Informed consent form:
Evaluation of *Novartis Access* in Kenya

Background

You are being asked to take part in this research study because you have been diagnosed with a non-communicable disease (NCD) and prescribed a medicine for this disease.

In Kenya, NCDs account for 27% of deaths (about 370,000 per year) among people between 30 and 70 years old. NCDs limit economic growth through increased expenditure on treatment of disease sequelae such as increased hospitalization. Out-of-pocket spending can result in catastrophic health expenditure and increased poverty.

Novartis/Sandoz recently decided to launch *Novartis Access*, an initiative aiming to provide a basket of 15 medicines for the treatment of NCDs, in Kenya in 2016. The portfolio of 15 medicines will be sold to local purchasers, including the Mission for Essential Drugs and Supplies (MEDS) at a cost of 150 Kenyan Shillings (KES), around US$1.47, per monthly dose.

Purpose

The purpose of this study is to evaluate the impact of *Novartis Access* on the availability and price of NCD medicines at health facilities and households using a cluster-randomized trial design.

What Happens In This Research Study

You will be one of approximately 800 subjects to be asked to participate in this study. The research will take place in 8 districts throughout Kenya.

The included districts and the health facilities in these districts have been put in two groups. Health facilities included in one group will receive the *Novartis Access* medicines to sell to their patients. Health facilities in the other group will continue to receive and sell the medicines they are currently selling right now.

If you agree to be in this study, we will ask you some questions about your health and your use of medicines, your perceptions about the affordability and quality of medicines, and how you learn about and share information about medicines. At the beginning of the study, and then again 12 months later, and once more 12 months after that, a data collector will visit your home and conduct a survey. Each visit will take approximately 30 minutes of your time. We may also ask to call you on the phone once every three months to ask you a few questions about the medicines you are taking. Each phone call will take 10-15 minutes of your time.

Risks and Discomforts

The home visits may take time to complete and this may cause you some inconvenience. You may also feel uncomfortable answering the questions in the presence of other people in your home. You do not have to answer questions that make you feel uncomfortable.

There is a potential for loss of confidentiality of your information. We explain steps taken to ensure confidentiality below.

Potential Benefits
You may not receive any direct benefits from participating.

Alternatives
Your alternative is to not participate in the study.

Subject Costs and Payments
There are no costs to you for participating in this research study. You will be provided with a small amount of cell phone air for each survey visit you complete.

Confidentiality
We will only collect identifying information one time and we will then keep this information separate from all other information that you provide. All files will be stored at the study headquarters in locked cabinets. Information collected during this study may be reviewed and photocopied by agencies such as the Institutional Review Board of Boston University Medical Center. Information from this study may be used for research purposes and may be published; however, your name will not be used in any publications.

Subject's Rights
By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep. If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by contacting:

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Right to Refuse or Withdraw
Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

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Subject (Signature and Printed Name) Date

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Person Obtaining Consent (Signature and Printed Name) Date

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Subject's Thumb Print