COVID-19 RESEARCH PROGRAM

Policy Number: 50GS

Effective Date: 6/01/2020

Revised Date: 11/09/2020

Scope

The policy on the COVID-19 Research Program applies to directors, officers, and members of the nonprofit organizations within the Stowers Group of Companies ("SGC" and "SGC Organizations"), including Stowers Institute for Medical Research ("SIMR") and Stowers Resource Management Inc. ("SRM"), and to individuals who make substantial use of a SGC Organization's facilities, such as post-doctoral research associates, pre-doctoral researchers and approved visitors (collectively, "Covered Individuals").

Purpose

This policy describes Covered Individuals' voluntary participation in human subjects research related to COVID-19.

SIMR's performance of human subjects research on COVID-19 will be governed by the following principles.

> *Human subjects research on COVID-19 has the potential to benefit the SGC as well as the broader community by improving our understanding of COVID-19 infection and immunity.*
>
> *Covered Individuals' participation in COVID-19 human subjects research is voluntary.*
>
> *Participation in voluntary human subjects research is distinct from mandatory COVID-19 testing for occupational health purposes.*
>
> *Although both research and the mandatory testing programs may both involve COVID-19 testing, the programs differ in their intent and management.*

The Graduate School of the Stowers Institute for Medical Research ("The School") is included in the Stowers Group of Companies ("SGC") Organizations and has adopted the following policy as its own.

Policy

Voluntary participation. Covered Individuals may opt to participate in COVID-19-related human subjects research.

Distinction from mandatory COVID-19-related testing. COVID-19 human subjects research is distinct from mandatory COVID-19 testing. The human subjects research seeks to support the development of testing capabilities or to understand additional details of infection or immunity. The mandatory testing focuses on protecting the health of Covered Individuals.

Guidelines and procedures. Covered Individuals who opt to participate in COVID-19 related human subjects research are responsible for adhering to the current guidelines and procedures associated with this policy.

Consequences of non-compliance. Participation in human subjects research is voluntary and will not have any impact on a Covered Individuals' employment status or other association with the SGC. Covered Individuals participating in human subjects research must conform with the requirements of the research study or withdraw from the study.

This policy was approved by the GSSIMR Board of Directors on June 18, 2020.
This policy was last updated by the GSSIMR Board of Directors on November 09, 2020.
This policy will be reviewed by the GSSIMR Board of Directors in 2022.

Policy 50C COVID-19 Research Program Guidelines

1. Overview

A.	*What policy do these guidelines reference?*	Policy Number 50C "COVID-19 Research Program"
B.	*What do these guidelines cover?*	Human subjects research related to COVID-19
C.	*Who must comply with these guidelines?*	"Covered Individuals," defined as directors, officers and members of the SGC or individuals who make substantial use of an SGC Organization's facilities.
D.	*What are the options for Covered Individuals?*	Covered Individuals may opt to participate in human subjects research related to COVID-19

2. Overview of research program

A.	*What are the current research protocols?*	The current research protocols are i. Protocol for Blood Specimen Collection from Volunteers for a COVID-19 Tissue Bank ii. Protocol for Swab or Saliva Collection from Volunteers for a COVID-19 Sample Bank iii. Protocol for COVID-19 Surveillance Research Program – Group Study
B.	*What are the current objectives of the COVID-19 research program?*	The current research objective of the protocol is to support the development of a low cost, high throughput testing capacity for COVID-19 virus and antibodies. The protocols will test various methods and devices for specimen collection, sample preparation, and analysis.
C.	*What are possible future objectives of the COVID-19 research program?*	Future research objectives may include the development of improved testing methods, the description and identification of COVID-19 strains in the community, the time course and distribution of viral load, and the timing or nature of the immune response to infection.
D.	*Who is the SIMR's collaborator in the research program?*	SIMR is performing this research in collaboration with MRIGlobal. MRIGlobal has a CLIA-certified laboratory that will be used to perform some of the testing for the research project. Some of the testing may also be performed at the Institute.

3. Relationship with occupational health-related COVID-19 testing

A.	*What are the differences between research-related and occupational health-related COVID-19 testing?*	The chief difference is the focus on performing research vs. protecting Covered Individuals' health. Participation in research testing is voluntary while participation in occupational health testing is mandatory. In addition, results from research will not be reported back to

		individuals while results from occupational health testing will be reported back to the individual and the Office of Infection Control.
B.	*What is the overlap in staffing between the two programs?*	Laura Remy serves as the Study Coordinator for COVID-19 related human subjects research and also as the head of the Office of Infection Control, which will oversee the COVID-19 related aspects of the occupational health program. Although the roles will be performed by the same person, the roles are distinct.
C.	*How might results from the occupational health-related testing influence the research program?*	Individuals who test positive in occupational health testing for COVID-19 virus or antibodies may be asked to volunteer to have additional specimens taken. These samples may be used to sequence the virus genome, measure viral loads, determine antibody titers or assess the effectiveness of different modifications to the testing procedure. Participation in this subsequent research testing will also be voluntary.

3. Voluntary participation

A.	*How do I volunteer to participate in human subjects research?*	You may volunteer for the human subjects research by responding to a solicitation.
B.	*What is the process for consenting to participate?*	You will meet with a study coordinator who will explain the potential risks and benefits of participating in the study. After the discussion, if you agree to participate, you will receive an informed consent form for your e-signature.
C.	*What are the obligations of participating?*	If you participate, you must comply with the specific study requirements that will be described in the informed consent form.
D.	*What if I change my mind about participating?*	You may withdraw from the study at any time without any adverse consequences.