# SAMPLE CONCISE SUMMARY

**With the Revised Common Rule that went in effect in January 2019 studies with longer consent forms or Federally funded studies a concise summary is required.**

The concise summary is meant to be brief. The purpose of the summary is for the participant to decide why he/she may want to participate but should also include information on why he/she may not want to participate in the study (for example a huge time commitment or other risks). The summary should not include all foreseeable risks but the risks that would be most likely or most severe to the participant.

The summary should include the following 5 elements:

1. A statement that the project is research and that it is voluntary.
2. A summary of the research (purpose, overview of procedures etc.)
3. Any foreseeable risks or discomforts
4. Any expected benefits to participants (if applicable)
5. If applicable, alternative procedures to course of treatment

## CONCISE SUMMARY EXAMPLE – Biomedical (non-drug/device study)

You are being asked to join a research study. The research is to help…….

Before you consider the research you should be aware of the following information:

* Research is voluntary. You do not have to be in this study.
* The study will require 2 visits to the lab for 2 hours (total time of 4 hours).
* We will ask you questions about your health.
* The study involves a blood draw to collect biomarker information and exercise testing.
* If you think you want to be in the study, you should read the rest of this document. The document explains what will happen to people in the study.

## CONCISE SUMMARY EXAMPLE – Social and behavioral

You are being asked to join a research study. The research is to help…….

Before you consider the research you should be aware of the following information:

* Research is voluntary. You do not have to be in this study.
* You will complete pre-screening surveys about your mental and physical health.
* You will have your blood pressure and heart rate measured.
* If after the screening you qualify for the study, you will return to the lab to complete some challenging mental stress tests. This part will be videotaped.
* The pre-screening will take 1 hour in the lab and the study will take 2 hours in the lab.
* If you think you want to be in the study, you should read the rest of this document. The document explains what will happen to people in the study.