data for a short period of time, given the nature of their responsibilities. Surveyors will have access to the primary data until the data has been cleared by either a field manager or the project manager after which the data will be erased from their Android tablets. Field managers and the project manager will have access to the de-identified data and have been fully trained in managing this information in a confidential manner and they have completed the training for data security measures. Only the study investigator and the research team who will be directly analyzing the data (Dr. Karra and Mr. Gautier) will have permission to access the raw data. All individuals with access to data have been indicated in the IRB applications on the study team.

Location of Study Visits: The study will be carried out in Lilongwe, the capital of Malawi. All research-related activities, including of the administration of the baseline and follow-up surveys, and data collection will be conducted in private spaces (participants' print shops).

SECTION R: MONITORING STUDY DATA

How will data be monitored?:

Note: The Data and Safety Monitoring Plan should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied

| | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Principal Investigator |
| <input type="checkbox"/> | Monitor/Monitoring Group |
| <input type="checkbox"/> | Data and Safety Monitoring Board (DSMB) |

| | |
|--|---|
| | <p>Note: The DSMB Charter must be submitted with this Application</p> <p>For more information regarding a DSMB, please refer to the following website: http://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DSMBGuidelines.htm</p> |
|--|---|

Describe the plan for monitoring study data. This should include a description of how data will be collected and analyzed as the project progresses to assure the appropriateness of the research, its design, and subject protections.

Data Monitoring:

The study Principal Investigator, Dr. Karra, will be assume overall responsibility for the safety, monitoring, and review of the data. He and Mr Gautier will oversee the weekly review of all data collected in the study and will be present during the administration of the baseline and the follow-up surveys. Dr. Karra will ensure that the data is treated as confidential and is stored in a secure location. For the proposed research, the local project manager at IPA Malawi, Suleiman Asman, will review adverse events. This information will then be provided to the Institutional Review Boards at BU and the NCRSH in Lilongwe. Unanticipated adverse events will be immediately reported to both the BU IRB and the NCRSH in writing within 5 business days.

Mr. Gautier, with support from Suleiman Asman and the IPA Malawi team, will be the immediate supervisor of study staff in the field. He will meet with the field staff on a weekly basis and will make sure that the study protocol and IRB regulations are being followed. On-site supervision will allow our research associate and research assistants to provide support for staff as well as quality assurance and confidentiality of study data. In addition, the local team and Boston-based team will be in regular contact via email in the interim to discuss the progress for the study protocol procedures. Dr. Karra will travel regularly to Malawi over the course of the study period and particularly during the data collection phases to monitor field activities. All regulatory documentation will be maintained for 7 years after IRB study closure.

Data Collection Process:

To effectively monitor participants over the study period, identifiable data on participating firms as well as the names of the employees we interact with will be collected. In addition, photographs of firms will be taken to facilitate identification at follow-up. All identifiable data collected from surveys (both baseline and follow-up) and from the intervention will be administered in an electronic Computer-assisted personal interview (CAPI) format using the Dimagi CommCare survey management system. Electronic survey data will be collected by interviewers on Android-based tablets, and data will be securely transferred from the Android tablets onto a CommCare-supported secure cloud server at the end of each working day. All Android tablets will be used for data collection only, and tablets settings will be adjusted so that field staff are blocked from accessing applications that are not applicable for data collection (e.g. internet browsing, social media, email). The CommCare cloud server will be HIPAA-compliant and will meet all the necessary security requirements for storing Level 4 identifiable data. Once the data has been securely transferred to the cloud server, the survey record on the Android tablet will be immediately erased. A technical overview of the CommCare system, including descriptions of the data transfer process and the HIPAA-compliant storage system, can be found at

<https://confluence.dimagi.com/display/commcarepublic/CommCare+Technical+Over-view>, and an electronic version of the CommCare Terms of Use / End User License Agreement (EULA) can be found at <https://www.commcarehq.org/eula/>.

Data Analysis Process:

Analysis of quantitative study data will be conducted using STATA and R where appropriate. Descriptive analysis will be performed for all variables and unadjusted comparisons between experimental arms will be conducted. Descriptive statistics will be performed, including frequencies, means, and standard deviations. In addition, chi-square tests and t-tests will be used to examine associations in the data. A probability value of less than 0.05 will be considered statistically significant for all statistical tests that are conducted. Continuous variables will be tested for normality, and non-normal values will be categorized or transformed appropriately.

Our main econometric specifications will 1) estimate the intent-to-treat (ITT) effect of being assigned a contract on the quality of the completed task; and 2) estimate the ITT effect of being assigned a tight contract compared to a loose contract. We will conduct several sub-group analyses in order to examine how our contracting intervention effects vary across key subpopulations. Subgroups of interest include: firms facing a high level of competition, small firms, firms that are innovative, firms that are owned by a family, firms which has a large share of non-permanent employees. Finally, robustness checks (5 percent and 10 percent sample truncations, coarsening of independent variables) and falsification tests, which include placebo regression, simulation, and resampling methods, will be conducted to ascertain the strength and significance of our estimates.

SECTION S: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

| YES* | NO | |
|--------------------------|-------------------------------------|--|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Is this research being conducted in a covered entity?</p> <p>The following components have been determined to be covered entities on the Boston University Charles River Campus:</p> <ul style="list-style-type: none"> • Sargent College Rehabilitation Services <ul style="list-style-type: none"> ○ Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation ○ Sargent Choice Nutrition Center • The Danielsen Institute • Boston University Health Plan <p>*If YES, contact the IRB office for assistance.</p> |

SECTION T: FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT

(FERPA): FERPA is the federal law that protects the privacy of student education records.

Research funded by the Department of Education or research conducted in educational institutions that receive funds from the Department of Education (for research or other purposes) must comply with FERPA.

| YES* | NO | |
|--|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Does this study involve collection of information from student school/university records? *If YES, refer to the following websites for guidance on FERPA: <ul style="list-style-type: none">• http://www.bu.edu/researchsupport/compliance/human-subjects/• http://www.bu.edu/reg/general-information/ferpa/• http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html If FERPA applies, you must complete the box below: |
| In accordance with FERPA, written consent must be obtained to access student records. The consent must: <ul style="list-style-type: none">• Specify the records that may be disclosed• State the purpose of the disclosure• Identify the person or class of parties to whom the disclosure can be made | | |
| <input type="checkbox"/> YES (REQUIRED) | | I confirm that I will comply with the FERPA policy that is in place at the educational institution where I am conducting my research. This includes, if applicable, the requirements for written agreement when requesting a waiver of consent for personally identifiable information. If an agreement is required, this agreement must be submitted to the IRB. |

SECTION U: PROTECTION OF PUPIL RIGHTS AMENDMENT (PPRA):

PPRA is a federal law that affords certain rights to parents of minor students with regard to surveys that ask questions of a personal nature. Research funded by the Department of Education or research conducted in educational institutions that receive funds (for research or other purposes) from the Department of Education must comply with the PPRA.

| YES* | NO | |
|--------------------------|-------------------------------------|--------------------------------|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Does PPRA apply to this study? |

| | |
|---|--|
| | <p>*If YES, refer to the following websites for guidance:</p> <ul style="list-style-type: none"> • http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html • http://www.bu.edu/researchsupport/compliance/human-subjects/ <p>If PPRA applies, you must complete the box below:</p> |
| <p>In accordance with PPRA, written parental consent must be obtained prior to subjects participation in the study.</p> | |
| <input type="checkbox"/> YES (REQUIRED) | <p>I confirm that I will comply with the PPRA policy that is in place at the educational institution where I am conducting my research.</p> |

SECTION V: CLINICAL TRIALS REGISTRATION:

The Food Drug and Administration Amendments Act (known as FDAAA 801) requires that “applicable clinical trials” be registered and have results reported on clinicaltrials.gov. The Responsible Party for a clinical trial must register the trial and submit results information. In addition, the International Committee of Medical Journal Editors (ICJME) and the National Institutes of Health (NIH) also have requirements for registration. Please see box below to determine if your study requires registration in accordance with either FDAAA 801, ICJME, or NIH.

| YES | NO | FDAAA 801 Requirements |
|--------------------------|-------------------------------------|---|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Does your study meet the definition of an applicable clinical trial and require registration AND results submission in accordance with FDAAA 801?</p> <p>. Applicable Clinical Trials include the following:</p> <ul style="list-style-type: none"> • Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation • Trials of devices (see note): 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA <p>The Responsible Party is defined as:</p> <ul style="list-style-type: none"> • The sponsor of the clinical trial or • The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the |

| | | |
|--------------------------|-------------------------------------|--|
| | | <p>trial, and has the ability to meet all of FDAAA's requirements for the submission of clinical trial information</p> <p>Refer to the following website for guidance:</p> <ul style="list-style-type: none"> • FDAA 801 Requirements: https://clinicaltrials.gov/ct2/manage-recs/fdaaa <p>Note: If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.</p> <p>NCT #: _____</p> |
| YES | NO | ICMJE Requirements |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Does your study meet the definition of a clinical trial and require registration in accordance with ICMJE?</p> <p>ICMJE definition of clinical trial: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.</p> <p>Refer to the following websites for guidance:</p> <ul style="list-style-type: none"> • ICMJE Clinical Trials Registration: http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/ <p>Note: If your study meets the requirement for registration, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.</p> <p>NCT #: _____</p> |

| YES | NO | NIH Requirements |
|--------------------------|-------------------------------------|--|
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | <p>Does your study meet the definition of an applicable clinical trial and require registration AND results submission in accordance with NIH?</p> <p>As of January 18, 2017, NIH is requiring that clinical trials be registered at ClinicalTrials.gov. Confirm whether this study meets the registration requirements for clinical trial registration in accordance with the definition of a clinical trial as defined by NIH. See definition below.</p> <p>Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those intervention on health-related biomedical or behavioral outcomes”. This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g. behavioral interventions.</p> <p>Of note, this requirement for registering and results reporting includes clinical trials beyond those already required by the FDA. The requirements are expanded to include to Phase I drug studies and NIH-funded clinical trials of social-behavioral interventions.</p> <p>For more information on this policy please refer to:</p> <ul style="list-style-type: none"> • NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22379.pdf • Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf • NIH Definition of Clinical Trial: http://osp.od.nih.gov/sites/default/files/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf <p>Note: If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.</p> <p>NCT #: _____</p> |

Certification / Signatures

- By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.

- I agree to conduct the describe research in an ethical manner.
- I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
- I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
- I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
- I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
- I verify that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and completed training as dictated at <http://www.bu.edu/orc/coi/forms/>, and returned the forms to the Office for Research Compliance COI Unit. **NOTE: If anyone checked “yes” to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

PI printed name: **Mahesh Karra**

PI Signature:  Date: **16 February 2021**

Submission

This form can be completed, signed, scanned and submitted to the IRB at irb@bu.edu. Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.

FACULTY Research:

The Department Chair signature is required: This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair then signature by the appropriate Dean is required. Department Chair signature is not required for student research.

By signing this form you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, hat he/she is qualified to serve as the PI for this study, he/she has the adequate resources, and the research utilizes acceptable practice for the discipline.

Department Chair (print name): Kevin Gallagher (Center Director) _____

Department/School: BU Global Development Policy Center _____

Signature:  _____

Date: 15 January 2020 _____

STUDENT Research

Student research: Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

By signing this form you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student's human subjects research.

Faculty Advisor (print name): _____

Signature: _____

Date: _____

IRB School Reviewer, if applicable (print name): _____

Signature: _____

Date: _____