

IRB Office use only Date submitted _____ FB _____ Exp. _____
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Note; This application is to be used for new Full Board and Expedited Studies submitted on or after January 21, 2019.

**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):	5126E
Protocol Title:	Exploring Behavioral Biases in Contraceptive Decision-Making: Evidence 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:	Kexin Zhang
Email:	kz628@bu.edu
Telephone:	+1-347-237-7223
<input checked="" 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: <ul style="list-style-type: none"> • 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		The William and Flora Hewlett Foundation
Title of Grant/Proposal		Women's Decision-Making and Empowerment in Reproductive Health: Evidence from Malawi and India
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		Sponsor Award ID: 2018-8083 SAP Grant Number: 55206777
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)	<p>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 <i>the Boston University Investigator Conflicts of Interest Policy for Research</i>.</p> <p>NOTE: You must attach a copy of the PI's COI submission confirmation email. COI submission confirmation emails for all other study staff should be maintained at the research site.</p>
<p>Of the financial interest disclosure forms submitted, did you check “yes” to any of the questions on either the FIND1 or NONFIND1 form?</p> <p><input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No</p>	

***If you 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
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: _____
Kexin Zhang, Ph.D., Economics, Graduate School of Arts and Sciences	Co-Investigator	<input checked="" type="checkbox"/> CITI <input type="checkbox"/> Other** : _____ Most Recent Date Completed: _____
Leah Eyob, M.A., Global Development Policy, Pardee School of Global Studies	Research Assistant	<input checked="" type="checkbox"/> CITI <input type="checkbox"/> Other** : _____ Most Recent Date Completed: _____
Amelia Dangerfield, M.A., International Affairs, Pardee School of Global Studies	Research Assistant	<input checked="" 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?
		1. Will this staff interact with subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Will this staff have access to identifiable information? <input type="checkbox"/> Yes <input type="checkbox"/> No 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	<input type="checkbox"/> Yes: Provide copy of IRB approval letter when available: <input type="checkbox"/> No (provide reason):
		1. Will this staff interact with subjects? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Will this staff have access to identifiable information? <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Is the work that the staff will complete related to his/her role	<input type="checkbox"/> Yes: Provide copy of IRB approval letter when available: <input type="checkbox"/> No (provide reason):

		or coursework at his/her affiliate institution.? <input type="checkbox"/> Yes <input type="checkbox"/> No	
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*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.**

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 no², explain the plan to obtain this approval. If the site is not engaged in the 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: Patrick Baxter pbaxter@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 Health Sciences Research Committee (NHSRC), for review and approval. All materials will be submitted by 30 March 2019, and the NHSRC 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 NHSRC 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. We will inform local community leaders (village heads, chiefs), ward counselors, and health service assistants (HSAs) who work 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, domestic violence, and abuse within the household.</p> <p>The ethical roles of the local institution, IPA Malawi, and of the local investigators, Dr. Bagrey Ngwira and Dr. Abiba Longwe Ngwira, will be covered by the NHSRC.</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>		

²If IRB approval will not be obtained at the site, describe the IRB oversight arrangements here:

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

YES*	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Is the BU PI the lead investigator OR is BU the lead site for this research? Note: This box only needs to be completed if the off-site location is engaged in the research.

*If **YES**, provide the following information in this box:

- The plan for collection and management of data from all the sites

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.

To effectively monitor participants over the study period, identifiable data on participants’ demographic backgrounds, personal contact information (household addresses, phone numbers, e-mails, and GPS locations), and household characteristics will be collected. In addition, photographs of participants and of the household 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 (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, data records on women's husbands, and a household 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 households at the one-month follow-up period. 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 Ms. Zhang, Dr. Ngwira, Dr. Longwe Ngwira, 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-Investigators, and project manager, Mr. Baxter). 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, Ms. Kexin Zhang, Dr. Bagrey Ngwira, and Dr. Abiba Longwe Ngwira 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. Four sets of de-identified data will be stored, one for each Dr. Karra, Ms. Zhang, Dr. Ngwira, and Dr. Longwe Ngwira.

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. Baxter, 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, Dr. Ngwira, Dr. Longwe Ngwira, and Ms. Zhang) 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 NHSRC in Malawi immediately by us. The local project manager at IPA Malawi, Mr. Baxter, the local co-investigators, Dr. Ngwira and Dr. Longwe Ngwira, 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 NHSRC 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, domestic violence, and abuse within the household, and we will refer participants and other members of the household to their nearest Victim Support Unit and to the Department of Social Welfare at the Lilongwe District Council Office. In addition to reporting any events from the baseline and follow up surveys we will make quarterly reports on consultations and reimbursements for family planning services for women.

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 NHSRC 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 employability. That said, information asked about a participant's sexual behavior, fertility preferences, or perspectives on family planning and reproductive health issues may adversely affect a participant's reputation. To protect participants' confidentiality and to minimize risk, we have taken several data security measures (refer to section above for additional information).

We do not anticipate that there will be any research-related injuries. Dr. Ngwira, Dr. Longwe Ngwira, and Mr. Baxter will train the field staff (surveyors, field managers, and interventionists) in first aid, and both Dr. Ngwira, Dr. Longwe Ngwira, and Mr. Baxter will be on call via mobile phone during the entire duration of the study. The field team will be trained to recognize basic signs of physical and psychological injury and will be instructed to immediately report any injuries that are incurred during the interview to Mr. Baxter. With the help of Dr. Ngwira, Dr. Longwe Ngwira, and Mr. Baxter, we will establish a link with a local primary clinic in Lilongwe and will refer respondents to this clinic if they experience research-related injuries. For emergency cases, we will identify the emergency care facility or hospital that is nearest to the interview location prior to each interview, and we will refer respondents to this facility in case of a medical emergency.

If a participant has a need for medical or psychological support services, the research team member present at the time will refer him/her to Mr. Baxter, the local project manager, who will be on call by mobile phone for the entire duration of the study. Should any participant indicate potential risk of harm or sign of distress, the team member present at the time will meet separately with the participant to assess for risk of harm and need for a higher level of intervention. All team members will be trained to recognize basic signs of physical and psychological injury and will be instructed to immediately report any injuries that are incurred during the survey or intervention to Mr. Baxter. All team members will also be trained to recognize and report signs of distress or adverse events that may not be research-related but that are observed within the context of the interaction with the respondent (e.g. domestic abuse, criminal activity within the household, etc.). We will implement the following protocols, which were recommended to us by the Department of Social Welfare in the Lilongwe District Council Office:

1. We will first report all adverse events related to violence, abuse, or intra-household conflict to local community leaders.
2. We will refer women and other family members requiring support to the nearest Victim Support Unit office for further counseling and assistance. The Victim Support Unit office is a special branch of the local police department that aims to provide local communities with conflict resolution services, violence and abuse support, and peer mediation. We have identified the three Victim Support Unit offices that are closest to our selected enumeration areas: 1) Kawale Victim Support Unit at Kawale Police Station; 2) Lingadzi Victim Support Unit at Area 18 Police Station; and 3) Lilongwe Victim Support Unit at Lilongwe Police Headquarters.

3. We will refer women and other family members requiring assistance to the Department of Social Welfare, which also offers social support and counseling services to women and children in Lilongwe.

With the help of Mr. Baxter and Dr. Ngwira, we have established a link with a local primary clinic in Lilongwe and will refer respondents to this clinic if they experience research-related stress, fatigue, or injuries. For emergency cases, we will identify the emergency care facility or hospital that is nearest to the interview location, and we will refer respondents to this facility in case of a medical emergency. Field staff will also have the contact information of the local police in Lilongwe as well as the Lilongwe District Council Office and will refer respondents to these authorities as needed.

Additional details on dealing with research induced distress in study participants are described in the standard operating procedures (SOP) document for dealing with research-induced stress (see Appendix K1).

All risk of harm cases will be discussed with the local project manager, Mr. Baxter, and will be reported to the PI and Co-Investigators, who will then report it to the BU IRB and NHSRC. 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, Dr. Bagrey Ngwira, Dr. Abiba Longwe Ngwira, and Patrick Baxter 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, Dr. Ngwira, Dr. Longwe Ngwira, and Mr. Baxter 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 Ms. Zhang 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 Ms. Zhang 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, Patrick Baxter, the local co-investigators, Dr. Ngwira and Dr. Longwe Ngwira, 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 NHSRC in Lilongwe. Unanticipated adverse events and protocol deviations will be immediately reported to both the BU IRB and the NHSRC in writing within 5 business days.

Conflict of Interest Statement

All study investigators have read and understood the BU IRB and NHSRC 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 NHSRC 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 NHSRC. 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 NHSRC 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 Patrick Baxter (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 Health Sciences Research Committee (NHSRC), for review and approval. All materials will be submitted by 30 March 2019, and the NHSRC 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 NHSRC 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), ward counselors, and health service assistants (HSAs) who work 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, domestic violence, and abuse within the household.

The ethical roles of the local institution, IPA Malawi, and of the local investigators, Dr. Bagrey Ngwira and Dr. Abiba Longwe Ngwira, will be covered by the NHSRC.

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

The National Health Sciences Research Committee (NHSRC) in Malawi 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.

In spite of declining birth rates and improvements to maternal health care, the total fertility rate in Sub-Saharan Africa remains high, and many of these births are unplanned. While women continue to face numerous barriers to accessing family planning, including opposition from their spouses and families, recent evidence indicates that take-up of family planning is low even when women agree with their husbands on spacing their next birth and are provided with greater access to services.

Unlike other domains in women’s health, delivering high quality family planning services is not only measured by the achievement of good reproductive health outcomes but also must consider the objective of helping women maximize a complex set of preferences around future fertility outcomes. In family planning, the role of the client as the key actor in her receipt of care is distinct from most other contexts in health decision-making where providers often play the leading role in determining which course of treatment is best for a patient. Indeed, family planning programs typically consider women to have a “right” to full information about contraceptive method options. For this reason, family planning programs dedicate significant resources into providing complete and accurate information so that women are able to make an “informed choice” about the full range of contraceptive methods that are available to them. Clients typically do not receive modern contraceptive methods without receiving a comprehensive consultation session with a counselor, during which time they are informed about the range of available methods. Because of the high value placed on fully informed choice, counselors may discuss as many as 15 different methods and describe as many as 10 method attributes (e.g. effectiveness at preventing pregnancy, ease of use, risk of side effects, duration of effectiveness, among others) for each method with a client. This intensive approach to counseling, which compels a client to interpret a large volume of information across several dimensions (attributes, methods), may reduce the salience of counseling while simultaneously increasing the potential for choice overload.

A number of studies have examined how the receipt of counseling shapes women’s contraceptive decision-making. However, little is known about how the choice architecture for family planning, which defines the structures and processes by which contraceptive methods and information are presented to women during their counseling session, shape women’s preferences and characterize how women actually make informed choices about their preferred method. Studies have shown

that a woman's fertility intentions, which affect her contraceptive preferences, are likely to be unstable over her reproductive lifetime and are sensitive to relatively small changes in her environment. A woman might therefore change her mind frequently over a relatively short time period such that her initially stated preference for contraception (what she says that she will do) could differ greatly from her actual choice of method (what she actually does). Being able to link a woman's stated preferences for family planning to her eventual contraceptive behavior may therefore have significant implications for family planning service provision.

In this study, we investigate some of the behavioral mechanisms that play a role in contraceptive decision-making through a field experiment, in which we manipulate the specific architectural conditions under which women are counseled on family planning. Our approach is motivated by evidence suggesting that women's stated and realized preferences for contraception are likely to be both malleable and highly sensitive to a range of biases. To this end, we explore how key biases are characterized through a woman's revealed preferences and decisions about a method. We test the following two hypotheses:

1. Women's stated preferences for and choices of contraception are sensitive to the number of method choices that are presented to them, consistent with prior evidence on choice overload. Specifically, decision-making under the presence of too many choices may either be determined heuristically, in which choices over methods are driven by key method attributes (e.g. effectiveness in preventing pregnancy, incidence of side effects, etc.) or may be avoided altogether (decision deferral).
2. Giving women the choice whether or not to involve their husbands or partners as part of the counseling process is likely to affect 1) women's decision-making around and choice of a contraceptive method; 2) the extent to which women are able to realize their preferences for family planning.

Our field experiment will be conducted among a sample of 700 women from Lilongwe, Malawi. We will recruit women who: 1) are married or living with partners; 2) are between the ages of 18 to 35; 3) live in the city of Lilongwe 4) are neither currently pregnant nor have gave birth within 6 months from the initial screening; 5) live with their husbands/partners; 6) Have neither been sterilized nor have had a hysterectomy; 7) have given birth to at least one child (one live birth) in their lifetime. Eligible women who consent to participate in our study will receive a baseline survey that will record women's current and past use and experiences with family planning, family planning knowledge, barriers to use, attitudes towards family planning and specific contraceptive methods, and their preferred contraceptive method. Particular emphasis will be given to understanding women's relative preferences for methods and for method-specific attributes and on how women may rank methods and method-specific attributes.

Following the baseline survey, women will be randomized into one of four treatment arms:

1. A control arm, in which women are visited by a trained family planning counselor and are presented with a free counseling session where they will receive the standard of care in family planning counseling in Malawi. The session will consist of methods being presented using a standardized flipchart that has been developed by the Malawi Ministry of Health and Reproductive Health Directorate. The flipchart lists all 15 available contraceptive methods in order of effectiveness in preventing pregnancy (most effective to least effective).

2. A treatment arm in which women will be presented with the choice to invite their husbands to the counseling session. Following the invitation, women and their husbands (should they choose to invite them) will receive the standard of care family planning counseling session described above.

3. A treatment arm that aims to minimize choice overload and increase the salience of a woman's most preferred method attribute (e.g. method effectiveness in preventing pregnancy, duration of use, ease of use, likelihood of method-related side effects, etc.). In this arm, a woman will be asked first to compare and rank method-specific attributes (e.g. does she prefer that a method have a lower incidence of side effects over a method that is more effective at preventing pregnancy?). Once a ranking of method attributes has been elicited, the counselor will identify the attribute that the woman reveals to be most important to her and will present a limited set of 5 methods that rank highest along that revealed attribute. Particular emphasis will be placed on making the order of presentation salient, in which women will be reminded and primed to consider the relative ranking of a method across the stated attribute.

4. A treatment arm that provides women both with the choice to invite their husbands (treatment arm 2 above) and presents a counseling session that minimizes choice overload across the woman's most preferred method attribute (treatment arm 3).

Following receipt of counseling, women in all treatment arms (including the control arm) will be asked to reveal their preferred choice of method. Following this elicitation, women in all arms of the study will be offered the following package of services:

1. A free taxi ride to our partner family planning clinic in Lilongwe, the Good Health Kauma Clinic, which has been previously identified as a high quality family planning clinic that provides the full range of contraceptive methods.

2. A free consultation with a family planning service provider at the Good Health Kauma Clinic.

3. Free family planning services at the Good Health Kauma Clinic.

These services have already been tested and implemented in the field as part of an ongoing family planning study in Lilongwe. To increase the salience of the offer, the package of services will be time-limited for one month following the counseling session. By offering the package of three services above, which together aim to reduce the barriers to accessing family planning services at our partner clinic, we will be able to elicit a measure of demand for family planning and will also be able to observe how a woman's demand (her final choice of method) aligns with her initially stated preferences for family planning immediately following counseling. A follow-up survey will be conducted one month following a woman's counseling session. Outcome data that capture a woman's preferences and decision-making around contraception will be collected at each survey (baseline, one-month follow-up), at the end of the counseling session, and at every clinic visit.

The primary objective of this study is to investigate the extent to which choice architectural elements around family planning can affect a woman's immediate stated preferences and intentions in a context where her preferences may be sensitive to a range of behavioral biases. Our main outcomes of interest include women's stated preferred method of contraception immediately following counseling, intention to use or not use contraception immediately following counseling. In addition, by observing whether women will seek family planning following their counseling visit, we will examine the short-run stability of their stated preferences and the extent to which these stated preferences are subsequently realized in the face of other barriers to use. Data examining the realization of women's eventual contraceptive preferences (e.g. contraceptive

uptake, eventual method choice) will be collected during clinic visits and at follow-up across the three arms.

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 checked="" 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 checked="" type="checkbox"/>	Secondary Data Analysis
<input type="checkbox"/>	Other (please describe):

SECTION I: SUBJECT POPULATION

<p>Number of Subjects to be Enrolled:</p> <p>If you have sub-groups or more than one arm, please separate out these enrollment numbers.</p> <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>700 women</p> <p>Intervention group 1 (200 women): receive standard of care counseling session on contraceptive methods, with option to invite husband to counseling session</p> <p>Intervention group 2 (200 women): receives abbreviated counseling session on contraceptive methods alone</p> <p>Intervention group 3 (200 women): receives abbreviated counseling session on contraceptive methods, with option to invite husband to counseling session</p> <p>Control group (100 women): receive standard of care counseling session on contraceptive methods alone</p>
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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.

Our primary subjects of interest are women of reproductive age (age 18-35) in Lilongwe, Malawi. These women may be vulnerable due to their unfamiliarity with research procedures. Some members of this population may be subject to the influence of other members because of power relationships internal to the household and the community. Women may also be subject to influence by their partners or other men because of cultural norms. In addition, some participants may be economically and educationally disadvantaged, and some women may also be illiterate.

All participants will be part of the study on a voluntary basis. The informed consent forms will outline all of the measures to protect participants' rights, including voluntary participation, risks or benefits associated with the study, and maintaining confidentiality of the data.

All data collected will be confidential and will be stored in a secure location. We will make every effort to avoid undue influence or any type of coercion on participants, and to protect their rights and welfare through respectful and culturally sensitive policies, including the following:

- Involve the Malawi Ministry of Health, the Reproductive Health Directorate, and other community leaders throughout the research process.
- Behave towards all members of the community in a respectful and culturally sensitive manner, while making it clear that we are invested in protecting the rights of all.
- Make clear the intentions and methods of the research to all members of the community with whom we have contact.
- Be respectful of community leaders, while making it clear that all opinions are important and valuable to the research (including those of women, children, etc.)
- Follow respectful recruitment policies and informed consent procedures with all participants, including separate private consents to allow each individual to speak for him/herself and ask any questions.

All interviews and activities related to the intervention with the respondent will be administered individually and in a private room within the household. However, we will train

interviewers and interventionists how to recognize situations where there may be a breach of confidentiality and how to resolve these situations immediately. In cases where the interview is interrupted by another person who is not the respondent, the interviewer or the interventionist will ask if a more private space in the household is available to continue the interview. If such a space is not available at that time, the interviewer will ask the respondent if she can return at a later date/time to complete the interview. If no alternate date/time can be arranged, then the interviewer will terminate the interview. The field team will be trained in identifying and dealing with distress in the event that psychological or physical harm is observed or disclosed during the study procedure. There is a referral process in place, which includes a visit by a counselor to manage the participant's distress. Additional details are provided in the standard operating procedures (SOP) document for dealing with research-induced stress (Appendix K1).

Eligibility Criteria

Inclusion Criteria:

For the initial part of our study, we will recruit women based on the inclusion criteria listed below:

1. Are married at baseline
2. Age between 18 and 35 at screening
3. Live in the city of Lilongwe (permanent residents)
4. Are currently non-pregnant and did not give birth in the 6 months prior to the initial screening
5. Have neither been sterilized nor have had a hysterectomy
6. Have given birth to at least one child (one live birth) in their lifetime
7. Live with their husbands at the time of the screening.

Women who successfully meet these inclusion criteria and who consent to participate in the main part of our study will be recruited. In addition, no two eligible women will be enrolled from the same household. If multiple women from the same household are potentially eligible to be recruited into this part of our study based on the four criteria inclusion above, we shall choose the youngest eligible woman from the household to participate.

In addition, we will interview the husbands of women who are invited to the counseling session to learn about their experiences with family planning, their family planning and fertility preferences, and their experiences with counseling.

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):

Women who fail to meet any one of the inclusion criteria will be excluded from the study. In particular, women who meet the following criteria will be excluded:

- Are not married at baseline
- Live outside Lilongwe city
- Are younger than 18 years of age
- Are older than 35 years of age
- Are currently pregnant
- Have given birth within 6 months prior to the time of the initial screening

- Have been sterilized or have had a hysterectomy
- Have never given birth to a child (one live birth) in their lifetime
- Do not live together with husbands at the time of the screening

Additionally, no two eligible women will be enrolled from the same household. If multiple women from the same household are potentially eligible to be recruited into the study, we shall choose the youngest eligible woman from the household to participate.

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.

Recruitment Process: We shall travel to Lilongwe, Malawi in May 2019 to initiate the study and complete preparations for the baseline survey and intervention. We will meet with our partner organization, IPA Malawi, the Malawi Ministry of Health (MOH) and Reproductive Health Directorate (RHD), the Malawi National Statistics Office (NSO), and our partner family planning clinic in Lilongwe, the Good Health Kauma Clinic, to:

1. Finalize the sampling strategy that we will use to identify and recruit women
2. Hire field staff. Field staff include: 5 surveyors who will be responsible for administering the baseline and follow-up surveys to the household respondents; 6 family planning counselors who will be trained to administer the counseling sessions to women in each intervention arm; 1 hired driver who will transport women to the Good Health Kauma Clinic from their homes; and 1 field manager who will supervise the survey enumerators and intervention staff (driver, counselors), monitor and spot-check the data for quality issues, and oversee administration of the intervention.
3. Confirm transportation logistics (hiring of vehicles for field staff transport to and from study sites, transportation allowances, etc.) and other related issues (mobile credit, internet, etc.) 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 the field manager to monitor surveyors and oversee field activities using the supervisor training manual. Finally, we will train interventionists (counselors and the driver) on how to administer their respective intervention components to women in the intervention arm.

Sample Identification and Selection

Using the most recent Demographic and Health Survey (DHS) and census maps of Lilongwe's enumeration areas and listings of households and neighborhoods, which will be provided to us by the Malawi MOH, NSO, and IPA Malawi, we will employ a two-stage sample selection procedure that is based on the sampling strategy used by the DHS. In the first stage, we will randomly select defined census areas in Lilongwe to be screened until we have selected enough enumeration areas to contain at least 5,000 households in total. In the second stage, our surveyors will proceed door-to-door to screen households in each selected enumeration area for

potentially eligible women. Surveyors will continue to screen households until they identify 700 women for the study in accordance with the inclusion and exclusion criteria listed in the sections above, and these eligible women will be recruited in accordance with the recruitment protocols outlined below. We shall ensure that eligible women who are selected for the study are sufficiently distant (at least 5 households apart) from each other. Based on our knowledge of participation refusal rates and the estimated number of eligible women in Lilongwe, we will need to screen an estimated 940 households in order to obtain a desired sample size of 700 women. We require a study sample of at least 700 women to achieve sufficient power for measuring our outcomes of interest. Recruitment from the selected enumeration areas will cease once 700 women have been found who meet the eligibility conditions and who consent to participate in the study.

Since receipt of the family planning counseling interventions will be randomized at the individual level, we shall ensure that no two eligible women will be chosen from the same household. If multiple women from the same household are eligible to be selected into the study, we shall choose the youngest eligible woman from the household to participate.

Who: Five trained surveyors who are hired by the IPA Malawi research team in Lilongwe will recruit women who satisfy the following inclusion criteria:

1. Are married at baseline
2. Age between 18 and 35 at screening
3. Live in the city of Lilongwe (permanent residents)
4. Are currently non-pregnant and did not give birth in the 6 months prior to the initial screening
5. Have neither been sterilized nor have had a hysterectomy
6. Have given birth to at least one child (one live birth) over their lifetime
7. Currently live with their husbands.

Women who successfully meet these inclusion criteria and who consent to participate in the main part of our study will be recruited. In addition, no two eligible women will be enrolled from the same household. If multiple women from the same household are potentially eligible to be recruited into this part of our study based on the four criteria inclusion above, we shall choose the youngest eligible woman from the household to participate.

When: Eligibility screening, recruitment of women into the study, and administration of the baseline survey to eligible women who consent to participate will begin at the end of May 2019 and is expected to conclude by early July 2019. Refer to the timeline (Table 1) for additional details.

Where: The study site is Lilongwe, Malawi. Surveyors will continue door-to-door in each of the selected enumeration areas and will approach each household to determine whether any women who are living in that household a) meet our inclusion criteria listed in the section above, and b) consent to participate in our study. To make this determination, surveyors will use a recruitment script to verify eligibility and will present the eligible woman with a consent form to participate in the study. Please refer to the attached recruitment script (Appendix H1) and the attached consent form (Appendix G1) for women respondents. Written informed consent will be obtained from all participating women before proceeding to administer the survey. Women

who meet the eligibility criteria and who consent to participate in the study will be recruited into the study. No two eligible women will be enrolled from the same household. If multiple women from the same household are potentially eligible to be recruited into the study, we shall choose the youngest eligible woman from the household to participate.

How Subjects Will Be Identified: Eligible respondents will be identified by trained surveyors in person through the eligibility screening process (refer to attached recruitment script, Appendix H1). To effectively monitor participants over the study period, identifiable data on participants' demographic backgrounds, and personal contact information (household addresses, phone numbers, e-mails, and GPS locations) will be collected. In addition, photographs of participants 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.

We require a baseline sample of at least 700 women to achieve sufficient power for measuring our outcomes of interest. In order to attain this sample size, we will need to screen at least 940 households across our randomly selected enumeration areas. Since women who are selected into the study will also be at least 5 households apart from each other, we will need to choose enough enumeration areas to have at least 5,000 households in total ($940 \times 5 = 4,700$ households among the women who make up our sample and who are at least 5 households apart, plus an additional 300 households that are screened but where women either do not meet the eligibility criteria or refuse to participate).

We account for any time needed to recruit participants and to obtain participatory consent in our study timeline (refer to Table 1). We expect for screening and recruitment of women into the study to take one month (from early June to mid July in our timeline). We have identified several local partners and collaborating organizations, and are confident that we will be able to reach our targeted enrollment through their support and existing networks. We are also confident that our local partners will assist us in the recruitment of participants to reach our target enrollment for the future phases of this study.

Recruitment scripts will not be required to select participants for the follow-up surveys; however, written informed consent will be asked from participants again at follow-up (i.e. each time they are asked to participate). As part of our recruitment scripts, we will provide participants with a short description of the study and outline the key objectives of the research – refer to the woman's recruitment script. We will receive written consent from participants to participate in the study – refer to the woman's consent form.

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.

A concise summary must be included in all consent forms. The concise summary must include the following information: 1) the purpose of the study, 2) the time involved for study participation, 3) the study procedures to be performed, and 4) risks of participating in the study.

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

Please refer to consent documents and recruitment protocols for details concerning the consent process. The process to obtain consent will be consistent for all potential participants. No monetary compensation will be provided to participants for participating in the study, which serves to minimize coercion. All women who participate in the study will receive a small token of appreciation (three bars of soap, a monetary equivalent of 500 MWK (\$0.66 USD)) after completing each survey.

Written consent to participate will be obtained from all participants before administering the surveys. Once participants have agreed to join the study, a copy of the consent form script will be read to them, and they will be given opportunities to ask questions and express concerns. Surveyors will check for comprehension throughout the consent process. This process is estimated to take between 5 to 10 minutes, although it may be longer if a participant has many questions. After completing the consent script, potential participants will be encouraged to ask questions, and asked if they would like to participate. If the participant would like to take further time to reflect, the surveyor and the participant will determine a time and method of reconnecting. If the potential participant agrees to be a part of the study, consent will be obtained and documented by obtaining the signatures of both the participant and the study staff member who conducted the consent. Upon consenting, the surveyor will then conduct the survey.

For follow-up surveys, verbal consent to participate will be obtained over the phone from only those participants who were originally recruited at baseline but since have either moved outside of Lilongwe or were unreachable in person after three contact attempts. The only respondents who will be re-contacted for the phone follow-up survey will be those respondents who were simply lost to follow up. Respondents who had previously indicated that they were no longer interested in participating in the study will not be contacted.

Throughout the consent process, the surveyor will clearly explain to the participant that even if she decides to participate and sign the consent form, she can decide at any time to end her participation. If the prospective study participant is not literate, then a witness who does not work for the study will sign the consent form. Moreover, participants are encouraged to contact the researchers with any further questions during the informed consent discussion or any time during the study. Consent will be obtained before any surveys are conducted. All participants will be informed that their participation is completely voluntary and that they may choose to not to participate in the study or to end their participation in the study at any time.

With regards to the intervention components, women will be offered each component by an interventionist from the study team. Women will not be coerced into taking up the interventions that are offered to them; they can take up and stop any or all components of the intervention at any time. Counselors will ask for a woman’s consent to participate in a counseling session each time they visit a woman’s home.

The recruitment scripts, consent forms, and survey instrument will be translated by a certified translator from English into Chichewa and will be back-translated into English by a second certified translator to ensure accuracy. We are currently in the process of having these documents translated, and we will submit the translated versions along with a completed Translation Attestation Form as we receive them.

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

Assent of Children (≤18 years of age)		N/A <input checked="" 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"> 1. <input type="checkbox"/> The capability of some or all of the children is so limited that they cannot reasonably be consulted 2. <input type="checkbox"/> The children are too young to provide assent 3. <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 4. <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>
<p>Guidance on age requirements for obtaining assent:</p> <ul style="list-style-type: none"> • Parental Permission for minors under 6 years of age • Verbal assent for minors 6-11 years of age • Written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects) 	
<p>Parental Permission N/A <input checked="" type="checkbox"/></p> <p>One of the following MUST apply</p>	
<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/>.

All study documents that will be administered to participants (recruitment scripts, consent forms, survey instruments, counseling materials, information sheets, etc.) will be translated by a certified translator from English into Chichewa and will be back-translated into English by a second certified translator to ensure accuracy.

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"/>
<input type="checkbox"/> Criteria 3		
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 subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm	<input type="checkbox"/>	<input type="checkbox"/>
There is an appropriate mechanism for documenting that informed consent was obtained	<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"/>
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BOX 2—WAIVE OR ALTERATION OF CONSENT

NON-FDA REGULATED STUDIES

WAIVER OR ALTERATION OF CONSENT N/A <input checked="" type="checkbox"/>	Yes	No
45 CFR 46.116 Waiver or alteration of consent [45 CFR 16.116]. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents ALL of the criteria listed below.		
All of the criteria below must be met in order to qualify		
The research involves no more than minimal risk to the subjects	<input type="checkbox"/>	<input type="checkbox"/>
The waiver or alteration will not adversely affect the rights and welfare of the subjects	<input type="checkbox"/>	<input type="checkbox"/>
The research could not practicably be carried out without the waiver or alteration	<input type="checkbox"/>	<input type="checkbox"/>
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	<input 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 type="checkbox"/>	<input type="checkbox"/>
Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):		

FDA-REGULATED STUDIES

Per FDA guidance issued in July 2017, the IRB may waive or alter informed consent requirements for certain minimal risk clinical investigations. The IRB can alter, some or all of the elements of informed consent or waive the requirements to obtain informed consent when the IRB finds and documents ALL of the criteria listed below:	Yes	No
The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects	<input type="checkbox"/>	<input type="checkbox"/>
The waiver or alteration will not adversely affect the rights and welfare of the subjects	<input type="checkbox"/>	<input type="checkbox"/>

The clinical investigation could not practicably be carried out without the waiver or alteration	<input 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 type="checkbox"/>	<input type="checkbox"/>
Additional Comments:		
This study is a non-FDA regulated study; for this reason, we have kept this section of the protocols blank.		

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.***

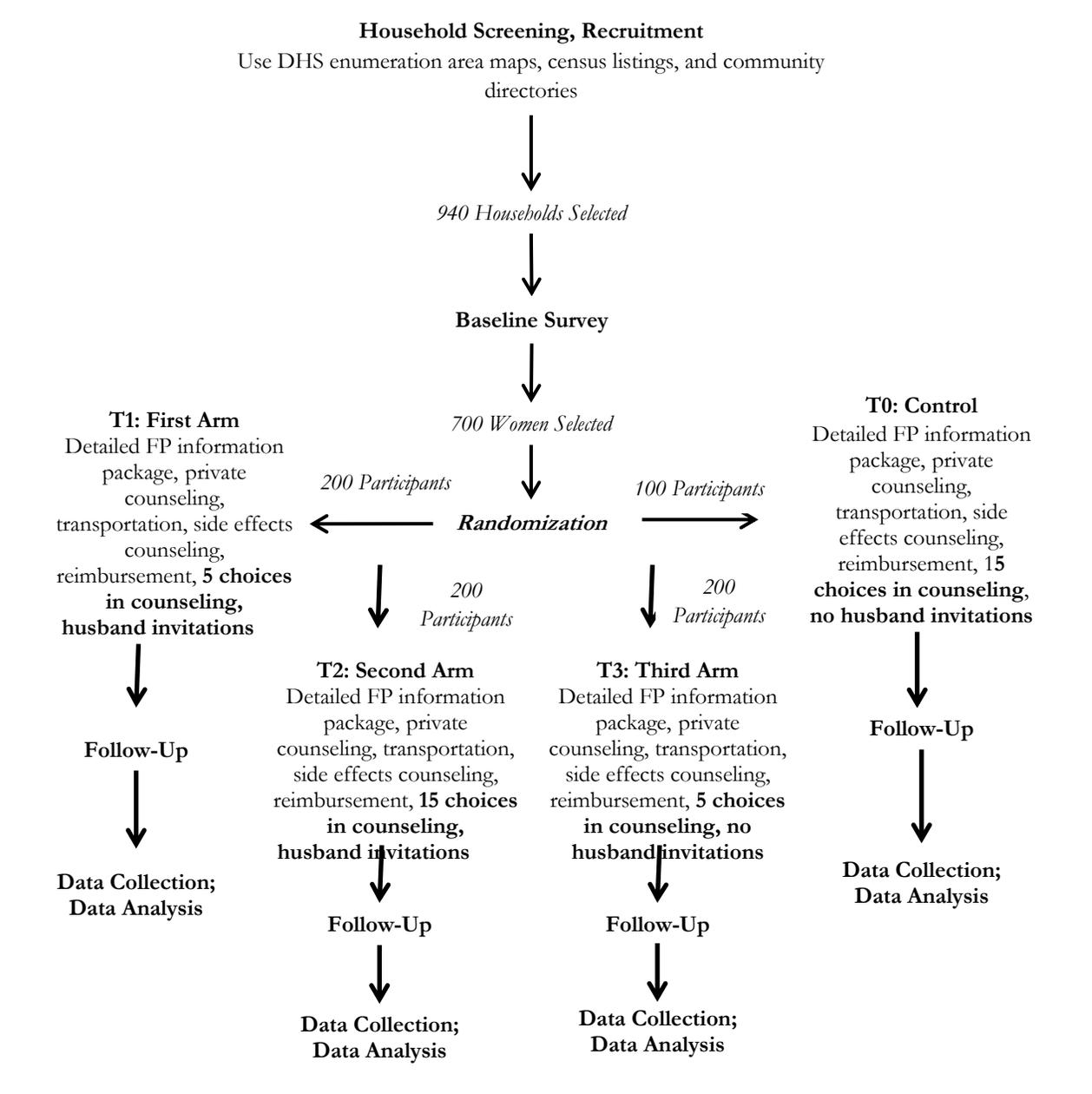
***Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit Appendix C: Device Form.**

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.

This study is a four-armed randomized controlled trial that consists of a baseline survey followed by implementation of our family planning interventions starting upon completion of the baseline. One follow-up survey will be conducted one month from the start of the intervention period either at the clinic, or through phone interviews. If the participants could not be reached in either way, a home visit will be paid to the households. **Figure 1** outlines the general framework of the entire field experiment.

Figure 1: Experimental Framework



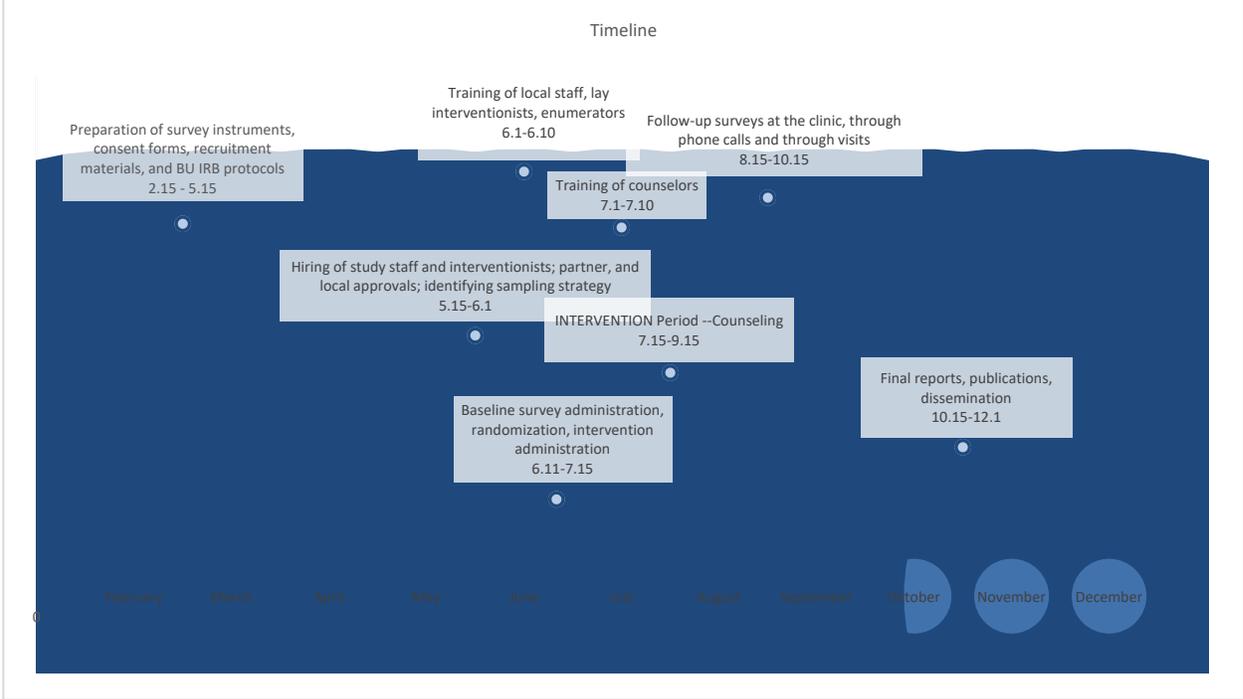
The study will span a total of 12 months from January 2019 to December 2019. Months 1 to 5 (1/2019-5/2019) will consist of finalizing local and BU IRB approvals, finalizing the electronic version of the survey instruments, preparing the counseling inserts, charts, and other intervention materials for the study. Months 5 and 6 (May 2019 to June 2019) will consist of hiring surveyors, other field staff (field managers), and intervention staff (counselors, a driver to transport women to clinics) and working with local partners and Malawi National Statistical Office, NSO, to identify the enumeration areas in Lilongwe and to finalize the sampling strategy. Training of intervention staff, field staff, and surveyor will be provided in early month 6 (June 2019) and will last less than 10 workdays. Household screening, recruitment, and consent of women will begin by mid-June 2019 and will continue until 700 women have been recruited to power the study.

Following recruitment, eligible women who consent to participate in the study will receive a baseline survey starting in month 6 (mid-June 2019). The baseline survey will be administered to all 700 participants from June 2019 to mid-July 2019 (months 6-7). Immediately following completion of the baseline survey, women will be randomized using a stratified covariate-balanced randomization to either the control arm or one of the three counseling intervention arms. Women will receive their respective counseling interventions from our team of counselors between mid-July 2019 and mid-September 2019. Respondents will be eligible to visit our partner clinic and receive additional family planning services up to one month after their initial counseling visit from our counselor team. Services to our partner clinic will continue until mid-October 2019. Women who visit the clinic will receive a short follow-up survey at the conclusion of their visit. Women who do not visit the clinic will receive a phone survey (an abbreviated version of the clinic survey). Women who do not visit the clinic and who are unreachable by phone will receive a home visit, during which an abbreviated survey will be administered. We expect to collect all 700 women’s follow-up data through either the clinic, phone, or home-based surveys by the end of mid-October. Closing activities related to data collection will commence in mid-October 2019 and will conclude by the end of October 2019. Study results will be analyzed between October 2019 and December 2019. The specific timeline is presented in Table 1 as follows:

Table 1: Study Timeline

	5.1-5.15	5.15-6.1	6.1-6.10	6.10-7.15	7.15-9.15	8.15-10.15	10.15-12.1
Preparation of survey instruments, consent forms, recruitment materials, and BU IRB protocols							
Hiring of study staff and interventionists; partner, and local approvals; identifying sampling strategy							
Training of local staff, lay interventionists, enumerators							
Baseline survey administration, randomization, intervention administration							
INTERVENTION Period -- Counseling							

Follow-up surveys at the clinic, through phone calls and through visits							
Final reports, publications, dissemination							



Based on the timeline:

- Study preparation activities (submitting the BU and local IRB approvals, finalizing the survey instruments and supplementary documents, etc.) began in February 2019 and will continue until May 2019;
- Following receipt of BU and local IRB approvals, study field activities (data collection, intervention implementation) will begin in June 2019 and will be completed by the middle of October 2019, and the findings from the study will be analyzed by the end of October 2019. The estimated time to study completion is December 2019.

Dr. Karra and the co-investigator, Kexin Zhang, will oversee all study activities over the full study duration. Ms. Zhang will be present in Malawi from May 2019 to September 2019 to oversee the setting up of the study, the training of surveyors and intervention staff (counselors and other personnel who will be interacting with study participants), selection of the study participants, and administration of the baseline survey. In addition, she 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 March 2019 and from May 2019 to June 2019 to assist in these activities 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, Ms. Zhang, Ms. Eyob, and Ms. Dangerfield, in collaboration with Dr. Ngwira and Dr. Longwe Ngwira will conduct the analysis of the results following fieldwork and data collection after the experiment is completed from October 2019 to December 2019.

Initial Preparations and Training of Field Staff

We shall travel to Lilongwe, Malawi in May 2019 to initiate the study and complete preparations for the baseline survey and interventions. We will meet with our partner organization, IPA Malawi, the Malawi MOH and RHD, the Malawi National Statistics Office (NSO), and our partner family planning clinic in Lilongwe, the Good Health Kauma Clinic, to:

1. Finalize the sampling strategy that we will use to identify and recruit women (discussed in greater detail in the recruitment section)
2. Hire field staff. Field staff include: 5 surveyors who will be responsible for administering the baseline and follow-up surveys to the household respondents; 6 family planning counselors who will be trained to administer the counseling component of the intervention to women in the intervention arm; 1 hired driver who will transport women in the intervention arm to the Good Health Kauma Clinic from their homes; and 1 field manager who will supervise the survey enumerators and intervention staff (driver, counselors), monitor and spot-check the data for quality issues, and oversee administration of the counseling interventions to the respective intervention arms.
3. Confirm transportation logistics (hiring of vehicles for field staff transport to and from study sites, transportation allowances, etc.) and other related issues (mobile credit, internet, etc.) 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. Finally, we will train interventionists (counselors and the driver) on how to administer their respective intervention components to women in the control and intervention arms.

Sample Identification and Selection

Using the most recent Demographic and Health Survey (DHS) and census maps of Lilongwe's enumeration areas and listings of households and neighborhoods, which will be provided to us by the Malawi MOH, NSO, and IPA Malawi, we will employ a two-stage sample selection procedure that is based on the sampling strategy used by the DHS. In the first stage, we will randomly select census areas to be screened until we have selected enough enumeration areas to contain at least 5,000 households in total. In the second stage, our surveyors will proceed door-to-door to screen households in each selected area for potentially eligible women. Surveyors will continue to screen households until they identify 700 women for the study in accordance with the inclusion and exclusion criteria listed in sections above, and these eligible women will be recruited in accordance with the recruitment protocols outlined above. We shall ensure that eligible women who are selected for the study are sufficiently distant (at least 5 households apart) from each other. Based on our knowledge of participation refusal rates and the estimated number of eligible women in Lilongwe, we will need to screen an estimated 940 households in order to obtain a desired sample size of 700 women. We require a study sample of at least 700 women to achieve sufficient power for measuring our outcomes of interest. Recruitment from the selected areas will cease once

700 women have been found who meet the eligibility conditions and who consent to participate in the study.

Since receipt of the counseling intervention will be randomized at the individual level, we shall ensure that no two eligible women will be chosen from the same household. If multiple women from the same household are eligible to be selected into the study, we shall choose the youngest eligible woman from the household to participate.

Baseline Survey

Women who are identified as eligible from the household screening and who consent to participate in the study will then receive a comprehensive 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 modules from the household and women's questionnaires of the Malawi Demographic and Health Survey (DHS), which is a nationally-representative survey that includes information on marriage, fertility, family planning, reproductive health, and child health (Macro International Inc., 2012), and modules on decision-making, women's empowerment, and husband's preferences from the World Bank's Living Standards Measurement Study (LSMS), the FP2020 and PMA2020 surveys, and other related family planning surveys.

The Household section of the survey will contain information on the following topics:

- Household listing, which collects information on every household member's age, sex, relationship to the head of the household, and parental survivorship and residence.
- Household characteristics, which asks about the dwelling and household assets.
- Mortality and Morbidity in the Household, which collects data on deaths, illnesses, and other significant life events that might have occurred in the household over the past 12 months.

The Women's Questionnaire section of the survey will be administered to each eligible woman and contains information on the following topics:

- Background characteristics: the woman's age, marital status, and place of residence
- Reproductive behavior and intentions, which cover birth histories, pregnancies that did not end in a live birth, fertility preferences, and future childbearing intentions.
- Contraception, which covers knowledge and use of family planning, source of methods, and unmet need for family planning. For women not using contraception, questions are included on intentions about future use.
- Women's mental health: including information on anxiety and depression.
- Women's marital history, sexual activity and relationships with their husbands / partners. Details on women's husbands' preferences for family planning, fertility intentions, and contraceptive use will be collected
- Spousal communication, women's access to care, decision-making, and measures of women's empowerment

The respondent for both the Household and Woman sections of the baseline survey will be the eligible woman respondent who is identified at the time of the screening. Asking questions about contraceptive use, family planning, and health is culturally acceptable in Malawi, provided that the appropriate privacy and confidentiality measures are taken. For these reasons, we will take the necessary steps to ensure that subjects' privacy and confidentiality are maintained. In addition, all questions that are related to family planning and health in our survey have been previously tested and administered as part of the Malawi DHS.

Prior to administering the survey, we will explain clearly the purpose of the study to respondents and will ask for their consent using the study consent forms. Baseline surveys will be administered in a private room in the woman's place of residence and will last approximately 75 minutes. Short breaks of 5 to 10 minutes will be given to the respondents at the following scheduled times:

1. Between the Household Questionnaire and the Woman Questionnaire
2. Household Questionnaire: after 25 minutes, before the start of Marriage and Sexual Activity section
3. Woman Questionnaire: after 40 minutes, before the start of Women's Empowerment and Decision-Making section

Additional 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 our participants over time, we will be collecting identifiable data, including names and contact information for each of the survey respondents (the woman, her husband), the names and background characteristics of other household members, the household address, contact phone numbers and e-mails, and GPS coordinates of the household. For the purposes of minimizing loss to follow-up, we will also be taking photographs of the household and of the survey respondents, and we will be asking respondents to provide the names and contact information of two contacts who do not live in the household and who would be contacted if the respondents cannot be directly located in the follow-up period. 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

A key feature our experimental study design lies in the randomization of women at the individual level. Following the baseline survey, women who participated in the study will be randomized into one of four experimental arms:

- 1) a control group (T0), where women receive a private counseling session on the full range of 15 contraceptive methods following the standard counseling process (N = 100);
- 2) an intervention group (T1) where women receive a private counseling session on a targeted 5 contraceptive methods based on her baseline preferences for family planning (N = 200);
- 3) an intervention group (T2) where women are given the choice to invite their husbands to a joint counseling session. Women (and their husbands should they choose to invite them) will then be

counseled on the full range of 15 contraceptive methods following the standard counseling process (N = 200); or

4) an intervention group (T3) where women are given the choice to invite their husbands to a joint counseling session. Women (and their husbands should they choose to invite them) will then be counseled on a targeted 5 contraceptive methods based on women's baseline preferences for family planning (N = 200).

Additional details for each of these intervention arms are provided below.

Randomization will take place after the baseline interview. We will randomize women to intervention and control arms such that intervention assignment is balanced according to the following baseline characteristics: neighborhood/household cluster, distance to the nearest family planning clinic, number of living children, months since last live birth, current use of family planning, age of marriage, educational attainment, and household wealth.

Counseling Session – Introduction

All women who are selected for the study (T0 – T3) will be offered one free, private family planning counseling session, which will include a risk assessment for clinical methods and detailed information on methods switching, side effects associated with each method, and the benefits of contraception and birth spacing. Women will receive a detailed information brochure on birth spacing and healthy timing of pregnancy. Strategies on how to communicate family planning messages with partners and on how to increase partner awareness will also be conveyed to all women. The counseling session will last no more than one hour and will be administered in a private room by a counselor who is trained to provide family planning and reproductive health services. Counselors will be hired and trained by IPA Malawi, and we will enlist the support of the Malawi RHD and several international NGOs who work on family planning in Malawi to help us develop training materials, brochures and flyers, and other counseling resources. We will also collaborate with the Malawi RHD to assist with the counselor training.

Counseling for Control Group T0

Following the introductory risk assessment and discussion on the benefits of contraception and birth spacing, women assigned to the control arm will be counseled on the full range of 15 available family planning methods following the standard approaches to family planning counseling in Malawi. Counselors will counsel women on each method individually and will follow the order of methods that is outlined in the standard-of-care contraceptive methods flipchart that is provided by the MOH and RHD.

Counseling for Intervention Group T1

Following the introductory risk assessment and discussion on the benefits of contraception and birth spacing, women assigned to intervention arm T1 will be counseled on a targeted range of 5 family planning methods based on the respondent's stated preferences for methods at baseline. The objective of this intervention arm is to minimize choice overload and increase the salience of a woman's most preferred method attribute (e.g. method effectiveness in preventing pregnancy, duration of use, ease of use, likelihood of method-related side effects, etc.), which she reported during the baseline survey. In the baseline survey, a woman would be asked to compare and rank method-specific attributes (e.g. does she prefer that a method have a lower incidence of side effects

over a method that is more effective at preventing pregnancy?). Based on her elicited ranking of method attributes, the counselor will identify the attribute that the woman reveals to be most important to her (e.g. methods with low incidence of side effects) and will present a subset of 5 methods that rank highest along that revealed attribute (e.g. male condoms, Standard Days Method, sterilization, etc.). Particular emphasis will be placed on making the order of presentation salient, in which women will be reminded and primed to consider the relative ranking of a method across the stated attribute. Counselors will counsel women on each of the 5 methods individually.

Counseling for Intervention Group T2

Prior to receiving the counseling session, women assigned to intervention arm T2 will be given the choice to invite their husbands / partners to participate in a joint family planning counseling session. Following the invitation, women and their husbands (should they choose to invite them) will receive the introductory risk assessment and discussion on the benefits of contraception and birth spacing. Women and their husbands will then be counseled on the full range of 15 available family planning methods following the standard approaches to family planning counseling in Malawi. Counselors will jointly counsel women and their husbands on each method individually and will follow the order of methods that is outlined in the standard-of-care contraceptive methods flipchart that is provided by the MOH and RHD.

Counseling for Intervention Group T3

Prior to receiving the counseling session, women assigned to intervention arm T3 will be given the choice to invite their husbands / partners to participate in a joint family planning counseling session. Following the invitation, women and their husbands (should they choose to invite them) will receive the introductory risk assessment and discussion on the benefits of contraception and birth spacing. In following the counseling protocols of the T1 intervention arm above, women and their husbands will be jointly counseled on a targeted range of 5 family planning methods based on the woman's stated preferences for methods at baseline. Counselors will jointly counsel women and their husbands on each of the 5 targeted contraceptive methods individually.

Post-Counseling Survey

Following the counseling session, counselors will conduct a brief survey with all women to record their experiences with the counseling service. Refer to Appendix F2 (to be prepared) for the post-counseling survey instrument. A particular aim of this follow-up survey will be to reveal women's preferred choice of contraceptive method immediately following counseling. Husbands of women who participated in the counseling session will also be briefly interviewed about their experiences with the counseling session. Interviews with women and with husbands who are present will take no more than 15 minutes and will be conducted privately in accordance with the standard interviewing procedures that were established for the baseline survey.

Post-Counseling Package of Services

Following the post-counseling survey, women in all treatment arms of the study and husbands who participated in the counseling session will be offered the following package of services from their counselor:

1. *Transportation Service:* Women (and applicable husbands) will be offered a free transportation service from their homes to the Good Health Kauma Clinic for a period of one month from the date of their counseling session. The transportation service will be provided by a driver who will

be hired and trained by IPA Malawi. Respondents will receive the driver's phone number and will be instructed to contact the driver to transport them to the Good Health Kauma Clinic during the clinic's normal working hours, which are between 8 AM and 5 PM from Monday to Saturday. The driver will maintain a daily schedule of the respondents who request his services, and respondents will be instructed to notify the driver at least one day before they wish to go to the clinic to make sure that the driver will be able to transport them. The driver will also provide one day's advanced notice to the Good Health Kauma Clinic to inform them of how many respondents from the study can be expected to attend the clinic on the following day. The Good Health Kauma Clinic has undertaken that respondents who come for services will not have to wait more than 1 hour before being seen by a medical professional. The driver will be accompanied at all times by the female field manager; the presence of another woman in the vehicle will also act to minimize potential stigma associated with a woman traveling alone in the company of a man and may also provide comfort to the participant.

2. Financial Reimbursement for Family Planning Services: Finally, women and participating husbands will be financially reimbursed for any out of pocket expenditures that they incur for receiving family planning care at the Good Health Kauma Clinic for the one-month post-counseling period. Costs that will be reimbursed at the Good Health Kauma Clinic include costs related to the procurement of family planning medications and contraceptive methods, family planning consultation fees, lab test fees, the treatment for any contraceptive-related side effects and contraindications, costs associated with switching and discontinuation of methods, and exam fees. The reimbursement allowance for each couple will be in the amount of 17,500 MWK (\$25.00 USD) and can be redeemed by the couple over multiple visits at the Good Health Kauma Clinic over the one-month period. For every family planning service that the woman or her husband receives, the cost of the service will be deducted from her 17,500 MWK reimbursement allowance.

In addition, women and participating husbands who experience any side effects due to contraceptive use over the course of the one-month intervention period will receive a series of services for the treatment of side effects. In the event that a woman or her husband experiences a side effect or contraindication, she may seek care at her nearest public clinic, public hospital, or the Good Health Kauma Clinic. The woman will be asked to keep receipts of any costs she incurs at the health facility so that she can be reimbursed later. Costs for which the woman will be reimbursed include costs of medications and lab tests, costs of additional consultations at the health facility, and costs of switching or discontinuing methods. Any reimbursement amount that a woman is eligible to receive for the treatment of family planning related side effects or contraindications will be deducted from her 17,500 MWK reimbursement allowance over the one-month intervention period. The reimbursement will apply to covering the cost for treatment for side effects for all family planning methods used by the woman and regardless of where the method or treatment was procured. All reimbursements for an incurred cost will be distributed as closely as possible to the time that the reimbursable cost was incurred, most likely within 2-3 business days by the field manager.

Following the counseling session with women and their invited husbands, the family planning counselor will present a Terms of Service document (see Appendix L (to be prepared)), which specifies the terms and conditions for each of these services above, to the woman. The counselor will answer any questions that the woman may have about the package of services and will then

ask for and confirm the woman's (and her husband's) understanding of these terms using the Terms of Service document (see attached). Each respondent will receive a paper copy of the Terms of Service document. Women may withdraw their participation from any activity at any time and may also rejoin at any time without any penalty over the one-month intervention period.

Follow-Up

Throughout and following the one-month intervention period, the entire study sample of 700 women will be resurveyed with an abbreviated version of the survey questionnaire that was initially administered at baseline. Resurveying participants in this manner will enable us to create a panel of individual women in which each woman is observed over two time periods. The same protocols regarding data security and confidentiality that were enforced at baseline will be implemented once again for each follow-up survey round.

In the follow-up round, we will collect survey data on short-term, intermediate, and longer-term outcomes of interest, including:

- Attitude/Knowledge of Family Planning, including: knowledge of family planning; knowledge of birth spacing and timing; and perceptions toward contraception (including intentions to use).
- Contraceptive Use, including: changes in contraceptive prevalence; changes in method mix; and adherence to methods (compliance, discontinuation).
- Pregnancy and Fertility Outcomes, including: pregnancy status; parity; delivery in a facility; months since last birth; wantedness of last birth; and intentions to become pregnant in future.
- Family planning preferences and decision-making
- Husband's preferences for family planning and fertility
- Women's autonomy, empowerment, and decision-making
- Household Assets and Wealth, including changes in asset ownership over time.

The follow-up survey will be administered as three phases: 1) a clinic-based survey that will be administered to women (and available husbands) who choose to visit the Good Health Kauma Clinic over their one month intervention period; 2) a phone follow-up survey that will be administered by phone to women who do not visit the Good Health Kauma Clinic over the one month intervention period; and 3) an in-person home-based follow-up survey that will be administered to women who neither visit the Good Health Kauma Clinic nor are available for a phone follow-up survey over the one month period.

Clinic-Based Survey

The one-month clinic-based follow-up survey will be administered by the local field team and in person to all women and husbands who visit the Good Health Kauma Clinic over the one-month intervention period. The clinic-based survey, which is an abbreviated version of the main baseline survey instrument, will take no more than 20 minutes and will be administered in a private room at the Good Health Kauma Clinic. All protocols related to consent and in-person survey administration that were established for the baseline survey will be followed in this survey. Refer to Appendix F3 (to be prepared) for the clinic-based survey instrument. Respondents who had previously indicated that they were no longer interested in participating in the study will not be

contacted. All survey responses will be collected on Android-based tablets, and data will be securely transferred to the CommCare-supported server.

Prior to administering the clinic-based survey, we will explain clearly the purpose of the follow-up to respondents and will ask for their written consent to participate in the survey. Following receipt of consent, we will ensure confidentiality and privacy of responses by asking that the respondent find a private room or space at the Good Health Kauma Clinic where their responses cannot be overheard by others. We will proceed with the survey only after having received confirmation from the respondent that her responses cannot be overheard. Please refer to the clinic-based survey instrument for additional details.

Phone Follow-Up Survey

For women who either have moved out of urban Lilongwe or who are unreachable at the Good Health Kauma Clinic, the field team will attempt to contact them by phone up to a maximum of three attempts, and women who are reachable by phone within these three attempts will be asked to participate in a phone follow-up survey. In order to maintain a respondent's privacy during an attempt to reach her by phone, the field enumerator conducting the call will leave no indication of the reason for the phone attempt (e.g. voicemail, text message) on the respondent's phone should there be no response to a call. In order to ensure that the respondent's participation remains private, the field enumerator will only continue with the phone call once she receives assurance from the woman that she is able to speak on the phone without being overheard or interrupted. Any disruption or interruption during the phone call will result in the postponement or termination of the call. The phone follow-up survey instrument (Appendix F3 (to be prepared)) will take no more than 20 minutes in total and is identical to the clinic-based follow-up survey instrument. The aim of the phone survey is to be able to maximize survey follow-up rates by attempting to include those women who were physically unreachable. The only respondents who will be re-contacted for the phone follow-up survey will be those respondents who were simply lost to follow up. Respondents who had previously indicated that they were no longer interested in participating in the study will not be contacted. All phone survey responses will be collected on Android-based tablets, and data will be securely transferred to the CommCare-supported server.

Prior to administering the phone survey, we will explain clearly the purpose of the follow-up to respondents and will ask for their consent to participate in the survey verbally over the phone. Following receipt of consent, we will ensure confidentiality and privacy of responses by asking that the respondent find a private room or space where their responses cannot be overheard by others. We will proceed with the phone survey only after having received confirmation from the respondent that her responses cannot be overheard. Please refer to the phone survey instrument for additional details.

Home-Based Survey

For women who are unreachable at the Good Health Kauma Clinic and who are uncontactable by phone, the field team will attempt to contact them at their homes up to a maximum of one attempt, and women who are reachable in person at their homes will be asked to participate in an in-person home-based follow-up survey. The home-based follow-up survey will be administered by the local field team and in person. The home-based follow-up survey instrument (Appendix F3 (to be prepared)) will take no more than 20 minutes in total and is identical to the clinic-based and phone follow-up survey instruments. The survey will be administered in a private room at the woman's.

All protocols related to consent and in-person survey administration that were established for the baseline survey will be followed in this survey. The aim of the home-based survey is to be able to maximize survey follow-up rates by attempting to include those women who were physically unreachable at the Good Health Kauma Clinic and by phone. Respondents who had previously indicated that they were no longer interested in participating in the study will not be contacted. All survey responses will be collected on Android-based tablets, and data will be securely transferred to the CommCare-supported server.

Prior to administering the home-based survey, we will explain clearly the purpose of the follow-up to respondents and will ask for their written consent to participate in the survey. Following receipt of consent, we will ensure confidentiality and privacy of responses by asking that the respondent find a private room or space in their household where their responses cannot be overheard by others. We will proceed with the survey only after having received confirmation from the respondent that her responses cannot be overheard. Please refer to the home-based survey instrument for additional details.

From each household with an enrolled woman, survey data will be collected at three time points (at baseline, during the implementation of the counseling intervention, and one month following intervention implementation) from the enrolled woman and her invited husband.

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.

Due to the sensitive nature of the questions being asked in the baseline and follow-up surveys, participants may be subject to minor psychological or emotional distress and may feel some personal discomfort, fatigue, or embarrassment during survey administration. However, we do not anticipate respondents to be subject to more than minimal risk or discomfort from participating in this study.

In addition, information asked about a participant's sexual behavior, fertility preferences, or perspectives on family planning and reproductive health issues may adversely affect a participant's reputation, and identifiable data on participants is being collected, so breach of confidentiality is another potential risk of this study. Our secure storage, encryption, and coding of all data, particularly identifiers, serves to minimize this risk.

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

Participants will be reminded that their participation is completely voluntary, and this also refers to specific questions. They do not have to answer any question that they do not feel comfortable answering, and they can decide to end their participation in the study at any time. In addition, short breaks will be taken in between survey sections, and participants may request additional breaks whenever needed. Refer to the section above for additional details on breaks.

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 NHSRC). Necessary measures will be taken to ensure that participants' responses will remain confidential. All surveys will be conducted in private rooms, and necessary data security measures will be implemented to ensure that participants' identities are protected. We will ensure that participants will feel that they can refuse to answer any question or stop participating in the study at any time. We will also ensure that participants understand that maintaining confidentiality is a requirement of participation, and we will ask that they do not share what is discussed with those outside of the interview.

If a participant has a need for medical or psychological support services, the research team member present at the time will refer him/her to Mr. Baxter, the local project manager, who will be on call by mobile phone for the entire duration of the study. Should any participant indicate potential risk of harm or sign of distress, the team member present at the time will meet separately with the participant to assess for risk of harm and need for a higher level of intervention. All team members will be trained to recognize basic signs of physical and psychological injury and will be instructed to immediately report any injuries that are incurred during the survey or intervention to Mr. Baxter. All team members will also be trained to recognize and report signs of distress or adverse events that may not be research-related but that are observed within the context of the interaction with the respondent (e.g. domestic abuse, criminal activity within the household, etc.). We will implement the following protocols, which were recommended to us by the Department of Social Welfare in the Lilongwe District Council Office:

1. We will first report all adverse events related to violence, abuse, or intra-household conflict to local community leaders.
2. We will refer women and other family members requiring support to the nearest Victim Support Unit office for further counseling and assistance. The Victim Support Unit office is a special branch of the local police department that aims to provide local communities with conflict resolution services, violence and abuse support, and peer mediation. We have identified the three Victim Support Unit offices that are closest to our selected enumeration areas: 1) Kawale Victim Support Unit at Kawale Police Station; 2) Lingadzi Victim Support Unit at Area 18 Police Station; and 3) Lilongwe Victim Support Unit at Lilongwe Police Headquarters.
3. We will refer women and other family members requiring assistance to the Department of Social Welfare, which also offers social support and counseling services to women and children in Lilongwe.

With the help of Mr. Baxter and Dr. Ngwira, we have established a link with a local primary clinic in Lilongwe and will refer respondents to this clinic if they experience research-related stress, fatigue, or injuries. For emergency cases, we will identify the emergency care facility or hospital that is nearest to the interview location, and we will refer respondents to this facility in case of a medical emergency. Field staff will also have the contact information of the local

police in Lilongwe as well as the Lilongwe District Council Office and will refer respondents to these authorities as needed.

Additional details on dealing with research induced distress in study participants are described in the standard operating procedures (SOP) document for dealing with research-induced stress (Appendix K1).

All risk of harm cases will be discussed with the local project manager, Mr. Baxter, and will be reported to the PI and Co-Investigators. 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.

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.

Women who participate in the study will receive several direct benefits for the duration of the study period. All women who participate in the study will receive a small token of appreciation (three bars of soap, a monetary equivalent of 500 MWK (\$0.66 USD)) after completing each survey. In particular, women will receive family planning counseling services and will be informed about the availability of nearby family planning and reproductive health services.

Women will also receive additional family planning services, including

1. Access to free transportation to a family planning clinic with low waiting times, and
2. Receiving free consultation, referral to a clinic, and financial reimbursement in the amount of 17,500 MWK (\$25.00 USD) for the receipt of routine family planning services, the coverage of the treatment of contraceptive-related side effects and contraindications, exam fees, medical tests, and other covered services.

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

Results from the baseline and follow-up surveys will be disseminated to local authorities and relevant institutions. The study findings will aid to inform the community of the local family planning environment by helping to identify the role of women's and couple's perceptions and attitudes towards family planning, preferences for children, and other related health behaviors in Lilongwe. The results from this study may also help the Ministry of Health and Reproductive Health Directorate to develop family planning services and interventions that take into account key drivers of intra-couple communication in family planning, decision-making behaviors of women and their husbands / partners, and contraceptive uptake among couples overall, with the goal of improving reproductive health outcomes in Lilongwe, Malawi.

More generally, our findings may also demonstrate to policymakers that the benefits of improving access to family planning are likely to extend beyond the health domain by also

improving women’s access and empowerment outcomes. Such findings can be used to develop policies, programs, and interventions that aim to improve health and well-being for women, couples, and households more generally.

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: All women who participate in the study will receive a small token of appreciation (three bars of soap, a monetary equivalent of 500 MWK (\$0.66 USD)) after completing each survey. No monetary compensation will be provided to participants for participating in the study, which serves to minimize coercion. 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 (household addresses, phone numbers, e-mails, and GPS locations) will be collected. In addition, photographs of participants and of the household 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 (EULA) can be found at https://www.commcarehq.org/eula/.</p>		
<p>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 households at the one-month follow-up period. After the study ends, the IPA Malawi research site will maintain the identified data in an encrypted file on a secure</p>		

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. Baxter). 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. Baxter, 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, Dr. Ngwira, Dr. Longwe Ngwira, and Ms. Zhang) 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, Dr. Ngwira, Dr. Longwe Ngwira, and Ms. Zhang 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).

SECTION Q: CERTIFICATE OF CONFIDENTIALITY

Complete this box if the study is **UNFUNDED** or **FUNDED** by any entity (e.g department, foundation, NSF, or other federal agencies) other than the NIH

On October 1, 2017 the NIH updated its policy for issuing Certificates of Confidentiality. The updated policy is located at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

Additional information regarding the policy can be found on the NIH FAQ’s website at: <https://humansubjects.nih.gov/coc/faqs>. Note: Sections C and D describe the process for obtaining a Certificate for studies not funded by NIH

YES	NO	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<p>Will you obtain a Certificate of Confidentiality?</p> <p>The NIH has updated the required consent form language. The language is at the following website: https://humansubjects.nih.gov/coc/suggested-consent-language. Note: A consent form with the applicable language must be included with this submission.</p> <p>Certificates of Confidentiality are issued by the National Institutes of Health (NIH). A Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.</p>

Complete this box if the study is **FUNDED** by the NIH

On October 1, 2017 the NIH updated its policy for issuing Certificates of Confidentiality. The updated policy is located at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

Note: Under the new policy, the investigator will not need to apply for a Certificate. All eligible research studies that are funded by NIH are automatically issued a certificate under the NIH Policy on Certificates of Confidentiality

Additional information regarding the policy can be found on the NIH FAQ’s website at: <https://humansubjects.nih.gov/coc/faqs>

YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	<p>Does this study qualify for a Certificate of Confidentiality under the NIH Policy or Issuing Certificates of Confidentiality?</p> <p>To determine if this study (which is conducted or supported by NIH) qualifies for a Certificate of Confidentiality, please answer the following question:</p> <ul style="list-style-type: none"> • Is the activity biomedical, behavioral, clinical, or other research? <ul style="list-style-type: none"> <input type="checkbox"/> YES <input type="checkbox"/> NO <p>If the answer to the above question is “NO”, then this study will not be issued a Certificate of Confidentiality by the NIH. If the answer is “YES”, please consider the questions below:</p> <ul style="list-style-type: none"> ▪ Does the research involve Human Subjects as defined by 45 CFR 46? ▪ Are you collecting or using biospecimens that are identifiable to an individual as part of the research? ▪ If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual? ▪ Does the research involve the generation of individual level, human genomic data? <p>If the answer to any one of the four questions above is “YES”, then this NIH policy will apply and will be considered to have a Certificate of Confidentiality by the NIH.</p> <p>If this study is covered under this policy, the consent form must include language about the protections and exceptions allowed with the Certificate. The NIH has updated the required consent form language. The language is at the following website: https://humansubjects.nih.gov/coc/suggested-consent-language. Note: A consent form with the applicable language must be included with this submission.</p> <p>Certificates of Confidentiality are issued by the National Institutes of Health (NIH). A Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive</p>

		information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena
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SECTION R: 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.

In order to maintain a respondent's privacy during an attempt to reach her by phone, the field enumerator conducting the call will leave no indication of the reason for the phone attempt (e.g. voicemail, text message) on the respondent's phone should there be no response to a call. In order to ensure that the respondent's participation remains private, the field enumerator will only continue with the phone call once she receives assurance from the woman that she is able to speak on the phone without being overheard or interrupted. Any disruption or interruption during the phone call will result in the postponement or termination of the call.

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, Dr. Ngwira, Dr. Longwe Ngwira, and Ms. Zhang 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, Dr. Ngwira, Dr. Longwe Ngwira, and Ms. Zhang) 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 on the two components of the family planning counseling intervention will be conducted in private spaces, either in participants’ homes (for the baseline survey, counseling intervention activities, and home-based follow-up survey), at the Good Health Kauma Clinic (for clinic-based follow-up survey), or in a private room at the IPA Malawi headquarters office (for phone-based follow-up survey). The follow-up survey will be conducted at the Good Health Kauma Clinic. For those women who do not visit the clinic, our field team will conduct a phone survey. For women who do not visit the clinic and who are unable to be contacted by phone, our field team will revisit them at their homes to conduct a home-based follow-up survey.

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

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 Ms. Zhang, will oversee the weekly review of all data collected in the study and will be present during the administration of the baseline, follow-up surveys, and the final round of survey at the clinic. 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, Patrick Baxter, and the local co-investigators, Dr. Ngwira and Dr. Longwe Ngwira, will review adverse events. This information will then be provided to the Institutional Review Boards at BU and the NHSRC in Lilongwe. Unanticipated adverse events will be immediately reported to both the BU IRB and the NHSRC in writing within 5 business days.

Ms. Zhang, with support from Patrick Baxter and the IPA Malawi team, will be the immediate supervisor of study staff in the field. She 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 participants' demographic backgrounds, and personal contact information (household addresses, phone numbers, e-mails, and GPS locations) will be collected. In addition, photographs of participants and of the household 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 our family planning intervention on fertility intentions, preferences, and other outcomes related to contraceptive behavior by directly regressing our outcomes of interest on a binary variable indicating receipt of the intervention; and 2) estimate downstream behavioral outcomes (such as women's uptake of the contraceptive options, the consistency between their revealed choice and their stated preference, etc.) using a two-stage least squares model, in which the intermediate counseling variable will be instrumented in the second stage with our family planning intervention. We will conduct several sub-group analyses in order to examine how our family planning intervention effects vary across key subpopulations. Subgroups of interest include: women who have / do not have their husbands' approval to access contraceptive methods, women who have previously used of family planning, women who expressed a desire to space or limit births at baseline, poorer women, women in larger households, and women with low educational attainment. 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.

Power Calculations

Our target baseline sample will consist of 700 women who will have met the eligible criteria and who will have consented to participate in the study. Our existing family planning study in Malawi has found that 25.5 percent of initially screened women either did not meet the eligibility criteria or refused to participate. Therefore, in order to meet our target sample size of 700, we will need to survey 940 households if we assume a combined ineligibility/refusal rate of 25.5 percent from the preliminary recruitment process. Since women who are selected into the study will also be at least 5 households apart from each other, we will need to choose enough enumeration areas to have at least 5,000 households in total ($940 \times 5 = 4,700$ households among the women who make up our sample and who are at least 5 households apart, plus an additional 300 households that are screened but where women either do not meet the eligibility criteria or refuse to participate). Of the 700 women who will be recruited into the study at baseline following the initial screening process, 600 women will be evenly assigned to the three intervention arms and the remaining 100 women will be assigned to the control arm.

Our unit of analysis is a woman. Our power calculations for our main outcome of interest, a woman's stated preferences for contraception, are based on data from the Malawi Demographic and Health Survey as well as an ongoing family planning experiment with married women aged 18-35 in urban Lilongwe. We estimate that, at baseline, 50 percent of women in our sample will state that they would be interested to use a method of family planning, while 60 percent of women who are interested in using family planning will state that they would prefer the injectable (Depo-Provera).

To guarantee enough power to detect an increase in the contraceptive prevalence rate after the interventions, we will increase our sample size to 700 women, among which we will assign 100 women to the control arm and 200 women each to the three intervention arms. To maximize power, we will also stratify our sample of women by parity and prior family planning use and will oversample older women who are more likely to be completing their fertility and who are not using family planning at the time of the baseline survey in order to be able to more easily detect treatment effects. Given our hypotheses of the impact of our intervention on our key outcomes, one-sided hypotheses tests will be conducted for all of our main analyses.

We have powered our study to detect effects in the following outcomes, i.e., 1) changes in contraceptive prevalence, and 2) preference-changing likelihood. In addition, we will also investigate the change in the uptake rate of a specific contraceptive tool in the data analysis stage (e.g., injectables).

Contraceptive Prevalence, Husband Interventions

Using modern contraceptive prevalence estimates for Lilongwe from the 2010 Malawi DHS, we expect a modern contraceptive prevalence rate of 50 percent among women aged 18 to 35 who are neither currently pregnant nor have given birth last 6 months at baseline. To infer a potential effect size for our intervention, we look to evidence from the Ashraf et al. study in Zambia, which found that the husband involvement intervention decreased the probability of seeking family planning services by roughly 19 percent over a two-year study period. Our study differs from Ashraf et al. study in that we do not force husbands to participate in the counseling procedure, but rather, offer women the option to invite their husbands. As a result, there might well exist a selection effect that the husbands that are present in the counseling sessions are those that are more supportive of women's family planning choices. Therefore, rather than leading to a decrease in the uptake rate of the family planning tools in the end, husband interventions in our study might well lead to an increase in the contraceptive prevalence rate. Assuming an attrition-adjusted sample of 700 women (400 women in "with husband invitations" arm and 300 women in "without husband invitations" arm) as described above, we will have 75.9 percent power to detect a 20 percent decrease in the modern contraceptive prevalence rate in the intervention arm from 50 percent to 60 percent ($\alpha = 0.05$).

Table 2 presents the levels of power $1 - \beta$ that will be achieved for various minimum effect sizes for modern contraceptive prevalence use (i.e. the difference in the modern contraceptive prevalence rate between the intervention and control arms at end line), assuming a baseline contraceptive prevalence rate of 50 percentage points in both intervention and control arms and a fixed end-line sample size of 700 women (400 in the "with-husband" intervention arm, and 300 in the "without-husband" arm).

Table 2: Power Calculations for Contraceptive Prevalence Rate, Husband Intervention

Power Calculations – Contraceptive Prevalence Rate					
Control CPR	Intervention CPR	Significance Level α	Control Sample Size	Intervention Sample Size	Power
50%	59%	0.05	300	400	0.6591
50%	60%	0.05	300	400	0.7509
50%	61%	0.05	300	400	0.8279
50%	62%	0.05	300	400	0.888

Preference-Changing Likelihood, Husband Interventions

Preference-changing likelihood is defined to be the proportions of women in the two groups who change their favorite type of contraceptive tools they would use after the counseling session. Since both groups have received identical counseling procedure on the contraceptive tools (either 5 or 15, balanced), I expect to see that women in the control group (without husband invitations) will only change their mind due to the information effect, i.e., the new information they obtain from counseling leads to the change in their stated preferences. As a note, it should not be the removal of access or financial barriers that cause their stated preferences to change because the pre-counseling survey extracts their preferences for family planning tools after assuming no financial or access constraints. Therefore, a deviation from the pre-counseling stated preference can only arise from the new information gained from the counseling.

Now our prior is that with husband interventions, the intervention group with husbands could have two potential impacts on women’s change of stated preferences: one in the direction of encouraging them to change their stated preferences by helping them better absorb the information through communication, and the other in the direction of discouraging them from changing their stated preferences by making women nervous and hence hide their real preferences. Women can choose whether to invite their husbands or not, so the husbands selected may vary in terms of their attitude towards family planning. Hence, we expect that husbands who are present are more likely to be supportive of women’s usage of contraceptive tools, which means the first channel should dominate in determining women’s deviation from their pre-counseling stated favorite tool. This means husbands being present facilitates the information-absorbing process during the counseling, and that the effective communication between husbands and wives will make women more likely to report a change in their preference (given that their initial preference is no). Assuming an attrition-adjusted sample of 700 women (400 women in “with husband invitations” arm and 300 women in “without husband invitations” arm) as described above, we will have 85.61 percent power to detect a 10 percentage points increase in the intervention arm from 20 percent to 30 percent ($\alpha = 0.05$).

Table 3 presents the levels of power $1 - \beta$ that will be achieved for various minimum effect sizes for preference-changing likelihood, assuming a baseline of 20 percentage points in both intervention and control arms and a fixed end line sample size of 700 women (400 in the “with-husband” intervention arm, and 300 in the “without-husband” arm).

Table 3: Power Calculations for Preference-Changing Likelihood, Husband Intervention

Power Calculations – Preference-Changing Likelihood					
Control	Intervention	Significance Level α	Control Sample Size	Intervention Sample Size	Power
20%	28%	0.05	300	400	0.6854
20%	29%	0.05	300	400	0.7805
20%	30%	0.05	300	400	0.8561
20%	31%	0.05	300	400	0.9114

Contraceptive Prevalence Rate, Limited Choice Set

Similar as the “Husband Intervention” above, we use the modern contraceptive prevalence estimates for Lilongwe from the 2010 Malawi DHS, and expect a modern contraceptive prevalence rate of 50 percent among women aged 18 to 35 who are neither currently pregnant nor have given birth last 6 months at baseline. Since there has not been much literature on how the amount of information delivered during the family planning counseling sessions would affect women’s choices, I will make some assumptions on the minimum detected size in Table 4 below. Assuming an attrition-adjusted sample of 700 women (400 women in “limited choice” arm and 300 women in “all choices” arm) as described above, we will have 75.09 percent power to detect a 20 percent increase in the modern contraceptive prevalence rate in the intervention arm from 50 percent to 60 percent ($\alpha = 0.05$).

Table 4 presents the levels of power $1 - \beta$ that will be achieved for various minimum effect sizes for modern contraceptive prevalence use (i.e. the difference in the modern contraceptive prevalence rate between the intervention and control arms at end line), assuming a baseline contraceptive prevalence rate of 50 percentage points in both intervention and control arms and a fixed end-line sample size of 700 women (400 in the “limited choice” intervention arm, and 300 in the “all choice” control arm).

Table 4: Power Calculations for Contraceptive Prevalence Rate, Limited Choices (Salience)

Power Calculations – Preference-Changing Likelihood					
Control	Intervention	Significance Level α	Control Sample Size	Intervention Sample Size	Power
50%	59%	0.05	300	400	0.6591
50%	60%	0.05	300	400	0.7509
50%	61%	0.05	300	400	0.8279
50%	62%	0.05	300	400	0.888

Preference-Changing Likelihood, Husband Interventions

Similar as above, preference-changing likelihood is defined to be the proportions of women in the two groups who report a change in their favorite type of contraceptive tools they would use after the counseling procedure. Assuming an attrition-adjusted sample of 700 women (400 women in “limited choice” arm and 300 women in “all choice” arm) as described above, we will have 85.61 percent power to detect a 10 percentage-point increase in the intervention arm from 20 percent to 30 percent ($\alpha = 0.05$).

Table 5 presents the levels of power $1 - \beta$ that will be achieved for various minimum effect sizes for preference-changing likelihood, assuming a baseline of 20 percentage points in both intervention and control arms and a fixed endline sample size of 700 women (400 in the “with-husband” intervention arm, and 300 in the “without-husband” arm).

Table 5: Power Calculations for Preference-Changing Likelihood, Limited Choices (Salience)

Power Calculations – Preference-Changing Likelihood					
Control	Intervention	Significance Level α	Control Sample Size	Intervention Sample Size	Power
20%	28%	0.05	300	400	0.6854
20%	29%	0.05	300	400	0.7805
20%	30%	0.05	300	400	0.8561
20%	31%	0.05	300	400	0.9114

SECTION T: 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

		*If YES, contact the IRB office for assistance.
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SECTION U: 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"/>	<p>Does this study involve collection of information from student school/university records?</p> <p>*If YES, refer to the following websites for guidance on FERPA:</p> <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 <p>If FERPA applies, you must complete the box below:</p>
<p>In accordance with FERPA, written consent must be obtained to access student records. The consent must:</p> <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)		<p>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.</p>

SECTION V: 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 W: 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 checked="" type="checkbox"/>	<input 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>
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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: May 6, 2019

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: May 6, 2019

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:
