Utilizing All Health System Contacts to Offer Postpartum Family Planning (PPFP) to Pregnant Women and Women within Twelve Months Postpartum in Ethiopia

Study Protocol

Jhpiego

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JHSPH IRB Research Plan for New Data Collection

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Study Title:	Utilizing All Health System Contacts to Offer Postpartum Family Planning (PPFP) to Pregnant Women and Women within Twelve Months Postpartum in Ethiopia
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I. Aims of the Study: Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

The objectives and sub-objectives of this study are to:

1) Assess the effect of contacts that women/couples have with the health system (from the *kebele* [sub-district] level to the health facility level and back), into which postpartum family planning (PPFP) messages are systematically integrated, on uptake of PPFP through 12 months postpartum in Ethiopia. These health contacts span several levels: at health facilities from trained health professionals, and at community settings from Health Extension Workers (HEWs) and Health Development Army (HDA), a cadre of community volunteers.
    a. Assess the extent and type of existing contacts that women/couples have with the health system during pregnancy, birth, and in the postpartum period and the degree to which they receive PPFP messages during these health contacts.
    b. Assess the relationship between frequency and type of contact to uptake of PPFP and recommended child feeding and immunization practices (estimate the dose-response effect of each additional health contact).
2) Estimate the added effect of a community-based intervention (i.e. beyond the health center) to promote PPFP messaging at antenatal and postpartum contact points by community health workers (HEWs, HDA) on uptake of postpartum family planning through twelve months postpartum in two clusters of health center and health posts, , as compared to health center-only PPFP counseling and services in two comparison clusters.
    a. Measure "baseline" PPFP uptake through recall of women with prior birth history and their PPFP use after those recall births (sub-sample of women with prior birth history)
    b. Prospectively assess uptake of PPFP among postpartum women by type of health contact, timing postpartum, and contraceptive method
3) Explore acceptability and feasibility among HC providers and health extension workers of using record keeping and review processes to track women's decision-making and contraceptive use from pregnancy through to 12 months postpartum,
    a. Test provider/health extension worker (HEW)/health development army (HDA) use of health record keeping systems as a tool for identifying women who need additional PPFP counseling (prenatal).
    b. Test use of a monthly data review process to combine HEW and HDA health records of pregnant and recently delivered women and their babies to ensure maximum coverage of critical health practices including antenatal care (ANC), postnatal care (PNC) home visits, PPFP uptake, immunization, infant feeding, etc.
4) Explore factors influencing women's/couples' adoption of PPFP during the first twelve months postpartum.

In both intervention and comparison sites, the study will implement the current Government of Ethiopia policy and standard of care concerning systematic integration of PPFP messages and services within antenatal care, labor and

delivery, postnatal care as well as a new proposed targeting of women bringing infants for immunization services with PPFP messages and referrals.

II. Background and Rationale: Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

Inter-pregnancy intervals of less than 24 months are associated with higher rates of newborn and child mortality, as well as higher probability of pre-term and low birth weight newborns, and malnutrition and stunting among children under five (Kozuki et al, 2013; Cleland 2012). An MCHIP secondary analysis of the 2011 Ethiopia DHS (MCHIP 2013) revealed that among all non-first births, 47% of pregnancies occur at less than the 24 month inter-pregnancy interval (13% of women are pregnant before the end of the first year postpartum). Looking at prospective unmet need (defined as whether women would like another child within the next two years), among Ethiopian women 0-2 years postpartum (*n* = 4,453), 94% of women did not wish another pregnancy at the time of the survey yet only 19% used a modern method of contraception, resulting in a prospective unmet need among postpartum women of 74%. This compares to an unmet need of 34% among postpartum women using the standard DHS method of calculating unmet need which uses a question about the desire for the recently born child for the subset of postpartum women in the total sample (Moore et al, 2015).

Exclusive or predominant breastfeeding offers protection against rapid fertility return during the first 6 months after childbirth; however, rates of exclusive and predominant breastfeeding drop off rapidly in Ethiopia starting in the second month of life. While 70% of newborns (0-1 month) are exclusively breastfed, only 32% of infants 4-5 months old are exclusively breastfed. Only 4% of children 6-23 months are fed appropriately based on infant and young child nutrition (IYCN) recommendations and 44% of children less than 5 years of age are stunted (DHS 2011).

Women in Ethiopia do not access formal health services as frequently as they should. Only 43% access any antenatal care services and 19% are seen for at least 4 ANC visits during pregnancy, with wide differences between urban and rural women. The majority of births (89.5%) still occur at home, are not attended (3.8%) or attended by a traditional birth attendant (TBA) (28.4%) or relative (56.6%). Only 6.7% of mothers and babies had a postnatal check within two days of birth. Vaccination coverage is higher with BCG at 79.6%, DPT-HepB-Hib1 at 80.0%, DPT-HepB-Hib3 at 65.7%, OPV1 at 90.1%, OPV3 at 70.5%, and measles at 68.2% (Ethiopia NICS 2012), though it falls short of international recommendations of country coverage of over 90%.

Globally, prior efforts to integrate family planning and MNCH including immunization either failed to record the impact of integration on MNCH or immunization coverage indicators or did not find any benefit of integration on improving immunization coverage. Ethiopia offers an opportunity to improve both MNCH/immunization rates and postpartum family planning use since these indicators, while trending upwards, still have room to improve. According to key informant interviews conducted in Ethiopia, challenges for PPFP include tracking use of contraception postpartum, limited availability of high-quality PPFP materials for clients, and difficulty in reaching the 90% of women who do not deliver at a health facility, highlighting the importance of health extension workers in visiting postpartum women in their homes (Sonalkar, Mody, Phillips, & Gaffield, 2013). These findings support a focus on improving tracking for uptake of PPFP, development of SBCC materials and messages, and implication of community-based resources like the HEWs.

MCHIP's work in Ethiopia expanded choices of contraceptive methods in the postpartum by supporting the Government of Ethiopia to introduce postpartum IUDs during facility births in selected facilities. Currently, Jhpiego MCSP is planning to support the Government in strengthening and potentially expanding this intervention with USAID field support funds. Yet facility-based PPFP counseling and services will only reach a small proportion of pregnant and postpartum women who need advice and services. To reach women and their families in their communities, the Ethiopian Government has

established the highly functional health extension program, involving formally recognized and government-paid Health Extension Workers (HEWs) at the *kebele* level, supported by community volunteers called the Health Development Army. The HEWs deliver a package of mostly preventive health interventions, including vaccines and a range of contraceptives that includes implants, along with selective curative interventions targeting newborns and young children (see http://www.moh.gov.et/hsep). Prior work on exploring acceptability of integrating family planning and immunization in multiple countries found that providers and clients did not have any concerns about linking these services (Ryman et al, 2012).

The Ethiopian health system envisages that a number of health contacts should occur for women and babies from pregnancy through to the extended postpartum. Figure 1 below illustrates these contacts.

Figure 1: Possible Contacts with the Health System for Pregnant Women in Ethiopia

Month	4	5	6	7	8	9		1	2	3	4	5	6
Client	**Pregnancy**						**Birth**	**Postpartum Period**					
HDA	x	x	x	x	x	X	Home	X	x	x	x	x	x
HEW	Quarterly visits: 2-3 times during last two trimesters of pregnancy							Quarterly visits: 2-3 times during first 12 months postpartum					
HC	ANC1 Before end of 4th month		ANC2 24-28 weeks		ANC3 32 weeks	ANC4 36 weeks	Facility	PNC w/in 48 hours; w/in 6 weeks					
									DPT1 6 weeks	DPT2 10-14 weeks		DPT3 14-22 weeks	

About 84% infants receive at least one dose and more than 60% receive two doses of basic vaccines. A substantial number of mothers also seek care for their child's fever, diarrhea and other illness from health providers. This study will take these contact occasions as opportunities for promoting PPFP, but also to reinforce the need to fully vaccinate children.

III. Study Design

A. Provide an overview of your study design and methods. The study design must relate to your stated aims/objectives. Details will be requested later. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).

This implementation research will use a quasi-experimental mixed method design with two arms. The intervention arm will have integrated PPFP messages at each level of health system contacts. The control arm will continue to deliver the existing FP services at primary health care centers only.

The primary study population is a cohort of pregnant women, enrolled between the 2nd and 3rd trimester of pregnancy in both arms, who will be followed to twelve months post-partum. We will interview the women at study enrollment and at the end of the study. We will track women's contacts with the health system, particularly regarding PPFP counseling, decision making and contraceptive adoption, through chart reviews of routinely collected facility and community based health records and registers (e.g. family folders that may be modified for study).

Prior to study implementation, we will conduct a readiness assessment of selected health facilities in both study arms to ensure that the supplies, equipment and commodities are available for PPFP counseling and service delivery capacity in all health centers. Gaps in PPFP service delivery will be addressed in both intervention and control study sites. Health center maternity staff will be trained in PPFP (PPFP counseling, postpartum IUD and implant provision, etc.) in accordance with current Government of Ethiopia PPFP expansion strategies. The rapid assessment will provide an understanding of service delivery capacity and needs and allow MCSP to ensure the same services and equipment are available in all sites.

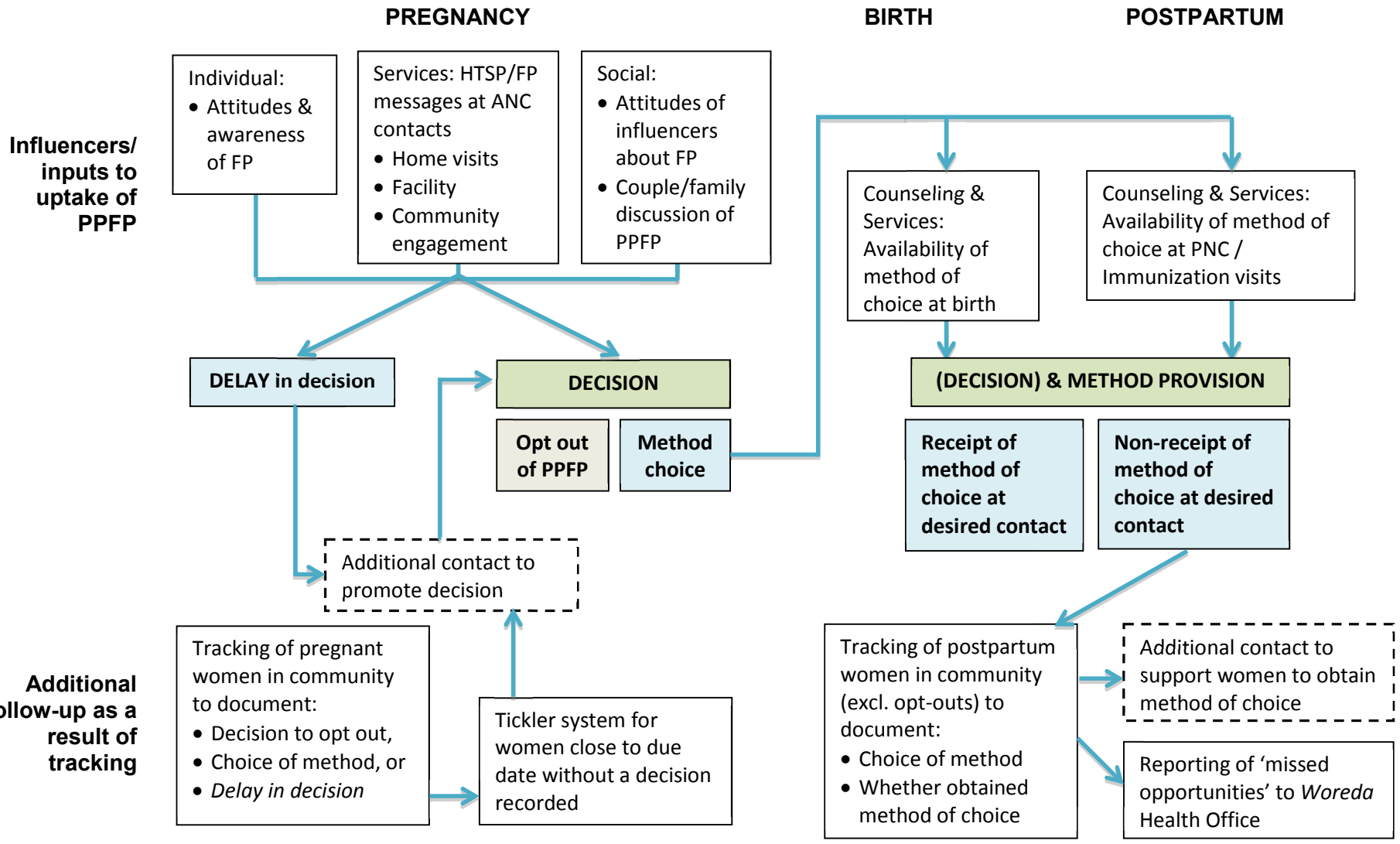
In intervention sites, both facility-based providers at primary health center and health post levels, including HEW and HDAs, will receive training on PPFP counseling and use of adapted health records. Should HEW require refresher training in implant provision or other methods, the study will also provide this.

In addition, we will conduct a rapid formative assessment to understand the health system and cultural contexts of PPFP needs during the preparatory phase of intervention implementation. This formative study will include household members of pregnant women, community health workers (HDAs), and facility-based providers, including HEWs, and managers. This rapid assessment will support the design of the intervention at the community level which will include designing and training HEWs to communicate PPFP messages as part of a bundle of messages that promotes high impact maternal, newborn, and child health (MNCH) practices and care-seeking behavior. HEWs at health posts in the intervention site only will receive additional training on tracking clients and providing PPFP messaging (as well as other FP/implant refresher as needed) at routine antenatal and postpartum contacts. HEWs in the intervention site will train HDAs on these messages and will receive job aids and tracking tools for PPFP messaging. Data from chart reviews and review of health records in the intervention and control arms will be analyzed to determine differences in PPFP counselling, decision-making on method choice, and uptake of PPFP by study arm.

More robust qualitative evaluation will take place at endline, where secondary participants will include community health workers (HDAs), and facility based providers, including HEWs, and managers. We will collect additional data from these informants through interviews, questionnaires and focus group discussions.

The following conceptual model illustrates the inputs and influencers that affect postpartum family planning uptake and how tracking pregnant women will improve the uptake.

Figure 2: Conceptual Model



The study will collect data from key actors in the implementation of the intervention. The Table 1 describes the actors, the type of data and instruments to be collected.

Table 1: Data Collection Tools and Type of Information Collected

Study Population	Data Collection Method	Type of Information/Data Collected
Health Extension Workers	Mixed methods questionnaire (going through each point of service – ANC, delivery, PNC and immunization)	• Integration of PPFP messages in ANC, PNC, and immunization contacts • Perceived barriers to uptake of PPFP in community • Experience with training, mentoring and supervision of HDA in promoting PPFP • Confidence (self-perceived skills and ability) and experience in counseling and delivering postpartum implants, LAM counseling & EBF support, and other methods • Ability and willingness to use record keeping and tracking tools to assess population level PPFP decision-making and uptake in the catchment of the health post
Health Development Army (HDA)/HDA team leaders	Focus Group Discussions	• Understanding of PPFP benefits, methods, etc. • Experience promoting MNCH including PPFP • Description of what they do and how (home visits, community meetings, etc.) • Decision making as to who they target besides pregnant women, barriers perceived, coverage of assigned households • Experience with support from HEWs, team leaders, village leaders, use of data at monthly meetings
Health providers (at Health Center)	Mixed methods questionnaire (going through each point of service – ANC, delivery, PNC and immunization)	• Integration of PPFP messages in ANC • Delivery of contraceptive methods at birth, including PPIUD, or in postnatal contacts • Experience with scheduling mobile services or referrals for permanent methods • Barriers to PPFP counseling and service delivery, including stock outs, organization of services, manpower, confidence to deliver, etc. • Experience with record keeping and analysis of PPFP data
District (woreda) health managers	Key Informant Interviews	• Attitudes towards PPFP integration; • Barriers/Facilitators • Experience with data reviews, analysis of data to address gaps • Experience addressing management or systems issues with FP service delivery
Pregnant and postpartum Women	Census of all pregnant women in the catchment area Questionnaire for all women 6-9 months pregnant F/U and re-interview all women 1 year later Review Integrated MCH/Family Health Card	• Attitudes and use of FP – past use, current use (once delivered) • Family support for FP, spouse, MIL, FIL (ask who are most influential) • Attitudes on immunization, facility delivery, plans for delivery, infant feeding, care seeking for self or sick baby • # of health contacts, # of ANC visits, place of delivery, PNC visits at facility or home, immunization visits, BF practices, return to fertility, timing of adoption of FP if adopted, rationale for not, what was most influential for those who did adopt (and didn't)

Table 1: Data Collection Tools and Type of Information Collected		
Study Population	Data Collection Method	Type of Information/Data Collected
		• Perception of risk of pregnancy and motivation to avoid another pregnancy • Experience with woman held card, if brought with them to all contacts with the system; was it helpful? Ability to communicate method choice without card
Registers, Referrals at Health Center, Health post level	(Revised longitudinal register)	Ability to track pregnant women's PPFP counselling, decision making on method choice and uptake of PPFP # of women in register, completeness of register Follow up mechanism

The Table 2 provides details on the general study timeline, program activities and study related activities.

Table 2: Study Timeline and Activities		
Timeline	**Program Activities**	**Research-related Tasks**
Preparatory phase (1st 4-6 months)	Woreda level engagement of stakeholders	
	Assessment of sampled health facilities readiness	Identification of data collectors
	Development and pretesting of SBCC and training materials for HEWs including how HEWs will train HDA (in adjoining woreda to avoid contamination)	Pre-testing of translated questionnaires for pregnant women and household members
	Development and pre-testing of HEW and HC M&E Tools	Abstraction tools for health records, development of monthly site monitoring visit documentation tool
	PPFP Counseling Training (2 day course, with more people)	Training of data collectors
	PPIUD/Implant Training (5 day course for subset)	
	Training of HEWs in PPFP counseling and promotion of PPFP messages at community level, assessment and refresher in implant skills	
Baseline		• Census of pregnant women, enrollment of study participants (research team member paired with HDA team leader), • Interviews of study participants and household members

Table 2: Study Timeline and Activities		
Timeline	**Program Activities**	**Research-related Tasks**
Intervention implementation run time (15 months)	• HEWs train HDA team leaders and team leaders train HDA • Ongoing household visits by HDA and HEW and promotion of PPFP at community level • Ongoing monthly meetings between HEWs and HDA team leaders – review of data on pregnant and recently delivered women • Post training follow up of PPFP/trained health providers and HEWs	Study Monitoring: • Monthly F/U of HC records, tracking of births and PPFP uptake among postpartum women using selected health facilities • Record review and abstraction of HEW data • Documentation of PPFP, PNC or immunization service delivery issues
Endline (after 15 months)		• Follow up interviews with enrolled women • Interviews of HCW, HEW, • Focus Groups with HDA • In depth interviews of Woreda stakeholders
Analysis and report writing (4 months)		Data analysis Report Writing Journal Writing
Dissemination		Dissemination workshop in Ethiopia

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

This study will be implemented 2 primary health care units (PHCUs), comprised of one health center and all kebeles/health posts in their catchment area, in Hitosa Woreda and 2 PHCUs in Lude-Hitosa Woreda. We randomly assigned 1 PHCU in each Woreda to the intervention and control arms. So out of 4 PHCUs in each Woreda, 1 was selected for intervention and 1 for control.

We obtained the total population for each PHCU. To estimate the number of women age 15-49 and expected pregnancies at the time of study survey, we used results from the Ethiopia mini DHS 2014: 43.6% of female residents of selected households were age 15-49 and 7.3% of women age 15-49 were currently pregnant at the time of the Mini DHS 2014.

Table 3: Estimation of eligible population

Arm	Total population	Female population (50%)	Expected females age 15-49 (43.6% of female pop)	Expected current pregnancies (7.3% of women 15-49)	Women 6-9 months pregnant (pregnancies / 3)
Intervention	72,138	36,069	15,726	1148	382
Comparison	52,508	26,254	11,446	835	278

For pregnant women, we calculated the minimum sample size requirements for this quasi-experimental design for the main outcome of interests (adoption of LAM and other modern method by 12-month PP) using the formula:

$$n' = \frac{\left\{z_{1-\alpha/2}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\right\}^2 (1+(m-1)\rho}{(p_1-p_2)^2}$$

$$where,\ p = (p_1+p_2)/2$$

Where p_1 and p_2 are the proportions of women adopting LAM or other modern method in the intervention and control arms, respectively, and Z's are the critical value of the normal distribution at α=0.05 and β=0.20; 1+(m-1) ρ captures the design-effect due to cluster based sampling of areas, where m= average size of the clusters and ρ=intra-cluster correlation. We consider a design-effect (deff) of 1.5 for adjusting higher intra-cluster correlation in the observations in the quasi-experimental design.

We require a minimum of 299 women in postpartum observation period in each arm to detect an increase of at least 10% contraceptive prevalence rate (CPR) in the intervention arm, compared to the women in the control arm (20% vs 10% in the intervention and control arm, respectively) with deff=1.5 at 80% statistical power. Assuming about 20% lost-to-follow-up and non-response rate, we target to enroll 375 women in each arm. We consider that it will be sufficient to select 1 PHCU and its attached *kebeles* in each of the two *woredas* to ensure adequate sample size, with 2 PHCU randomly assigned to the intervention area (1 per woreda) and 2 to the control area (1 per woreda). The eligible women in 3rd trimester who consent to participate in the study voluntarily will be recruited and be interviewed at enrollment and at 12-month PP.

We used p1=0.2 (20% PP contraceptive uptake by the final round of observation in the intervention arm) and p2=0.1 (10% in the comparison arm). We considered deff=(1+[m-1) ρ]= 1.5. Because we are targeting 375 sample size of pregnant women in each arm consisting of 2 PHCUs, this implies m=188 AND ρ=0.0027.

Because the selected PHCUs are adjoining woredas of the same zone, it is expected that they will be quite similar, and in addition, the underlying population are all similar in terms of postpartum status; hence ρ very small (the larger the heterogeneity, the larger the ρ value). The Ethiopia DHS 2011 results suggest that the deff of contraceptive use in all 11 regions are much smaller than the national level deff of CPR (Appendix B – Estimates of Sampling Errors); woreda level deff is expected to be much smaller due to less heterogeneity at woreda level, compared to the region/state level. In all regions, method specific deff was <1.5. So, we considered that of deff=1.5 is applied in this study is reasonable and practical. A study on postpartum use of contraceptive method at a woreda level in Ethiopia also had deff=1.5 (Abera Y, Mengesha ZB, Tessema GA. Postpartum contraceptive use in Gondar town, Northwest Ethiopia: a community based cross-sectional study. BMC Women's Health. 2015;15:19.)

Sample size requirements are included below based on the average number of providers and HDAs and managers in each kebele. See Table 4: Sample Size Summary

Table 4: Sample Size Summary

Study Participant	Intervention (2 PHCU)	Comparison (2 PHCU)	Total
Pregnant women	375	375	750
Facility Providers working in ANC, L&D, postnatal care, immunization, family planning	10	10	40
District managers and stakeholders	Not applicable	Not applicable	6
Health Extension Workers (10 HPs in intervention clusters and 8 in comparison clusters; each HP has 2 HEWs)	20	16	36
HDA/HDA Team Leaders (2 FGD/PHCU, 10 people per FGD)	40	40	80
Total Sample Size	455	449	910

Since the expected number of eligible women in the selected control PHCUs is less than we require to meet this sample size, we will enroll women from adjoining kebeles (villages) in non-study PHCUs to reach the required sample size. The kebeles will be selected with local leadership and with the aim to minimize contamination by selecting villages further from the intervention PHCU. If we do not reach the required sample size in intervention PHCUs, we will also select adjoining kebeles to each the sample size minimum; the HEWs and HDA from these will be trained in the intervention package. All health centers in the entire woreda are receiving the same strengthening inputs, so no additional inputs will be necessary.

IV. Participants

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

A. Inclusion criteria:

- Pregnant women (including emancipated minors)
- Providers (HDA, HEW, HCW, district managers providing PPFP messages or services in study area)
- Willing to give informed consent

C. Exclusion criteria:

- Non – pregnant women, women living outside study area, facility providers not working in ANC, L&D, PNC or immunization. Providers from other points of service study facilities.

NOTE: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.

V. Study Procedures

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.

A. Recruitment Process:

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

   Prior to the development of this protocol, a concept note was written and the Federal Ministry of Health was consulted about the general idea for this study. The Federal Ministry of Health convened a stakeholders meeting where input on the priorities for research questions were discussed and incorporated into this protocol. Furthermore, the research team contacted the national and regional/ woreda level authorities in person and writing, describing the study to them and received permission to carry out the study.

   Prior to the study start, the relevant authorities will communicate to the selected Woreda (and health facility leaders) about the study through usual channels such as letters introducing the research team to them. Working in conjunction with woreda health managers, the study team will orient the site and community health staff to the purposes of the study. Jhpiego/ MCSP staff will provide training on PPFP counseling, promotion of PPFP to HDAs and provide orientation to the modified health record tools. MCSP-recruited data collectors will work with HEWs and HDAs to develop lists and approach pregnant women in their catchment area and describe the study to them using Study Tool R1: Recruitment Script for Pregnant Women. If they are interested in learning more about the study, a full consent script will be read as described below in Section 5B of this protocol.

   For district managers, health providers, health extension workers and health development army data collection will take place at the end of the study. The research team will contact regional health bureau and woreda authorities in intervention and control sites and work through government administrative structures to recruit participants using Study Tools R2: Health Extension Workers, HDA, R3: Health providers (at Health Center), and R4: District Managers. If interested in learning more about the study, consent process will begin as described below.

2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

   The recruitment will take place in a private location in the community, either in or outside the home, or in a quiet location near the home at the discretion of the participant. There is limited risk to participants during the recruitment.

B. Consent Process:

   Members of interview teams including supervisors and data collectors will be trained using the JHSPH Human Subjects Research Ethics Field Training Guide. Interview team members will also be oriented on the study protocols, data storage procedures, recruitment and consent forms and data collection tools. Additional training will be provided on interviewing techniques. Jhpiego/ MCSP Program Technical and M&E staff will supervise the interview team during the data collection process. Throughout field-based activities, the data collected will be reviewed weekly to identify any potential issues with the interview tools or interviewers. Participants will be assigned study IDs.

   If the pregnant woman is interested in learning more about the study, the trained data collector will use the consent form (C1: Pregnant Women) to obtain oral consent to participate in the study. Data collectors will explain the purpose of the study, how the pregnant woman was selected, interview procedure, risks and

benefits. The participants will be informed they can stop the interview or withdrawal from the study at any time. Emancipated minors (according to local legal definition) who are 15-17 years and pregnant, will provide their own consent as participants. Respondents will be asked to suggest a private location in the homestead or close by where an interview can be conducted in private; all interviews will be conducted at locations that assure audio privacy. Privacy and confidentiality will be maintained during interviews and handling of data obtained.

For health providers and managers, health extension workers and health development army, if they are interested in learning more about the study, a trained data collector will use the consent form (C2: Health Extension Workers, HDA, C3: Health providers (at Health Center) and C4: District Managers to obtain oral consent to participate in the study. Respondents will be asked to suggest a private location in the facility or surrounding area where an interview can be conducted in private; all interviews and focus group discussions will be conducted at locations that assure audio privacy. Privacy and confidentiality will be maintained during interviews and handling of data obtained.

We are seeking a waiver of written consent for several reasons. This study is minimal risk and involves only interviews with women once during pregnancy and again at about a year postpartum, facility and community providers and some senior family members. . Many of the clients will be low-literate and a signature may not be feasible.

For providers, including health center, health post/HEW, a waiver of signed informed consent allows for better protection of confidentiality as no identifiers will be collected, including signatures. Provider questionnaires will be administered using tablets, with a built in consent script and yes/no pause, with the no button ending the interview. By not having the participant sign or mark a consent form, we can avoid collecting or keeping any identifiers.

Similarly, for focus group discussions with HDA, a waiver of signed informed consent allows for better protection of confidentiality as no identifiers will be collected, including signatures. Many of the HDAs have low or no literacy. The FGD will be recorded for ease in transcription and translation of the discussion, but any names or nicknames will be removed from the transcripts. FGDs will be audio recorded; recordings will be kept in a locked cabinet or room and will be destroyed after the study is complete and the file is closed.

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	Consent Document(s) (adult consent, parental permission, youth assent, etc.)	Languages
Ethiopia	Consent	Amharic, Afan Oromo

C. Study Implementation:

See Table 5 for information on study implementation

Table 5: Study implementation procedures					
Study Population	Main Data Collection Method	Other Study Procedures	Number of contacts	Duration of Research Interview (Only)	Place of Interview
Health Extension Workers	Post intervention Questionnaire (covering each point of service – ANC, delivery, PNC & immunization)?	Orientation to study Training on PPFP counseling and promotion of PPFP to HDA Training on health records tools Monthly follow up	~19: Pre study training and start up (~3); monthly during study (15 months); Endline (1)	60 minutes	Health Post
Health providers (at Health Center)	Post intervention Questionnaire (covering each point of service – ANC, delivery, PNC & immunization)	Orientation to study Training on PPFP counseling Training on PPIUD and implants (subset of providers) Training on health records tools (and analysis?) Monthly follow up	~19: Pre study training and start up (~3); monthly during study (15 months); Endline (1)	60 minutes	Health Center
Health Development Army (HDA)/HDA team leaders	Post intervention Focus Group Discussions	Existing HEW/HDA contacts utilized for study activities.	1: FGDs	120 minutes	Health Post
District (woreda) health managers	Post intervention Key Informant Interviews	Orientation to study Ad hoc debrief on study monitoring	~6	45 minutes	Woreda Health Office
Pregnant and Postpartum Women	Pre-intervention questionnaire for all women 6-9 months pregnant Post intervention F/U questionnaire 6-9 months postpartum		2	Pre-Interview: 60 Post-Interview: 60	Household

Table 5: Study implementation procedures					
Study Population	Main Data Collection Method	Other Study Procedures	Number of contacts	Duration of Research Interview (Only)	Place of Interview
	Review Client held Integrated MCH/Family Health Card (post intervention)				
Registers, Referrals at Health Center, Health post level	(Revised longitudinal register) For HEW monitoring tool: Ease of use, helpful for data review meetings, etc		12: monthly data review and abstraction	N/A	Health Post and Health Center

4. Provide a brief data analysis plan and a description of variables to be derived.

After data have been thoroughly examined for quality, the study team will perform exploratory data analysis of the key variables for checking frequency distributions, measures of variability, central tendency, and data outliers. We will also check for incomplete data and undertake an imputation strategy, if needed.

We will examine the differences in contraceptive use behavior by study arms for the following outcomes:

- Baseline only: % with past use of postpartum family planning among women with non-first pregnancies
- % of postpartum women who choose a method prior to delivery (by # of ANC contacts)
- % uptake of FP by PP timing (Delivery, PNC, immunization) and type of method
- % of ANC and PNC contacts where FP was discussed or provided (by type of contact, i.e., HDA, HEW, HCW, other)
- Duration of exclusive breastfeeding/Introduction of complementary foods
- % initiated LAM and the duration of LAM use
- % of women received counseling during immunization
- Immunization coverage of infants of enrolled women by month postpartum (doses of DPT1, 2 and 3 and drop out rates)

We will perform both “intent to analysis” to examine the net differences between the two study arms, adjusted for confounding covariates, and “per-protocol analysis” to examine “dose-effect” of health system contacts. We will fit multivariable logistic regression models for examining the differences in binary outcome variables (e.g., method selection during ANC; FP discussions during contacts, etc). We will use hazards regression model for examining the duration (discontinuation) of LAM use in first 6-month PP and for analyzing the uptake of modern contraceptive method by timing since delivery.

1. Describe whether you are collecting or storing personal identifiers, and if yes, why you need them, and when and how you plan to dispose of them. Signatures on consent forms are considered to be identifiers.

For pregnant women enrolled in the study, each woman will be assigned a unique study ID. The information linking the women's personal information and study ID will be kept in a separate locked, password protected file only accessible by study personnel. For other study participants, we will not collect personal identifiers on any of the questionnaires, in-depth interviews, or focus group discussions and transcripts.

A study logbook will also be maintained to track providers participating in the study including the provider name, study ID, date of interview and interviewer. This logbook will be kept by the data coordinator at each facility in a locked, secure place during data collection along with logbooks referenced above. This will only be accessible by the counselor and Jhpiego/MCSP study staff. The names of providers will not be entered into the electronic database and the logbook will be destroyed 6 months after completion of the study.

VI. Data Custody, Security, and Confidentiality Protections

The sections below describe types of data sources and how they will be protected. For the type(s) of data you will have, put an "X" in the appropriate box to the left of the section that best describes how you will minimize the risk of a breach of confidentiality for your study. Note, as appropriate, how you will record/store data. These descriptions represent MINIMAL measures; you may add more stringent protections and other relevant information in B.

<u>Confidentiality:</u> The *LOSS OR THEFT* of 1) original/duplicate version of physical data collection instruments (forms, tapes, etc) or 2) physical devices containing electronic data (i.e. laptop/mobile device, external flash drive(s), is a threat to subject confidentiality. Risk of such a loss/theft is increased during movement/transport of data (in any format), such as in a vehicle or other move. Be sure to train anyone (co-investigators, staff, students, etc.) who might be engaged in the oversight of data handling/storage about this problem. Some typical risk-mitigation strategies would include:

- **minimizing the physical movement of data and/or devices containing data**
- **encrypting electronic data (especially when stored on any mobile device, including flash memory tools, phones, tablets, etc, or when transferring across networks)**
- **making use of reliable courier services (FedEx, DHL, etc) when physical transport of bulk data forms is necessary**
- **minimizing the transfer of identifiable data in physical or electronic form (i.e. removing/separating/destroying identifiable data, when physical transfer of data is necessary)**

A. Data Storage

1. Hard Copies of Data Collection Forms.	
	This activity will not involve receiving and/or accessing hard copies of data
X	Health workers and volunteer. Data collection forms RECORD NO PERSONAL IDENTIFIERS connecting study participants, and there are no codes providing a link. Data are anonymous.
	Data collection forms INCLUDE IDENTIFIERS. The forms are locked in a secure cabinet or room with limited access by authorized individuals. Forms will be kept in study team's possession during transport and will not be left unattended in a vehicle. When possible, de-identified copies will be used for coding and analysis.
X	Women's survey. Data collection forms ARE CODED with study participants' random study ID numbers. Codes/links between study IDs and identifiers are stored securely in a separate place (locked storage cabinet or secure electronic database.)
	Other:

2. Electronic Data	
X	Audio files of health workers and volunteers. The data do not contain personally identifiable information
X	Women's survey. These data are stored on a secure server protected by limited access and strong password systems. Data are coded when possible. Portable electronic devices will not contain identifiable information unless encrypted.
	Other:
3. Other Identifiable Data Storage, Retention, and Destruction (Audiotapes, videotapes, photographs, etc.) will be retained and stored securely (locked in cabinet or room) until:	
X	Transcription is complete, then audio files will be destroyed a maximum of 3 months later.
	Analysis is complete, then will be destroyed.
X	Study is complete and file is closed.
	Indefinitely. Provide justification for indefinite retention:
4. Existing Biospecimens to be used in this study: N/A	
	HAVE NO PERSONAL IDENTIFIERS.
	INCLUDE IDENTIFIERS AND ARE CODED; the PI will not have access to the link or code connecting the identifiers to the specimens.
	INCLUDE IDENTIFIERS, and the PI has access to those identifiers or to the link/code connecting specimens to individuals. The identifiers and/or code will be stored securely until the study is complete.

B. Certificate of Confidentiality
Will the study data stored in the United States be protected by a Certificate of Confidentiality? If yes, explain who will apply for and maintain the Certificate. (http://grants.nih.gov/grants/policy/coc/appl_extramural.htm)
N/A

C. Data Security and Sharing
PIs have the responsibility for responsible stewardship of data and protecting data confidentiality. This responsibility includes protecting physical custody of the data, storage and sharing with appropriate data use agreements that contain the appropriate security provisions. Describe any additional plans beyond those identified in the table that you have for storing and sharing the study data and/or materials, and how responsibility for the data will be managed. Include the following details:

1. Where will the study data be stored?
2. Who controls access to the data?
3. Will data be shared only if de-identified?
4. What additional (if any) security controls will be in place?

Data will be collected either on paper or on mobile devices. The women's surveys will be captured on mobile devices, while the health worker and volunteer data will be captured on paper and with audio-recordings. In general, the data collectors will keep the completed questionnaires securely in sealed envelopes and bring them back to the Jhpiego/MCSP Ethiopia office once the data collection is finished. Study personnel (e.g., supervisors and the study manager) will be allowed access to the written data during the field work. Once the Jhpiego/MCSP Ethiopia Study Manager obtains the completed data collection forms, the data will be entered into electronic databases on password-protected computers at the MCSP office. Hard copies will be stored in locked cabinets in the Jhpiego/MCSP Ethiopia office. Names and participant identifiers will be maintained in a study log book that is kept locked in a separate location from the completed data collection forms. At all times, the data will be treated confidentially and only the study staff

will be allowed access to the raw data. De-identified and/or aggregate data may be analyzed by the study team. Data collected on tablets using a software that allows for data encryption.

VII. Risks of the Study

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

There are no anticipated physical risks for participation in this study. The potential non-physical risk for recent mothers and health workers include their personal information being shared with the study personnel, Ministry of Health personnel or community members. This can be considered minimal risk, as little or no information of a confidential nature will be collected. All information collected during the assessment will be treated as confidential. During focus group discussions, some participants might feel a bit uncomfortable discussing some of the topics. This will be mitigated by assuring the participants of confidentiality of information during the consent process. Participants will also be assured that they may choose not to continue with the questionnaire or focus group at any time. Furthermore, study identifiers will be used on paper and in electronic database further ensuring confidentiality.

B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing “x” test/assessment, or dispensing “y” drug, how often do you expect an “anticipated” adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

Expected harm as a result of participating in this study is minimal for all participant types.

C. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it.

Interviews will be administered in a private area within the homestead or nearby – respondents will not be required to travel away from their homes in order to participate. These respondents and health providers will assist in identifying a suitable location.

D. Describe the research burden for participants, including time, inconvenience, out-of pocket costs, etc.

The only burden for respondents is time they spend participating in an interview. There will be no payments or monetary compensation of study participants since the interviews will be done at their homes.

E. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

Private locations will be located for interviews to project participant privacy. No sensitive questions, such as HIV status, will be asked.

VIII. Direct Personal and Social Benefits

A. Describe any potential direct benefits the study offers to participants (“payment” for participation is not a direct personal benefit).

There will be no direct benefits to individual study participants; they will not receive any payment or other compensation.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

It is expected that through the study information; community level coverage of PPFP knowledge and services will improve which may lead to improved health situation or outcomes in the community.

IX. Payment:

A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

No payment will be made to study participants.

X. Study Management

A. Oversight Plan:

1. Describe how the study will be managed.

The PI will oversee the study. She will work with the study team to carefully establish study procedures, including human subject protection, training tools for data abstractors and data collection steps. She will be in regular contact with the study team and provide oversight for data collection, review, analysis and report writing. In Ethiopia, there will be a co-investigator and study manager to recruit data abstractors, oversee and manage the data collection at health facilities. This person will be responsible for local data management, texts and phone calls with providers. The co-investigators are expected to lead the orientation of study managers and support training of data abstractors. The study managers will be drawn from M&E staff in the Jhpiego office in Ethiopia. The PI will establish weekly check in calls during the data collection period with the co-PIs responsible for data collection to review procedures, challenges and discuss opportunities to explore additional datasets.

2. What are the qualifications of study personnel managing the project?

Anne Pfitzer, MHS, is the PI and is the Family Planning Team Leader for the global USAID-funded Maternal and Child Survival Program. She is responsible for interactions with the donor funding this study in addition to managing oversight of the study.

Deborah Sitrin, MHS, is a co-investigator on this study and is a Sr. Monitoring and Evaluation Advisor for Jhpiego and the Maternal and Child Survival Program. She has extensive prior experience working in international health including based in Africa as well as in research in Ethiopia. She is a member of the Jhpiego/MCSP Family Planning team.

Ephrem Daniel is a co-investigator on this study. He is Jhpiego and MCSP Monitoring and Evaluation Advisor based in the Addis Ababa office. He was involved at the beginning of the study in its design and brings background experience with other implementation research efforts in Ethiopia.

Firew Ayalew Desta is co-investigator on this study. He is Jhpiego/MCSP Research Team Leader based in the Addis Ababa Office. Firew is leading the coordination of the Ethiopia study team and interfacing with the Federal Ministry of Health in Ethiopia and the Arsi University co-investigator.

Gebir Hussein, Epidemiologist at Arsi University, is a co-investigator with the study. The Federal Ministry of Health asked that we work in partnership with a local university. Arsi University is near to our study area. He will be engaged in data collector training, supervision of baseline and endline, and when feasible monthly visits to sites.

Dr. Tsigue Pleah is co-investigator on this study and will act as Study Manager, provide support to the implementation of PPFP clinical activities, support development of tools for abstracting records and collecting clinical data and support analysis and interpretation of clinical data.

Tigist Worku Belete is co-investigator in this study. She is FP/RH Advisor for MCSP/Ethiopia based in the Addis Ababa office. Her role will be to ensure technical support to providers and health workers delivering integrated services. She is also the overall program manager for the study.

Dr. Eva Bazant has been added as a co-investigator to the study, with a specific mandate to support more rigorous implementation and analysis of the endline qualitative data. She is Jhpiego's Research Team Lead, in the Monitoring, Research and Evaluation Office. She will provide training to qualitative interviewers as well as guide the qualitative data coding and analysis.

3. How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide on our website.)

   All co-investigators have completed the CITI course and uploaded a copy of their certificates. All in-country data collectors will be trained by the PI in human subjects using the JHSPH guide.

4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

   The study manager and co-investigators involved in data management are Jhpiego employees and experienced in human subject research. Weekly telephone calls will take place during data collection.

B. Recordkeeping:

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact housecall@jhsph.edu.

Protocol, IRB regulatory correspondence and other study documentation: We will establish a regulatory binder and keep it in the PI's office. A short binder of key forms will be shared with field co-investigators. We will develop and maintain a password protected study database for data management. Only de-identified data will be entered into the database. For logbooks that include identifiable data, these will be kept by the local study manager, under lock and key.

Study Data Collection Forms: Paper forms will remain in-country during data collection. They will be stored securely in the study team's possession or in a locked cabinet in each main Jhpiego country

office, under the supervision of a Monitoring and Evaluation Officer. Once entered into a database, and the data cleaned, paper forms will be destroyed.

C. Safety Monitoring
N/A

D. Reporting unanticipated problems/adverse events (AE's) to the IRB (***all studies must complete this section***):
Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

NOTE: The IRB does not require submission for all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.

Any adverse events will be reported to both the local and JHSPH IRBs in writing as soon as possible after the event occurs. Any loss of data will be reported using the IRB-mandated procedures. Any misinformation or incident related to the study, the data collection process or involving access to patient data will first be reported urgently to the PI who will gather as much information as possible, then report to IRB. The IRB support team at Jhpiego will be called upon to assist in such an eventuality.

E. Other IRBs/Ethics Review Boards:
If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).

The Oromia Regional Health Bureau IRB will review this study.

F. Collaborations with non-JHSPH Institutions:
For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

	Jhpiego	MOH (national and regional)	Arsi University
Primary Grant Recipient	X		
Collaborator		X	X

For the following, indicate "P" for "Primary", "S" for "Secondary" as appropriate to role and level of responsibility.) Add additional items if useful.

1	Human subjects research ethics training for data collectors	P	S	S
2	Day to day management and supervision of data collection	P	HEWs - S	S
3	Reporting unanticipated problems to the JHSPH IRB/Sponsor	P		S

4	Hiring/supervising people obtaining informed consent and/or collecting data	P	HEWs - S	S
5	Execution of plan for data security/protection of participant data confidentiality, as described in Sect. 5.	P		S

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

XI. Secondary Data Analysis of Existing Data: see above

XIII. Creation of a biospecimen repository: N/A

XIV. Data Coordinating Center: N/A

XV. Drug Products, Vitamins, Food and Dietary Supplements: N/A

XVI. Investigational Medical Devices: N/A

Appendix 1. FP [and MNCH] Tasks by type of facility and cadre

Level of facility	Type of health personnel available	FP Services*	MNCH Services
Health Post	Health Extension Workers	• Counsel on FP and other RH issues • Counsel on natural FP methods • Provide injectables • Insert Implanon • Refer to health center for other long-acting and permanent methods • Do planning based on local data	• Limited ANC + Referral to Health Center • PNC • Immunization
Health Center	Health Officers (HOs), Midwives, Clinical Nurses, Public Health Nurses, Laboratory Technicians	The above activities, plus: • Conduct general physical and pelvic examinations, including VIA/VILI • Insert and remove implants • Insert and remove IUCD • (Where a trained GMP/HO is available), provide tubal ligation and vasectomy • Manage complications and side effects • Provide syndromic management of STIs • Provide HCT, including care • Train community-level workers and junior health professionals in FP • Conduct monitoring and facilitative supervision	The above activities, plus • Labor and delivery (BeMONC)
Primary Hospital	Non physician clinicians, GMPs, HOs, Midwives, Clinical Nurses, Public Health Nurses, Laboratory Technicians	The above activities, plus: • Provide permanent methods of contraception • Receive referrals • Manage complications and side effects • Do work-ups for infertility	The above activities, plus: • Caesarean section • Blood transfusion • Receive Referrals • Manage Complications • KMC
General and Referral Hospitals	Obstetrician-Gynecologists, GMPs, HOs, Midwives, Clinical Nurses, Public Health Nurses, Laboratory Technicians	The above activities, plus: • Manage infertility • Manage complicated STIs • Manage complications and side effects of contraceptive methods • Manage ROCs Perform research	The above activities, plus: • Emergency obstetric and newborn referral service

**Content on FP services taken verbatim from "National Guidelines for Family Planning Services in Ethiopia", Federal Ministry of Health, 2011.*