**Appendix 6: Participant Information sheet**

***Protocol Title:*** "*Safety of integrated mass drug administration of azithromycin, albendazole and ivermectin versus standard treatment regimens: a cluster randomised trial in Kofele woreda, Oromia Region, Ethiopia"*

***Note: If you are a parent or guardian of a child below 18 years old, please read "you" as "your child".***

**Introduction**

Neglected tropical diseases (NTDs) remain to be important public health challenges in Ethiopia. In 2013, NTDs were the cause of 873,500 Disability-Adjusted Life Year (DALYs) annually lost which is 1.9% of the total DALYs lost due to any causes. In addition, in the same year NTDs caused 3.9 deaths per 100,000, which is 0.5% of the total deaths in the country. Thus, Ethiopia prioritized intervention against eight of the NTDs: Trachoma, Onchocerciasis, and Schistosomiasis, Soil transmitted Helminthiasis, Lymphatic filariasis, Podoconiosis, Leishmaniases and dracunculiasis for elimination as public health problem by 2020. The main way out in this effort is mass treatment (MDA) of eligible communities.

MDA have been practiced over two decades in Ethiopia. Yet, as many as 5 NTDs could be co-endemic in a given community at a given time a coordinated approach; like co-administration of MDA drugs could be both cost effective and minimizes efforts.

**Purpose of the research**

This clinical trial aims to establish the safety of Ivermectin, Azithromycin and Albendazole co administration in a cohort event monitoring CEM) approach. This is because CEM will allow as documenting on rare AEs, thus giving enough evidence to establish the safety of the Co-administration approach to programmatic use in Ethiopia and beyond.

**What will happen if I/my child (ren) participate? What data and samples will be collected?** If you are happy to participate the following will happen:

1. We will ask you to sign a sheet confirming that you agree that you your minor to participate 2. We will collect data on your age, your sex, body height, weight, and conduct normal physical examination
3. Record on if you had meal or not before taking the co-administration, if
    a. you/ a minor in your family participating in the study had any illnesses,
    b. If you/a minor in your family participating in the study are on medication and the type of medication
    c. Deaths of any cause occurred within your family in the past 6 months.
4. We will then ask you/your minor to take the study drugs

We will make sure that confidentiality is maintained at all levels, all documents bearing your name will be kept under key and lock; only the PI and your physician will have access to such documents. We will publish our findings at study end. We will do so without making it possible for anybody to identify you as

one of the study participants.

**What are the risks if I/my child(ren) participate?**

There could be minimum chance of infection. We will use standard aseptic methods during physical examination and administration of drug to minimize such risk. Also, there is a small chance of temporary illness and/or discomfort related to the drugs. We will follow make sure that all necessary procedures and means are ready to handle any complaint, and minimise risk. In case of the rare SAEs and not possible to handle at the site we will make sure you will be evacuated to appropriate referral centre. All your treatments will follow standard procedures at no cost to yourself. If ASE(s) with potential future effect occurs appropriate compensation will be provided.

**What are the benefits of this study?**

Being part of this study will allow as get the information on the safety of the co administration and you are given a good treatment against the targeted NTDs. It will also assist in developing a strategy in the effort for elimination of NTDs as public health problem in Ethiopia by 2020. Also the result might build the evidence base for adopting co-administration of the three drug agents as MDA worldwide in the fight against NTDs.

***Participation is on VOLUNTARY bases; if you do not wish to participate in this trial IT WILL NOT COMPROMISE IN ANY WAY YOUR RIGHT TO RECEIVE STANDARD HEALTH CARE, or.*** You can withdraw your consent from the study at any point in time and still receive the standard health care you deserve.

✓ **If you have any questions about this study**: you may contact Dr XXX on XXX or the study doctors in _____, or the ethics committee _____. ✓ **In case of an emergency:** you should return to _____ or call the study coordinator at any time of the day (24 hours).

✓ **If you have a complaint about the study** : you can address it to the PI at XXX and/or ethics committee at_____

✓ **If you wish to learn what this study showed**: we will have a community feedback session and this will be communicated to the community representative minimum of three months ahead, please keep in-touch with your community representative.