

Incentives for Postnatal Care Demand  
NCT02936869

July 7, 2016



**Instructions:** The purpose of this research protocol is to provide IRB members and reviewers with sufficient information to conduct a substantive review. If a separate sponsor’s protocol exists, submit it in addition to this document.

Complete all of the sections below. For more detailed instructions, consult the Investigator’s Manual or IRB website (links provided below).

GENERAL INFORMATION	
<b>Protocol # (if assigned): IRB16 - 0923</b>	
<b>Version Date: 7/7/2016</b>	<b>Version Number: 1</b>
<b>Principal Investigator: Margaret McConnell, Ph.D.</b>	
<b>Protocol Title: Partnering with Traditional Birth Attendants (TBAs) to Increase Postnatal Care Demand in Nigeria</b>	

## 1. Specific Aims

- a) To determine perceptions of TBA involvement in postnatal care referrals among health care providers, TBAs, and mothers
- b) To define barriers and enablers of TBA involvement in postnatal care referrals
- c) To estimate the impact of performance-based monetary incentives to TBAs on postnatal care referrals of delivery clients
- d) To estimate heterogeneity in impact of performance-based monetary incentives to TBAs on postnatal care referrals of delivery clients

## 2. Background

### 2.1 Provide the scientific background and rationale for the study

The traditional birth attendant or TBA is a traditional, independent (of the health system), non-formally trained, and community-based provider of pregnancy-related care (WHO, 2004). TBAs often do not understand how to appropriately manage complications during child birth, so that mothers and neonates they care for are at higher risk of death from delivery complications relative to those cared for by skilled health workers (Itina, 1997). The World Health Organization recommends that the best role for the TBA is to serve as an advocate for skilled care (WHO, 2004). However, there are strong social norms of pregnant women patronizing the TBA for antenatal care and delivery services as TBAs are highly respected in their communities. The TBA is also paid for her services. Therefore, referring women to skilled health providers for antenatal and delivery care goes against the financial and social interests of the TBA. The pronouncement that TBAs are not part of the Nigerian health system has not changed patterns TBA patronage for antenatal and delivery care (Owens-Ibie, 2011).

In contrast to antenatal and delivery care, only 4 percent of Nigerian mothers receive postnatal care from a TBA indicating that there is potentially less competition between the TBA and skilled health workers after delivery for the high-risk mother (NPC and ICF International, 2014). Postnatal care within 48 hours of childbirth (early PNC) offers the opportunity for early detection of complications, prevention of mother to child transmission of HIV, and provision of other critical support, to reduce mortality risk. There is therefore the potential for partnerships with TBAs to be effective in increasing uptake of early PNC among Nigerian mothers, which in turn could reduce preventable mortality.

### 2.2 Describe the significance of the research, and how it will add to existing knowledge

There are few studies that explore the involvement of TBAs in referrals for postnatal care. There is also no experimental evidence on the effectiveness of performance-based incentives for TBA referrals in the postnatal period. We propose to conduct a mixed methods study on the engagement of TBAs for postnatal care demand-generation among their delivery clients (mother who are attended at delivery by the TBA). The qualitative study will involve focus group discussions with TBA delivery clients, TBAs, and skilled health workers, to clarify



perceptions about, barriers to, and enablers of TBA engagement in postnatal care referrals. Informed by a recently completed qualitative pilot study (there was no control group), we will also identify the causal impact of performance-based incentives in increasing postnatal care referrals by TBAs, via a randomized controlled trial (Oyebola, et al., 2014). The persistent high rates of non-facility births attended by TBAs across Africa imply that the findings of this study can broadly inform policy aimed at reducing preventable maternal and neonatal death on the continent.

### 3. Study Setting

#### 3.1. Identify the sites or locations where the research will be conducted.

The study will be conducted in approximately 67 purposively selected villages in South-Eastern Nigeria, in Ebonyi State. The intervention focuses on villages rather than health care facilities, as traditional birth attendants do not work from facilities and they are the focus of the intervention. We have not selected study villages at this point in the study and can add the full list as a modification – we need IRB approval to observe postnatal care to decide on villages with adequate facilities. We anticipate that at 1 facility per village, we will end up with at least 67 facilities. Some mothers will attend postnatal care in facilities outside their village as well though so that the full list of attended facilities cannot be obtained ex ante. It will be ascertained in the follow-up survey of delivery clients of traditional birth attendants.

The villages will be chosen such that:

1. there is a facility offering postnatal care within 1-hour walking distance of most households;
2. postnatal care practice in the facility involves routine visits within 24-72 hours, 7-14 days, and 42 days of delivery in line with national recommendations; and
3. the relationship between TBAs and health workers is sufficiently cordial to encourage partnership on postnatal care referrals.

A list of villages chosen for the study will be added as a modification.

#### 3.2. Describe the Principal Investigator’s experience conducting research at study site(s) and familiarity with local culture

The Principal investigator has worked on a number of health studies in similar contexts across Africa. These include “Financing the Delivery or Efficient, Effective, and Equitable Primary Health Care Systems in Africa” (PI: Peter Berman); “Do Financing and Fathers Lead to Better Birth Preparedness and Safer Motherhood? Proposal for a Randomized Controlled Trial in Nairobi, Kenya” (PI: Jessica Cohen); “Negotiating Delivery: Can Spousal Involvement Improve Maternal Health?” (PI: Jessica Cohen and Margaret McConnell, Funders: Lab for Economic Applications and Policy); “Identifying Barriers to Investments in Health: Making the transition from biofuel to gas cooking in Ghana” (PI: Margaret McConnell, Funder: Harvard Sustainability Science Program); “Behavioral Economics and Demand for Maternal Health Services: A Series of Experiments in Kenya” (PI: Jessica Cohen and Margaret McConnell).

#### 3.3. Is the research conducted outside the United States?

No  Yes: If yes; describe site-specific regulations or customs affecting the research, local scientific and ethical review structure

We are required to obtain ethical approval from the the Research and Ethics Committee, Federal Teaching Hospital Abakaliki, prior to commencing data collection. Local ethical approval will be attached to the Harvard IRB application when it is obtained, and will cover all local implementing partners and local research staff in this study.

- #### 3.4 Are there any permissions that have been or will be obtained from cooperating institutions, community leaders, or individuals, including approval of an IRB or research ethics committee?
- No  Yes: If yes; provide a list of the permissions (also include copies with the application, if available)



We will obtain permissions from the following prior to implementation, which will be uploaded via a modification:

- a) Community heads of participating villages for access to community spaces
- b) State office of National Primary Health Care Development Agency for access to health care facilities
- c) Health Research Ethics Committee of the University of Nigeria Teaching Hospital, Enugu State for ethical approval of the study

#### 4. Study Design

##### 4.1. Describe the study design type

We will conduct a mixed methods study on the engagement of TBAs for postnatal care demand-generation among their delivery clients. The qualitative study will involve focus group discussions with TBA delivery clients, TBAs, and skilled health workers, to clarify perceptions, barriers, and enablers of TBA engagement in postnatal care referrals for non-facility births. We will also conduct a randomized controlled trial to identify the causal impact of performance-based incentives in increasing postnatal care referrals of TBA delivery clients.

##### 4.2. Indicate the study's duration - and the estimated date of study completion

We anticipate that the study will extend from 14 July 2016 to 31 May 2017, over 10 months and 18 days.

##### 4.3. Indicate the total number of participants (if applicable, distinguish between the number of participants who are expected to be screened and enrolled, and the number of enrolled participants needed)

The qualitative study will recruit up to 10 TBA delivery clients, health workers, and traditional birth attendants each, aiming for a minimum of 6 participants in each category who consent and join the focus group discussions.

The randomized controlled trial will screen 200 traditional birth attendants in all and requires a minimum of 160 TBAs to consent and enroll into the study as justified in the power calculations below. The total TBA enrollment for the study will not exceed 200. We expect that TBAs will deliver an average of 5 clients per month. We intend to survey each of these clients. Thus, over the 5-month intervention period, the randomized controlled trial team will approach up to 5000 TBA delivery clients (200 \*5\*5).

##### 4.4. List inclusion criteria

###### Focus Group Discussions

S/No	Group	Inclusion Criteria
1	TBA delivery clients	Mother beyond 42 days after culmination of first pregnancy, who have thus had the opportunity to choose to attend postnatal care given current policy recommendations; resident in community; was delivered by a TBA; willing to participate in study; over 18 years of age
2	TBAs	Resident in community; TBA role (on-formally trained, independent of health system, provider of pregnancy-related care) confirmed by village head; willing to participate in study



3	Health Workers	Involved in postnatal care delivery within formal health care system, precisely direct patient care; works in same community; willing to participate in study
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Randomized Controlled Trial

TBAs will be identified as community-based providers of antenatal and/or delivery care, and who are non-formally trained. TBAs must be resident within the community, must not plan to relocate over the intervention duration, must be reachable via mobile phone, and will be identified in partnership with community leadership. They will be willing to participate fully in the study, including having their clients contacted to verify delivery details and postnatal care use.

All delivery clients of TBAs will be interviewed, that is women who gave birth assisted by TBAs (and reported by the TBA to the study team as described below).

We will conduct baseline surveys of facilities in potential villages in which the study will be conducted. These surveys will involve anonymized observations of random postnatal care visits to ascertain process quality of care received. Villages in which postnatal care is of adequate quality will be selected.

**4.5. List exclusion criteria**

Focus Group Discussions

S/No	Group	Exclusion Criteria
1	TBA delivery clients	First pregnancy before 42 days of culmination; unwilling to participate in study; was not delivered by TBA; under 18 years of age; non-resident in community
2	TBAs	TBA role not confirmed by village head; unwilling to participate in study; under 18 years of age
3	Health Workers	Not involved in postnatal care delivery; unwilling to participate in study; under 18 years of age

Randomized Controlled Trial

We will exclude TBAs that plan to relocate over the intervention duration, who cannot be contacted via mobile phone, and who are not confirmed by community leadership. We will also exclude TBAs that do not provide informed consent for the entire study protocol including agreeing to have their delivery clients contacted to verify deliveries.

**4.6. Describe study procedures**



### Focus Group Discussions

The study will involve approximately 60-minute group discussions with 6-10 TBA delivery clients, TBAs, and health care providers separately. The discussions will be scheduled at the participant's convenience and to hold prior to the start of the randomized controlled trial. These discussions will be moderated by a trained qualitative researcher in the local implementing partner organization, Health Policy Research Group, using semi-structured discussion guides. An audio recording of the discussions and hand-written notes will also be made by another member of the local study team. Following transcription of audio recording to Microsoft Word of the discussions, all recordings and participation sheets with identifiers will be destroyed. Data analysis will involve de-identified data. Quotes by respondents will be identified by labels as follows: gender, age, occupation, e.g. Female, 40 years, Midwife. Focus group discussions will be held in quiet, secluded community spaces pre-identified with the help of community leaders in the language preferred by the majority of discussants – English or Igbo language. The choice of location will depend on the community leadership and participant preferences. We will ask for secluded and quiet spaces in selected communities that are options for meeting places. We will then sample opinions among discussion participants for the option that is most convenient for majority of participants. We will also make photo and video records of brief (~2min) segments of the discussions for presentation purposes.

The focus group discussions will collect the following data:

- i. From TBA delivery clients:
  - Perceived need for postnatal care
  - Understanding of community postnatal care norms – provider, location, timing, content
  - Perceived barriers and enablers of postnatal care attendance
  - Perception of the TBA role across the continuum of maternal care – from the antenatal to postnatal period
  - Potential implications of both referrals and incentives for referrals on perception of TBA role
- ii. From TBAs:
  - Services provided in community – content, timing, client base
  - Motivation for service provision
  - Perception of service quality relative to formal health care providers
  - Relationship between TBAs and formal health care providers in community
  - Current participation in referrals across the continuum of maternal care
  - Perceived barriers and enablers to participation in referrals for postnatal care
  - Potential implications of incentives for referrals on program participation
- iii. From health care providers:
  - Perception of maternal and neonatal need for routine PNC
  - Understanding and practice of current PNC recommendations – timing, content, provider
  - Perception of TBA role across the continuum of maternal care
  - Relationship between TBA and health care providers in community
  - Perceived health worker factors that enable or act as barriers to TBA participation in identified roles

### Randomized Controlled Trial

The primary outcome for this study is the proportion of delivery clients each TBA successfully refers for postnatal care within 48 hours of delivery.

The team will conduct postnatal care observation surveys in potential study villages. We will select villages that meet the criteria outlined in Section 3.1.



At baseline, trained enumerators will interview TBAs and complete a survey over 60 minutes in a private location chosen by the TBA. The information collected will include demographic data, stated motivation for services, description of services provided, and social network of the TBAs. We will make photo recordings of these interactions (between TBAs and enumerators) for the purpose of presentation as described below.

All TBAs that participate in the study will receive the following:

- Information on the study aims (attached to submission), the need for postnatal care attendance, and verbal encouragement to refer delivery clients to postnatal care within 48 hours of childbirth
- Offer of two-weekly cumulative payouts of \$0.70 per reported delivery they take that is verified by client.
- Each TBA will be assigned an identification number (TBA ID) and randomized with 50-50 probability to the referral incentive or control arm.

TBAs randomized to the referral incentive arm will also receive an offer of two-weekly cumulative payouts of \$2.00 per successful referral of delivery clients to early postnatal care in a facility if it is verified by the client. Delivery clients are women who have given birth assisted by the TBA. Verification is described below.

Thus, the required follow-up surveys will be conducted every two-weeks, consisting of:

- Self-reported deliveries by TBAs obtained via SMS messages sent by TBAs to the study team. TBAs will be asked to send a text message after each delivery they oversee. TBAs will text the name and contact details (phone number and address) of clients delivered over the past two weeks. Two-weekly calls will also be made by the study team to the TBAs to ensure that all deliveries are reported. Data to be recorded includes TBA name as well as TBA delivery client name, phone number, and address.
- Calls to women who TBAs report they delivered (TBA delivery clients) – these calls will ascertain delivery by TBA, date of delivery, date and location of attendance of postnatal care (if attended), referral to postnatal care by TBA, incidence of delivery and postnatal complications. In these contexts, delivery of a child and where delivery occurs is often common knowledge. The TBA is often involved in the naming ceremony that holds soon after. The study team will nevertheless recruit TBAs who are willing to share this information and allow both TBAs and their clients to opt out of the study.
- For a random subset of mothers, we will back-check the facility attendance registers to confirm postnatal care attendance. We will attach approval for access to patient information as a modification.

The anticipated duration of the intervention is September 2016 to January 31, 2017.

As part condition for the receipt of one of the study grants (Women and Public Policy Program's Cultural Bridge Fellowship), the study coordinator will blog on field research activities related to both the focus group discussions and randomized controlled trials. These blogs will contain pictures of survey respondents or focus group participants, for which informed consent will be sought.

**4.7. Does the study involve the collection of data/specimens (including the use of existing data/specimens)?**

No  Yes: If yes; indicate how, when, where and from whom specimens or data will be obtained

**4.8. Is there a data and safety monitoring plan (required for greater than minimal risk studies)?**

No  Yes: If yes; describe the plan



**4.9. Are there any anticipated circumstances under which participants will be withdrawn from the research without their consent?**

No  Yes: If yes; describe the circumstances as well any associated procedures to ensure orderly termination

TBAs, TBA delivery clients, and health workers will not be withdrawn from the study without their consent.

**5. Data/Statistical Analyses Plan**

**5.1. Briefly describe the plan for data analysis (including the statistical method if applicable)**

Qualitative Data Analysis:

If carried out in Igbo, interviews will be translated to English language. All interviews will be transcribed verbatim in Microsoft Word, following which recordings will be destroyed. Transcription will ensure that grammar, sentence structure, pauses, and unfinished sentences are preserved as much as possible. Written notes will be expanded immediately after the discussions. For both written and recorded notes, we will label discussion inputs using pseudonyms as described above – all personal identifying information will be destroyed within one month of discussions. Finally, ahead of analysis, we will read each transcript and set of notes twice to ensure immersion within the dataset. Qualitative data will then be analyzed using thematic analysis to unearth themes salient in the group interviews. We will structure and depict these themes using thematic networks as described by (Attride-Stirling, 2001). The software for this analysis is NVivo.

Randomized Controlled Trial Data Analysis:

We aim to identify the intention-to-treat effect of incentives on the proportion of early PNC referrals of TBA delivery clients.

$$y_{ij} = \beta_0 + \beta_1 * T_j + X_{ij} + \varepsilon_{ij}$$

Where:

- $y_{ij}$  is the total proportion of referrals for TBA  $i$ , and village  $j$  of all her delivery clients;
- $T$  is a dummy variable indicating if the TBA is in the treatment arm;
- $X_{ij}$  is a set of baseline individual-level covariates;
- $\beta_1$  is the coefficient of interest and gives the average mean difference between the treatment and the control arms.

We will also identify interactions between incentives and baseline TBA characteristics (considered proxies for social preferences) in order to clarify pathways through which the intervention might have worked. I will specify a series of equations:

$$y_{ij} = \beta_0 + \beta_1 * T_j + \beta_2 * T_j * Var_{ij} + Var_{ij} + X_{ij} + \varepsilon_{ij}$$

Where:

- $Var_{ij}$  is a binary baseline characteristic for TBA  $i$  in village  $j$  previously included in  $X_{ij}$ ;
- $\beta_1$  is interpreted as the treatment effect when  $Var_{ij} = 0$ ;
- $\beta_2$  is the additional effect of  $Var_{ij}$

**5.2. Is there a sample size/power calculation?**

No  Yes: If yes; describe the calculation and the scientific rationale, and, if applicable, by site and key characteristics such as participant demographics

Qualitative Study Sample Size

The qualitative study does not require power calculations. However, the recommended size for focus group discussions is 6-12 participants (Kielman, Cataldo, & Seeley, 2012). We will thus recruit 10 participants in each group and aim to have at least 6 attendees in each group.



### Randomized Controlled Trial Sample Size

Power calculations for this study are based on a comparison of proportion of TBA referrals for early PNC between 2 equal-sized arms for  $H_0=0$  against alternative that it is not. Qualitative evidence of a similar intervention in Nigeria was associated with an average of 5 facility referrals per recruited TBA per month (Akpan & Lah, 2012). The crude birth rate in Ebonyi State is approximately 42 births per 1000 population annually (NPC and ICF International, 2014). If 70 percent of mothers deliver at home, then TBAs can potentially deliver up to 29 births per 1000 population in a year. Thus, a total of 68092 births in Ebonyi State are eligible for referrals in a year, given the state population of 2.4 million (FMOH, 2011). There is an average of 3 TBAs per village and 30 villages per LGA. Thus approximately 90 TBAs work in each of the 13 LGAs in Ebonyi state (1170 TBAs in total). At an average of 60 deliveries per year (68092/1170), there are approximately 5 deliveries per month to each TBA. We have powered the study to detect a difference in proportion of referrals of 0.20, that is 1 extra referral/TBA/month given 5 deliveries. Assuming standard deviation in proportion of referrals equivalent to study by (Rai, 2014) of 0.37 and alpha of 0.05, a minimum sample size of 160 TBAs can detect this effect at the 5 percent level with 90 percent power. With 200 TBAs, we can detect this effect size with over 90 percent power at the 5 percent level. Given an average of 5 TBA delivery clients per month and 5-month intervention period, we expect to enroll at the minimum 4000 TBA clients. With 200 TBAs, we may enroll up to 5000 TBA clients.

The randomized controlled trial study procedures, analysis, and other aspects of the protocol will be registered with the American Economic Association's Registry for randomized controlled trials (<https://www.socialscienceregistry.org/>) prior to baseline data collection.

## **6. Recruitment Methods**

### **6.1. Does the study involve the recruitment of participants?**

**No: If no, skip to 7.1**

**Yes: If yes; indicate how, when, where, and by whom participants will be recruited**

### Focus Group Discussions

The study team will approach community leaders that will identify TBAs who are eligible for the study and TBA delivery clients to join the study. We will aim to recruit up to 10 TBAs and delivery clients respectively. Health workers will be approached in health facilities within the same community. We will aim to recruit up to 10 health workers. Recruitment will be done by field enumerators in any of the villages in Ebonyi State, and will be conducted in July 2016.

Communities are organized differently in this context. There is often a naming ceremony held within the first week, to which everyone is invited, the TBA or nurse or midwife is lauded for successful delivery, people rub powder on their faces and give the mother gifts. Generally, delivery is celebrated like a wedding. Identifying TBAs who are eligible is akin to identifying women leaders - the community leader will help ensure that women who are not truly performing this function do not end up in our study. The write-up states we will identify TBA clients (without any comment on eligibility, which is something the study team needs to do in line with criteria above).

### Randomized Controlled Trial

The study team will purposively select 67 study villages from Ebonyi State, where the randomized controlled trial will be carried out. We will identify eligible TBAs via consultation with community leaders. These consultations will be led by field enumerators in July 2016. Health workers will be recruited from primary health care facilities in the study villages in South-Eastern Nigeria by the field work team. TBAs will provide consent to inform the study team of all delivery clients during the study, and these clients will be approached by the study team. Recruitment for the trial will commence in August 2016.



To study the outcome of postnatal care attendance, we need to know if clients delivered by TBAs attend postnatal care. We cannot know ahead of time which women will choose to deliver with the TBA versus the facility. Thus unless we could enumerate every single mother who might deliver with a TBA – which is beyond the study budget – we have to identify these clients ex post, after they have chosen to delivery with a TBA. As only the TBA can provide this information, we ask if she is willing to provide it at recruitment. If she is unwilling, she is allowed to drop out of the study. In contexts like this, given the public naming of children and celebration of childbirth, the following are often public knowledge - that a woman was pregnant, that she delivered, the approximate age of the child (and thus the date of delivery) and the address of the woman (or a landmark in lieu of her address). The piece of information that may be concerned private is the clients mobile number. TBA clients will be asked at first contact if they are willing to participate in the study and can drop out if they so desire.

**6.2. Are there any materials that will be used to recruit participants, e.g., emails, posters, and scripts?**

No  Yes: **If yes; provide a list of the materials (also include copies with the application)**

Focus Group Discussions

- Recruitment Script (Community Leader Meeting – Focus Group Discussion)
- Recruitment Script (TBA – Focus Group Discussion)
- Recruitment Script (Mother)
- Recruitment Script (Health Worker)

Randomized Controlled Trial

- Recruitment Script (Community Leader Meeting – Randomized Controlled Trial)
- Recruitment Script (TBA – Randomized Controlled Trial)
- Recruitment Script (Delivery Client)

**7. Available Resources**

**7.1. Describe the feasibility of recruiting the required number of participants within the recruitment period**

The team will spend June 2016 to August 2016 in Nigeria laying the groundwork for the study, that is obtaining the Harvard and local ethical review, obtaining permission from the state health facility board to meet with facility heads and use facility data, meeting with community leaders, selecting study sites in partnership with local leadership in communities and facilities, and hiring and training the study team. We will collaborate with Health Policy Research Group, University of Nigeria, which has extensive research and training experience in program evaluation within the study area, and will oversee the field research activities and administration of the intervention. Recruitment for the study will begin in July 2016 and we anticipate will continue until September 2016.

**7.2. Describe how the Principal Investigator will ensure that a sufficient amount of time will be devoted to conducting and completing the research**

A member of the study team is a doctoral student that has completed all other thesis papers, and will be focused on this project for the rest of her doctoral program, spending June 2016 to September 2016 in Nigeria and monitoring activities closely after that.

**7.3. Are there research staff members, in addition to the Principal Investigator?**

No: **If no, skip to 7.5**

Yes: **If yes; outline training plans to ensure that research staff members are adequately informed about the protocol and study-related duties**



### Harvard-based Study Partners

The Harvard research team assisted in the development of the research protocol and assigning study-related duties.

### Local Study Partners

Field work training will help to ensure that enumerators are trained to the same standards to minimize variation that may occur during the data collection exercise. While training focuses on thoroughly familiarizing enumerators with the questionnaire, it also asks that enumerators understand research ethics and how to create an atmosphere in the interview process that allows respondents to feel comfortable in answering sensitive questions. We will also teach enumerators how to emphasize the confidentiality of the interview and how to obtain the respondent's informed consent to participate in the study in a non-coercive manner. It will be the responsibility of the principal investigator and field work manager to train field work enumerators. The enumerators practice interviews will serve as pre-tests of both versions of the questionnaire – English and Igbo language. Debriefing sessions will capture feedback on translations. Training will occur over two days.

#### **7.4. Describe the minimum qualifications for each research role (e.g., RN, social worker) their experience in conducting research, and their knowledge of local study sites and culture**

##### A. Field Work Enumerator

#### Tasks

1. Participate fully in field work training
2. Assist field work manager and principal investigator in all activities related to the project – including data collection, pre-tests, study pilots, and participant enrollment
3. Travel to study districts and other duties as necessary

#### Job Requirements

1. Secondary school or higher education from a recognized school
2. Prior experience collecting survey data with study partner, Health Policy Research Group
3. Fluent in English and Igbo Languages
4. Comfortable communicating with key study stakeholders – mothers, traditional birth attendants, health workers, community leaders, and policy makers

##### B. Field Work Manager

#### Tasks

The person will report to and work with the principal investigator to perform a variety of tasks including but not limited to:

1. Supervise the implementation of field operations for the pre-test, pilot, and project, in South-Eastern Nigeria
2. Manage the team of field work enumerators in supporting field operations
3. Ensure compliance with ethical standards and data management procedures for the study
4. Manage systems and processes for tracking and monitoring survey activities and report to the principal investigator on a frequent basis
5. Lead focus group discussions
6. Work with principal investigator to train field work enumerators
7. Manage and appropriately document field team expenditure, supported by receipts
8. Store and safely keep all study equipment including android tablets and audio recording devices

#### Job Requirements

1. Master's degree in public health or related field
2. Full-time staff of the study partner, Health Policy Research Group
3. At least 3 years of experience in implementing field operations for multiple projects



4. Prior experience in the use of android devices for data collection, research compliance, and data security protocols
5. Familiarity with randomized controlled trials and focus group discussion methods
6. Excellent communication skills/ fluency in English
7. Fluency in reading, writing and speaking Igbo Language
8. Excellent management and organizational skills

C. Translator

Tasks

1. Attend an initial conceptualization and familiarization meeting, a synchronization meeting, and a pre-test meeting in connection with the survey and focus group discussion tool translation
2. Translate surveys and focus group discussion tools into Igbo language as used in day-to-day conversations

Job Requirements

1. At least 5 years of experience in Igbo translation
2. Preferably, a journalist working in a local translation

As translator will be hired by the local implementing partner. When the translator is hired, a locally approved version of the signed translation attestation form will be attached as a modification with the name of the translator.

**7.5. Briefly describe how the research facilities and equipment at the research site(s) support the protocol's aims, e.g., private rooms available for interviews, etc.**

Focus Group Discussions

Focus group discussions will hold in secluded, quiet locations identified in the community by the study team and community leadership

Randomized Controlled Trial

In-person surveys will be conducted in a convenient location decided by the respondent at recruitment.

**7.6. Are there provisions for medical and/or psychological support resources (e.g., in the event of incidental findings, research-related stress)?**

No  Yes: If yes; describe the provisions and their availability

In the event of research-related stress, study participants will be referred to the hospital affiliated with the local implementing partner (University of Nigeria Teaching Hospital) for counselling.

**8. Vulnerable Populations**

**8.1. Are there any potentially vulnerable populations (e.g., children, pregnant women, human fetuses, neonates, prisoners, elderly, economically disadvantaged, employees or students of the investigator or sponsor, undocumented, terminally ill, cognitively impaired or mentally ill, etc.)?**

No: If no, skip to 9.1

Yes: If yes; identify all vulnerable populations

The study may involve data collection from individuals who are unable to communicate in English language.

**8.2. Describe safeguards to protect their rights and welfare**



We will translate all data collection tools and consent forms into the local language (Igbo) so that participants understand the terms of participation and can fully engage in the study. Focus group discussions and interviewer-led surveys will be facilitated by study staff who can converse fluently in the local language, have collected data in this setting before, and who are trained to elicit consent appropriately irrespective of literacy. A signed translation attestation form will be attached to this application as a modification.

## 9. Consent Process

### 9.1. Will consent to participate be obtained?

No: If no, skip to 9.5

Yes: If yes; describe the setting, role of individuals involved, timeframe(s), and steps to minimize coercion/undue influence during the consent process (at the time of initial consent and throughout the study)

#### Focus Group Discussions

Informed consent will be obtained by field enumerators. Given the varying literacy level of the target population, the consent form will be delivered orally in the preferred language (English or Igbo language) and a signature will be asked for. The consent discussion will last about 20 minutes and be followed by an invitation to the venue for the focus group discussion at a later date. The field enumerators will be trained to avoid coercion during the consent process. Study staff will continue to ensure participants understand what the research is about and what their participation involves. There will be numerous opportunities during recruitment and obtaining informed consent for participants to opt out of the study. Any new information which might influence a participant's decision to continue participation will be provided to participants including re-consent.

Attached:

- Focus Group Discussion Consent Form – TBA delivery client
- Focus Group Discussion Consent Form - TBA
- Focus Group Discussion Consent Form – Health Worker

#### Randomized Controlled Trial

Informed consent will be obtained by field enumerators. In the case of TBA delivery clients, the consent form will be delivered orally in the preferred language (English or Igbo language). A signature will be asked for, for in-person interviews in the case of TBAs. The consent discussion will last about 20 minutes. Potential participants will be given the opportunity to opt out, postpone the decision about joining, consent and postpone the survey, or consent and partake in a survey. The field enumerators will be trained to avoid coercion during the consent process. Study staff will continue to ensure participants understand what the research is about and what their participation involves. There will be numerous opportunities during recruitment and obtaining informed consent for participants to opt out of the study. Any new information which might influence a participant's decision to continue participation will be provided to participants including re-consent.

Attached:

- Randomized Controlled Trial Consent Form – TBA
- Randomized Controlled Trial Consent Form – TBA Delivery Client (verbal consent only via phone)

We will provide each participant with the contact information of a local research team member to communicate their request to have results sent to them when available.

### 9.2. Are there any special populations?

No  Yes: If yes; describe the process to obtain consent, permission or assent



**9.3. Will consent of the participants be documented in writing?**

Yes  No: **If no; describe the rationale for requesting a waiver or alteration of documentation of consent (and/or parental permission)**

Consent will be collected verbally for TBA delivery clients in the RCT. In all other cases – TBA in FGDs, Health worker in FGDs, TBA delivery clients in FGDs, TBA in RCT – consent will be collected in person.

**9.4. Will participants be provided with a copy of their signed consent form or information sheet (when a consent form is not signed)?**

Yes  No: **If no; explain any extenuating circumstances that make it impossible or inappropriate to meet this requirement, i.e., doing so may place participants at increased risk, if inadvertently disclosed**

In all cases where consent is collected in writing, participants will be provided with a copy of their signed consent form. In one case, for TBA delivery clients in the RCT, consent will be elicited over the phone. In this case, participants will not receive a copy of their signed consent form unless they request it.

**9.5. Is a waiver or alteration of consent (and/or parental permission) being requested?**

No  Yes: **If yes; describe the rationale for the request. If the alteration is because of deception or incomplete disclosure, explain whether and how participants will be debriefed (include any debriefing materials with the application)**

Randomized Controlled Trial

The consent form for the TBAs will not include information on the referral incentive intervention. The intervention offers TBAs in the referral incentive arm an incentive for referring mothers to postnatal care in facilities. Informing TBAs in the control arm about this incentive during informed consent at baseline will have negative consequences, and the research cannot be practicably carried out without this alteration. TBAs in the control arm receive information on the need for postnatal care and an incentive for reporting each client they deliver (TBAs in the referral incentive arm receive what the control arm receives in addition). We will be unable to measure the pure effect of incentives and will instead capture the effect of receipt of incentives by referral incentive TBAs and anger or collusion by control TBAs in response to exclusion from receiving the referral incentive. We can thus not answer the research question intended. The information that will be elicited during the randomized controlled trial do not constitute more than minimal risk to subjects. This information is common knowledge in the community including TBA service patterns, demographic information, delivery client base etc.

Debriefing

All TBAs will be provided with additional information on the intervention when all follow-up survey data has been collected using the attached debriefing script. Each TBA will be approached in her home (which often doubles as the work place) within the community by one of the field enumerators. We will provide information on the incentive used in the study, the probability of selection into each study arm, and the opportunity to drop out of the study if so desired.

In addition, contact information of TBA delivery clients will be given by TBA to the study team prior to initial contact with delivery clients. This information will be collected via follow-up survey tools. This is akin to the receipt of contact information for TBA from community leaders prior to initial contact by study team from a cultural standpoint – the TBA is not a health worker. She is one community member with no training providing a service to another community member. Everyone knows her, and many women deliver with her. I could for example, collect this information from the community leader or women leader instead of the TBA – and they would probably know who had just delivered and potentially where.



To try and inform delivery clients ahead of time of the possibility of their contact information being shared and being contacted by the research team for recruitment into the study, we can hold a village meeting in every village we do the study in and inform everyone about the study. We cannot know every woman who will visit a TBA ahead of time, she may come from a village in which we have no selected TBA, but this would ensure we've tried to inform as many possible participants ahead of time.

We cannot anticipate which women will visit the TBA (rather than the clinic) ex-ante and obtain informed consent beforehand. Constraints in study funding also prevent the enrollment of all pregnant women in every study village at baseline. Nevertheless, the receipt of services from the TBA by clients is often common knowledge in these communities (see below) so that this information is unlikely to constitute more than minimal risk to clients. Delivery clients will be given the opportunity to opt out of the study at multiple points – enrollment, during elicitation of consent, during the follow-up survey, and after the survey. When informed consent is elicited by study enumerators, delivery clients will be intimated on how their contact information was obtained – that is they will be informed explicitly that the study team is contacting them based on patronage of a TBA who gave the team their contact information.

The ceremony surrounding the birth of a child in these contexts implies the community knows the woman was pregnant, has delivered a baby, was delivered by a TBA (who is often involved in the naming ceremony and sometimes gives the child one of her/his names), and where she lives (because they all come for the ceremony – anyone who hears can stop by and eat food/bring a gift etc.). The phone # is the one piece of information that may be private (primarily because that is not typically how people contact each other). We will allow both her TBA and herself to opt out if they consider this an invasion of privacy.

## 10. Risks

### 10.1. Are there any reasonably foreseeable risks, discomforts, and inconveniences to participants and/or groups/communities?

No  Yes: If yes; indicate probability, magnitude, and duration of each (note that risks may be physical, psychological, social, legal, and/or economic)

Foreseeable Risks and Mitigation – Focus Group Discussion

Foreseeable Risks and Mitigation – Randomized Controlled Trial



#	Identified risk	Description	Risk mitigation
1.	Loss of time for conduct of antenatal or delivery care may be a discomfort for TBAs.	This is likely to occur for all TBAs for the entire duration of the study.	The activities involved in participation will be clearly identified and the estimated time commitment provided so that potential participants can make an informed decision.
2.	TBAs may fear that research projects will tend to conclude that their services are undesirable as has been the case in the past and may not want to participate in research that furthers such conclusions.	This is unlikely to occur given the study design that focuses on TBA inclusion in formal care via the creation of a new role.	This research project has been designed to create an alternative long-term role for the TBA that has hitherto been excluded from Nigerian health systems; TBAs will be honestly informed about the purpose of research to increase postnatal care use in facilities.
3.	Some of the survey questions may be considered private such as income from services, causing discomfort.	Similar survey questions such as the World Bank Living Standards Measurement Study Survey have not been accompanied by discomfort. Thus we do not expect that this will occur with high probability. There will be a 60 minute baseline survey, and two-weekly 15-minute surveys throughout the study duration.	The information collected using the surveys is justified by the study rationale - to define the TBA for whom the intervention works so that the study findings are easy to translate to policy; The study data management plan will minimize the risk of compromise of information security; All study participants will be informed of their right to withdraw from the study if they find any of the procedures uncomfortable.
4.	Participants may be concerned about the use of information they provide.	The information elicited is common knowledge in the community and should not cause concern among TBAs. There is a low likelihood of this risk occurring.	Informed consent will include a clear description of the intended uses of study information and protections of identity of members; Individuals will be offered the opportunity to speak with investigators in private about data use concerns.
5.	Under-reporting of deliveries and postnatal care attendance by TBA clients (mothers they deliver) may be a source of psychological stress for the TBA, and of tensions in the relationship between the TBA and client	The TBA depends on delivery clients for future streams of income so we do not anticipate that the introduction of incentives for referrals will interrupt future relations between the TBA and her client. There is however a low risk of misreporting by clients. Given the status of TBAs in communities as trusted and respected providers of community care, there is very little incentive for mothers to fail to report delivery or postnatal care referrals.	We will be able to resolve misreporting using facility postnatal care registers, so that TBAs can be remunerated for their efforts if they notice disparities.



#	Identified risk	Description	Risk mitigation
1.	Loss of time due to study participation may be a discomfort for respondents.	This is likely to occur for all participants.	The activities involved in participation will be clearly identified and the estimated time commitment provided so that potential participants can make an informed decision.
2.	TBAs may fear that research projects will tend to conclude that their services are undesirable as has been the case in the past and may not want to participate in research that furthers such conclusions.	This is unlikely to occur given the study design that focuses on TBA inclusion in formal care via the creation of a new role.	This research project has been designed to create an alternative long-term role for the TBA that has hitherto been excluded from Nigerian health systems; TBAs will be honestly informed about the purpose of research to increase postnatal care use in facilities.
3.	Some of the survey questions may be considered private such as income from services, causing discomfort.	Similar survey questions such as the World Bank Living Standards Measurement Study Survey have not been accompanied by discomfort. Thus we do not expect that this will occur with high probability.	The information collected using the surveys is justified by the study rationale; The study data management plan will minimize the risk of compromise of information security; All study participants will be informed of their right to withdraw from the study if they find any of the procedures uncomfortable.
4.	Participants may be concerned about the use of information they provide.	The information elicited is largely common knowledge in the community and should not cause concern. There is a low likelihood of this risk occurring.	Informed consent will include a clear description of the intended uses of study information and protections of identity of members; Individuals will be offered the opportunity to speak with investigators in private about data use concerns.
5.	Under-reporting of deliveries and postnatal care attendance by TBA clients (mothers they deliver) may be a source of psychological stress for the TBA, and of tensions in the relationship between the TBA and client	There is a low risk of misreporting by clients. Given the status of TBAs in communities as trusted and respected providers of community care, there is very little incentive for mothers to fail to report delivery or postnatal care referrals.	We will be able to resolve misreporting using facility postnatal care registers, so that TBAs can be remunerated for their efforts if they notice disparities and we verify their claims. There is little incentive for mothers to under-report care received.
6.	Clients may be concerned that TBAs will provide contact information of delivery clients to the study team to ascertain the study outcome - the incidence of postnatal care referrals.	This is the basis for potential inclusion of clients. In this context, the following are often public knowledge in the community - that a client is pregnant, that she has delivered a child, that she delivered with a TBA, the approximate date of delivery, and her address. A contact phone number might however not be public knowledge and a cause of concern.	We will select TBAs whose relationship with their clients allows them to share this information with the study team. Both TBAs and delivery clients will be allowed to opt out of the study at any point if privacy is a concern, and their information will not be used if they do, nor will they face any penalty for dropping out.

**10.2. Identify whether any of the information collected, if it were to be disclosed outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant’s financial standing, employability or reputation.**

No, we anticipate that information collected is largely common knowledge within these communities related to maternal delivery service choices and the livelihoods of traditional birth attendants.

As the TBA does not have an employer per se (she is a woman who in her home or her church delivers women), she has no formal training and no supervisor. She is often mentored by another TBA who does not owe her a salary and to whom she does not pay a salary. Her services are many times unremunerated. She is given payment or gifts depending on the ability of her clients.

**10.3. Outline provisions in place to minimize risk**

See within charts above.

**11. Benefits**

**11.1. Describe potential benefits of study participation (indicate if there is no direct benefit)**

There is no direct individual benefit to participation in the focus group discussion.



### Randomized Controlled Trial

Should the intervention prove to encourage TBAs to refer women they deliver to postnatal care, delivery clients of TBAs in the experimental arm may be more likely to seek postnatal care and receive the attendant health benefits.

#### **11.2. Describe potential benefits of the research to the local community and/or society**

Mothers who give birth outside facilities and without skilled attendance have a higher risk of death. Increasing the use of postnatal care can prevent fatal complications in both mothers and their newborns. The widespread involvement of unskilled traditional birth attendants in deliveries across Africa mean the study findings have implications for maternal and neonatal mortality reduction on the continent.

### **12. Reportable Events**

#### **12.1. Outline plans for communicating reportable events (e.g., adverse events, unanticipated problems involving risks to participants or others, breach of confidentiality)**

All reportable events will be reported to the HLMA IRB within 5 days of the PI becoming aware of the situation as per OHRA policy.

### **13. Research Related Injuries (this section must be completed for any greater than minimal risk research)**

#### **13.1 Are there provisions for medical care and compensation for research-related injuries?**

No  Yes: If yes; outline these provisions (Please note that although Harvard's policy is not to provide compensation for physical injuries that result from study participation, medical treatment should be available including first aid, emergency treatment and follow-up care as needed. If the research plan deviates from this policy, provide appropriate justification.)

### **14. Participant Privacy**

#### **14.1. Describe provisions to protect participants' privacy (their desire to control access of others to themselves, e.g., the use of a private interview room) and to minimize any sense of intrusiveness that may be caused by study questions or procedures**

Group and individual interviews will be conducted in a private place, at the participant's convenience.

In the randomized controlled trial, we will ask TBAs to give us the names, addresses, and phone numbers of clients they deliver on a two-weekly basis. Follow-up calls to these clients will involve eliciting consent for inclusion in the study and ascertaining that delivery and referral by the TBA occurred. That is, we obtain information on the primary outcome of the study through follow-up surveys with TBA clients. Self-reports by TBAs given the incentives offered are likely to be unreliable.

The procedure of informed consent will be non-coercive and conducted in the language of choice for both the TBA and her clients. In these settings, it is not generally private information that a woman was pregnant, where she lives, and that she has delivered, and where she delivered. However, we will allow both the TBA and her clients to opt out of the study at any point that they consider the study procedures intrusive. The TBA and her clients will be informed of this provision. As long as drop-out of the study is non-differential across arms and is not in high proportions, this will not affect our ability to estimate effects.

### **15. Data Confidentiality**

#### **15.1. Will the information that is obtained be recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants?**

No: If no, skip to **16.1**



**Yes: If yes; either state that participants will be told that their data will be public or describe provisions to maintain the confidentiality of identifiable data, e.g., use of password protections (please refer to the Harvard Research Data Security Policy (HRDSP), at <http://vpr.harvard.edu/pages/harvard-research-data-security-policy>, for additional information about required data security measures) [NOTE: The HRDSP does not always apply if data are not being stored at Harvard facilities. Please consult the HRDSP for additional information.]**

Data is classified as Level 3, that individually identifiable information which if disclosed could reasonably be expected to be damaging to reputation or to cause legal liability.

### Focus Group Discussions

1. Responses will not be shared outside of the research team
2. During data analysis, names of participants will be replaced with an ID code, and the key linking names and ID codes will be kept in a secure location- stored in encrypted and password-protected electronic files in locked cabinets in locked offices.
3. Data will be stored in encrypted and password-protected electronic files; paper data and audio or videotapes (indicated in section on study procedures) in locked cabinets in locked offices.
4. We will destroy audio recordings of focus group discussions after transcription and not more than one month after recording
5. Names will not be used to identify participants in publications

### Randomized Controlled Trial

Confidentiality throughout the trial is maintained according to the Harvard University Information Security Policy by:

1. Password characteristics:
  - Strong passwords – Passwords must be of sufficient length and complexity to reasonably protect them from being guessed by humans or computers
  - No shared passwords – Passwords to devices used for data collection and other access credentials will not be shared
  - Protect passwords – All passwords must be protected
  - Compromised passwords – Passwords must be changed immediately if there is suspicion of compromise
2. Devices
  - Configuring devices - All devices used for collection, storage, and transportation of information will be configured for secure operation, limiting access to authorized persons
  - Loss and disposal of devices – The information on the device must be protected against access if the device is lost, disposed of, or stolen. Loss, theft, or improper use of a device storing confidential information will be reported promptly.
3. Information sharing
  - Accessing confidential information – Confidential information must only be accessed for authorized purposes
  - Sharing confidential information – Confidential information must only be shared with those authorized to receive it



**15.2. Describe i) whether data will be transmitted, and if so how; ii) how long it will be stored; and iii) plans for the data at the end of the storage period (how will it be destroyed, or will it be returned to data provider)**

All audio recordings from focus group discussions and participant sheets, following transcription within a month of discussion will be destroyed. Respondents will be identified using gender + age + occupation labels.

Data collected by field enumerators offline on the field during surveys will be uploaded in the partner office, Health Policy Research Group, to a secure server at the end of each work day. Android devices are stored by the field work manager, locked cabinets in locked offices. Following the intervention in January 2017, data will be de-identified prior to analysis. During data analysis, names of participants will be replaced with an ID code, and the key linking names and ID codes will be kept in a secure location - in encrypted and password-protected electronic files - accessible only to the Harvard study team.

**15.3. Indicate how research team members and/or other collaborators are permitted access to information about study participants**

Field enumerators will only have access to data when during collection. Only the Harvard study team will have access to the entire study data.

The field work manager requires access to identifiable information about traditional birth attendants to implement the intervention – providing rewards for postnatal care referrals. Thus traditional birth attendants will inform the study team on a two-weekly basis of deliveries taken. Follow-up of these clients to ascertain postnatal care referrals will form the basis for determining rewards.

**15.4. If future use of data, data sharing, i.e., required of NIH-funded studies using/generating large-scale human genomic data, or future open access, i.e., free availability and unrestricted use, of data is planned or likely, indicate how data will be shared/released.**

No directly identifiable information will be made available to anyone other than the PI and Harvard faculty collaborators. Data in which names of participants will be replaced with an ID code may be shared with other collaborators as permitted in the consent form.

**16. Costs and Payments**

**16.1. Identify any costs that participants may incur during the study, including transportation costs, childcare, or other out-of-pocket expenses**

Randomized Controlled Trial

The TBA is expected to encourage her delivery clients to take up postnatal care. The means through which she does this is at her discretion and will not be manipulated by the study team. However, these means might include phone calls, text messages to clients, visiting clients at home to encourage postnatal care attendance, or escorting clients to the clinic for postnatal care. The TBA thus incurs opportunity cost (fees for services) of not attending to delivery or antenatal clients if she escorts women to the facility for postnatal care or visits them at home to encourage them to come. She also spends her own resources on phone calls and text messages.

**16.2. Is there any payment or reimbursement that participants may receive during the study?**

No  Yes: If yes; specify the amount, method and timing of disbursement. (Please refer to Harvard University Financial Policy on Human Subject Payments at <http://policies.fad.harvard.edu/pages/human-subject-payments>)



### Focus Group Discussions

Participants in the focus group discussions will receive a stipend of 2000 Naira (\$7) for participation in the discussion.

### Randomized Controlled Trial

Traditional birth attendants recruited into the randomized controlled trial will receive a two-weekly phone credit transfer for notification of delivery clients, at a rate of 200 Naira (\$0.70) per verified delivery client. Traditional birth attendants in the referral incentive arm will in addition receive 600 Naira (\$2) for verified postnatal care referrals.

The compensation that TBAs receive for their services is highly variable, often depends on the ability of the client to pay, and may be given in-kind (rather than as cash) (Itina, 1997). The amount of compensation used in this study is informed by Nigerian pilots that did not include control groups but were well-received by TBAs (Akpan & Lah, 2012) (Oyebola, Muhammad, Otonomeruke, & Galadima, 2014). Delivery by the TBA is associated with a higher risk of death for both mother and newborn. The expectation is that the incentive is well-received and leads to a higher number of referrals to postnatal care for mothers and newborns, who would otherwise not receive skilled care around childbirth. As compensation is restricted to referrals of clients, we aim to reduce risk of death among mothers who choose to receive attendance from the TBA at birth, despite the associated dangers.

## **17. Multi-site Study Management**

### **17.1. Is this a multi-site study?**

**No**  **Yes: If yes; describe plans for communication among sites regarding adverse events, interim results, protocol modifications, monitoring of data, etc.**

## **18. Investigational Drug/Biologic/Device**

### **18.1. Does this study involve an Investigational Drug/Biologic/Device?**

**No: If no; skip to 19.1**  
 **Yes: If yes; identify and describe the drug/biologic/device (e.g., marketing status: Is there an IND/IDE, classification of a device as significant vs. non-significant risk)**

**18.2. Describe its administration or use**

**18.3. Compare the research drug/biologic/device to the local standard of care**

**18.4. Describe plans for receiving, storage, dispensing and return (to ensure that they will be used only for participants and only by authorized investigators)**

**18.5. If proven beneficial, describe anticipated availability and cost to participants post-study; plans (if applicable) to make available**

## **19. HIPAA Privacy Protections**

**19.1. Are HIPAA privacy protections required? Please note that only Harvard University Health Services and Harvard School of Dental Medicine are covered entities at Harvard. Harvard is otherwise not a HIPAA covered entity. If, however, data is derived from a Covered Entity (e.g. a hospital or community health center), mark 'yes' and address the items below.**

**No: If no; skip to 20.1**  
 **Yes: If yes; include at least one of the following:**



**Describe plans for obtaining authorization to access protected health information**

**Provide the rationale for a waiver of authorization or limited waiver of authorization request**

## **20. Data and Specimen Banking**

### **20.1. Does the study include Data and Specimen Banking?**

**No: If no; skip to 21.1**

**Yes: If yes; identify what will be collected and stored, and what information will be associated with the specimens**

### **20.2. Describe where and how long the data/specimens will be stored and whether participants' permission will be obtained to use the data/specimens in other future research projects**

### **20.3. Identify who may access data/specimens and how**

### **20.4. Will specimens and/or data be sent to research collaborators outside of Harvard?**

**No**  **Yes: If yes; describe the plan**

### **20.5. Will specimens and/or data be received from collaborators outside of Harvard?**

**No**  **Yes: If yes; describe the plan**

## **21. Sharing Study Results**

### **21.1. Is there a plan to share study results with individual participants?**

**No**  **Yes: If yes; describe the plan**

We will provide each participant with the contact information of a local research team member to communicate their request to have results sent to them when available.

### **21.2. Is there a plan to disseminate aggregate results to the community where the research is conducted?**

**No**  **Yes: If yes; describe the plan**

In August 2016, we will present preliminary results from the qualitative study to the research and policy community in South-Eastern Nigeria, in collaboration with Health Policy Research Group. At the study conclusion, in April 2017, we will again present results to the research and policy community in South-Eastern Nigeria. We will also prepare a manuscript for a peer-reviewed publication in May 2017.

In the event that the study team shares educational resources with the TBA delivery clients (or extra information on postnatal care with the TBAs), we will submit these materials as a modification prior to implementation.

## **22. Regulatory Compliance**

### **22.1. Describe plan for monitoring regulatory compliance, in order to ensure proper record keeping and retention of required regulatory documents**

To ensure compliance with regulations, the principal investigator will:

1. Conduct one-monthly and ad-hoc reviews of study documents and participant files as needed to monitor compliance with IRB policies and procedures
2. Respond to complaints and non-compliance to identify areas for improvement
3. Provide training for field work staff to ensure familiarity with study protocol and regulatory requirements



4. Examine executed informed consent forms and on select days, observe the informed consent process
5. Report to IRB serious or continuing non-compliance
6. Ensure that changes to protocol are approved by IRB
7. Ensure accurate compliance records are kept and stored for up to 7 years following the completion of the study.

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