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| **SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY**  **& NYC Health + Hospitals, Kings County**  *(if not applicable, delete one of the above lines and the “&”)*  **BROOKLYN, NY 11203**  **INFORMATION SHEET** |
| Title:  Researcher(s):  Researcher Contact Information:  Sponsor: |

**Key Information for You to Consider:**

Researchers are asking if you would like to be in a research study. The boxes below provide key information about this research to help you to consider whether to participate. Please consider all of the details on the pages that follow.

Edit any of the following sections as applicable to the study:

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| --- | --- |
| **What is the purpose of this research?** | *[Insert a short, 1-2 sentence summary of the purpose of the research]* |
| **What will happen to you during the study?** | *[Insert a high-level summary that explains the procedures and activities of the study and include a description of any experimental procedures.]*  When enrolled in this study, you will receive ABCXYZ in the Clinical and Translational Science Center at Downstate. You will be asked to complete surveys about your health and will have exams and procedures done for the study purposes. Each visit will last 2-3 hours. |
| **How long will you be in the research?** | *[Insert a description of the length of duration of the study participant’s participation]* |
| **Could being in this research harm you?** | *[Insert a description of any foreseeable risks and discomforts related to research participation.*  Some of the foreseeable risks and discomforts of your participation include [describe the most important risks in lay terms. Consider the most probable and/or highest magnitude of harm]. |
| **Will being in this study help you in any way?** | There is no benefit to you for participating in the study.  -OR-  We cannot promise that you will get any benefits from taking part in this research study. However, possible benefits to others may include <describe>. |
| **Are there any costs to participate?** | Researchers do not foresee any additional costs to you for your participation in the research. |
| **How do researchers protect your information?** | Researchers will keep information about you in a secure location. Only those approved to have access will see your information. |

**Additional Detailed Information:**

Please review the rest of this document for additional details before making a decision about whether to participate in this research.

**Could being in this research harm you? (Detailed Risks)**

*Add any additional risks not noted above. If none, delete this section.*

**Who can you talk to about the research?**

If you have questions, concerns, complaints, or think the research hurt you, please contact the researcher(s) listed on the top of the first page.

This research is reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee that provides ethical and regulatory oversight of human research. You may talk to the SUNY Downstate Medical Center IRB & Privacy Board by calling (718) 613-8480, if

* You have questions about your rights as a research participant
* Your questions, concerns, or complaints are not being answered by the research team,
* You cannot reach the research team,
* You want to talk to someone besides the research team, or
* You want to get information or provide input about this research.

**What happens to the information collected for this research?**

*Add a statement about the type of information and/or specimens collected for the research.*

*Add a statement about storing coded materials if applicable. It is best practice to store coded materials rather than identifiable materials.*

Researchers will securely store your information <and specimens> in a coded format. The code can be used to link to materials back to you. Only the researchers approved by the IRB may have access to the code.

*If the research involves the collection of ‘identifiable private information’ or ‘identifiable specimens’ federal regulations requires one of the following:*

The researchers will not use or distribute your identifiable private information (and identifiable specimens) collected for this research for future research studies, even after removal of identifiers.

**How do researchers protect your information?**

*Describe how the study maintains the confidentiality of participant data:*

The researchers will keep information about you in a secure location with limited access. The researchers will not reveal your identity in any publication or public presentation of the results of the study.

*Include if applicable:*

The researchers will destroy your information <and your specimens> after the study is complete. The researchers will not use the specimens or information for future studies; however, the researchers will keep information about you as long as required by regulations and institutional policy.

*Include if applicable:*

The researchers will obtain video/audio records/pictures/images of you for research purposes. Only the research staff approved to be on this study may have access to these materials. These materials will be stored in a locked cabinet and used only for the research. The researchers will keep these materials only for as long as needed for this research. These materials will be (SELECT OR EDIT) destroyed after the required retention period has ended after the study is complete / stored for archival purposes and used only for the purposes approved by the Institutional Review Board / will be destroyed after the recording is transcribed.

*Add the following when recruiting patients into a study when there is a Certificate of Confidentiality:*

The researchers will file a copy of this consent in your medical record. The researchers will place a note in your medical record to let other healthcare providers know that you are participating in a clinical trial.

**Is this research covered by a Certificate of Confidentiality?**

*Include for NIH funded study or when a Certificate of Confidentiality covers non-NIH funded studies.**For more information on COCs and their limitations, see the NIH CoC* [*FAQs*](https://humansubjects.nih.gov/coc/faqs) *on this topic or* [*http://grants.nih.gov/grants/policy/coc/*](http://grants.nih.gov/grants/policy/coc/)

***IMPORTANT REMINDER: A copy of the signed informed consent document which includes the CoC disclosure language must be filed in the medical record to prevent unintentional disclosure by Health Information Management (HIM) pursuant to a request that does not require patient authorization (e.g. court subpoena).***

A **Certificate of Confidentiality** from the National Institutes of Health covers this research. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use.

This certificate prevents disclosure of protected information, documents, or biospecimens to anyone else who is not connected with the research; however, the Certificate of Confidentiality does not prevent disclosure as required by federal, state, or local law when required to share your information with the relevant agency for reporting the following:

* Suspected elder or child abuse or neglect
* Certain communicable diseases
* Possible threat or harm to yourself or others

The Certificate does not cover disclosures for which you have consented, including your medical treatment. The Certificate does not cover disclosures used for other scientific research, as allowed by federal regulations protecting research participants.    
  
*Include the following for federally or state funded/conducted studies, otherwise delete:*

The Certificate does not prevent disclosure of information to the [add US or State Agency/Department sponsor(s)] for the purposes of auditing or conducting a program evaluation.

*Include the following for FDA regulated clinical investigations, otherwise delete:*

The Certificate does not prevent disclosure of information necessary to meet the requirements of the federal Food and Drug Administration (FDA).

*Keep for all studies:*

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must first authorize the researchers to release it.

The Certificate of Confidentiality does not prevent disclosure for any purpose you have authorized within this informed consent document.

**What additional information should I know?**

The researchers will inform you of any significant new information that may affect you in a timely manner. Such information may help you decide if you want to stay in the study. The researchers will share any new information with you if it affects your ability to stay in the study.