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| **INFORMATION SHEET FOR RESEARCH** |

**Instructions: \*The information in red is for guidance. Please remove and replace all red text (including these instructions) and insert study specific information in black ink prior to submitting this document with your IRB application for formal review.**

**TITLE:** “Insert the complete title of the study which needs to be in quotation marks”

**PRINCIPAL INVESTIGATOR:** (Insert the PI’s complete name)

 (Insert the title of PI)

 (Insert the address of PI)

 (Insert the e-mail of PI)

 (Insert the phone number of the PI)

**KEY INFORMATION ABOUT THIS RESEARCH:**

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form. [The following should be all one paragraph:]

The purpose of this study is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

You will be asked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [include a brief statement of the procedures that will be done. For example: You will be asked to complete a survey and a follow-up interview] We expect that you will be in this research study for \_\_\_\_\_\_\_\_\_\_\_\_\_. {hours/days/months/weeks/years, until a certain event] The primary risk of participation is \_\_\_\_\_\_\_\_\_\_\_\_\_\_. The main benefit is \_\_\_\_\_\_\_\_\_\_\_\_\_.

**Purpose of the study**

You are invited to fill out a survey about (insert the topic of the survey (e.g. sexual harassment, smoking, etc.). The purpose of the study is to (insert the purpose of the study in layman terms).

Up to (insert the total number of subjects involved in the study) subjects will participate in the study with up to (insert the number recruited from this site) from this site. Filling out this survey will take about (insert the approximate length of time to participate in this study).

##### Study Procedures

In this section describe, in detail, all procedures that subjects will be asked to complete as part of this study.

**Duration**

In this section describe how long it will take for subjects to complete each procedure explained above and how long it will take to complete the entire study.

## Risks

In this section, describe the potential risks associated with the surveys, procedures or anything else involved with the study. Explain about the risk of confidentiality breach if the study is not anonymous. Also explain any potential risks if this is a survey. (e.g. that some questions may upset the individual, they may become tired or bored.) **Please do not state here that there are no risks in this study. There are risks in EVERY study.**

## Benefits

In this section, list all potential benefits related to the study. If there is no direct benefit to the subject, the following text may be used in this section: “There will be no benefit to you from participating in this study. We hope this study provides information, which contributes to the knowledge of (insert subject of the survey)”.

### Costs

In this section, list all costs incurred by subjects as a result of participating in this study. If there are no costs involved in the study, state: "There is no cost to you for participating in this study."

**Confidentiality**

Unless required by law, only the Principal Investigator and study staff, sponsor representatives involved in this study, independent ethics committees and inspectors from government regulatory agencies will have direct access to the study information. Your name will not be on any documents in the study.

**Voluntary Participation / Early Withdrawal**Your participation in this study is voluntary. You can choose not to take part in the study, or you can quit at any time. (If this study involves students, insert the following “Your decision whether or not to participant in this study will in no way affect your academic standing.”)

**Conflict of Interest:**

## This research is funded by (insert either state the sponsor’s name or state “not funded”). The research team (“is” or “is not”) being compensated by the sponsor for conducting the study. The researchers (“do” or “do not”) however, hold a direct financial interest in the sponsor or product being studied.

**Impartial Third Party Contact**

If you wish to contact an impartial third party not associated with this study regarding any concerns you may have about the study or if you have questions about your rights as a subject in this study, you may contact Steve Schmidt, Ph.D., Human Protections Administrator, Northeast Ohio Medical University, Rootstown, Ohio, 44272, by phone (330) 325-6465 or e-mail sschmidt@neomed.edu for information and assistance.

Include the following sections only if applicable to your study:

**Data Use**

Include 1 of the 2 statements below only if your study includes the use of identifiable private information or biospecimens.

“This study includes the use of your identifiable data or biospecimens. The identifiers might be removed from the identifiable private information/biospecimens and after such removal, the information or biospecimens could be used for future research studies. The unidentifiable date could also be distributed by another investigator for future research studies without additional consent from you.”

OR

“Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

**Commerical Profit:**

The specimens we collect from you may be used for commercial profit. You (will/will not) share in this commercial profit.

**Return of Research Results:**

Clinically relevant research results, including individual research results, will/will not be disclosed to you. (If they will be returned, describe under what conditions)