SAMPLE INFORMATION SHEET - APPROVAL OF A SIMILAR DOCUMENT REQUIRES APPROVAL OF YOUR IRB

Participant Information Sheet

Determination of non-Inferiority of Prototype Nasopharyngeal (NP) Swabs vs. Controls
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What is the purpose of this research study?
The Covid-19 pandemic has created an international shortage of the swabs used to collect samples for testing. To address this crisis, a team at Beth Israel Deaconess Medical Center has been working with manufacturers to develop "prototype" swabs that are able to be produced in large quantities, which we are testing.
The main purpose of this study is to collect an extra sample from you using a prototype swab to compare its performance to standard swabs. We will use the testing information to answer questions about how to resolve the testing swab shortage. Specifically, we are interested in determining which prototype swabs perform acceptably compared to standard swabs as it pertains to testing for Covid-19 and other respiratory pathogens.

What will happen if I am interested in taking part in this research study?
If you agree to take part in the study, you will be asked if you are willing to undergo a prototype swab test in addition to the standard swab test. The data from the prototype test results will be stored electronically in a secure database in a secure facility without any of your personal information (e.g., name and phone number) for up to 6 years. This data will only be accessible to members of the BIDMC study team and the manufacturers for analysis. The results of the study swab will not be shared with you and will not be a part of your medical record. We will compare the study swab with the standard swab test.

Who is conducting this research study?
Dr. Ramy Arnaout, MD, DPhil, and his colleagues at BIDMC, working together with the manufacturers of the prototype swabs.

Who will be taking part in this research study?
People like yourself who are being tested for Covid-19 or other respiratory pathogens using a nasopharyngeal (NP) swab.

There are benefits and risks to taking part in a study:
Benefits may include: Your participation may help us provide a new resource to address the critical nationwide shortage of swabs for Covid-19 testing.
Possible risks may include: Risks of participating in this study include temporary minor discomfort and minimal nasal bleeding from the additional prototype swab test. To minimize likelihood of these, we have already evaluated the prototypes as best we can do without actual swabbing (this study). We do everything we can to protect your privacy. You can stop your participation at any time.

Costs covered by the study:
You will not be charged for the swab, tube, fluid in the tube, packaging, handling, testing, or anything else that is strictly only part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

Cost of Research Related Injury:
If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and

deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

What if I decide not to take part in this research study?
Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. If you decide not to participate in the study or decide to leave the study early, your decision will not affect you or your spouse's relationship with his/her doctor or with Beth Israel Deaconess Medical Center.

Questions? Feedback?
Please contact Ramy Arnaout MD, DPhil, Principal Investigator: rarnaout@bidmc.harvard.edu with questions about this study. If you have questions about your rights participating in research or would like to speak with someone independent from the research team, please contact the Human Subject Protection Office (617) 975-8500.