

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE COVID-19 SCREENING FOR VISITORS	
SOP#: 6.1.2	Original Approval Date: 3/13/20
Version#: 2.0	Current Revision Dates: 4/3/20

1.0 PURPOSE/BACKGROUND

The purpose of this SOP is to provide guidelines for COVID-19 screening of external approved visitors traveling to the MCW Cancer Center Clinical Trials Office (CCCTO). As of March 19th, 2020, Froedtert & Medical College of Wisconsin do not allow visitors/vendors on campus except for certain limited circumstances. On March 25th, 2020, the governor of Wisconsin issued a statewide “Safer at Home” order. Medical College of Wisconsin met that with a work-from-home mandate for all non-essential employees, directly impacting the CCCTO staff.

2.0 SCOPE

This SOP applies to all CCCTO employees and external visitors visiting the MCW CCCTO for research related purposes.

3.0 RESPONSIBILITY

All CCCTO employees and their immediate supervisor.

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Additional definitions:

COVID-19: a highly infectious, highly contagious respiratory disease caused by a novel coronavirus.

“Safer At Home”: A state government order that mandates all residents stay at home as much as possible and non-essential businesses and operations must cease, with limited exceptions for minimum basic operations and working from home.

5.0 ROLES AND PROCEDURES

1. The Medical College of Wisconsin, Froedtert Hospital, and the MCW CCCTO reserves the right to restrict visitors to the CCCTO for safety purposes at any time. As more and more communities are being impacted by COVID-19 and the CDC recommends the practice of social distancing, the CCCTO is asking study monitors to utilize remote monitoring capabilities until further notice. The CCCTO is asking that Site Initiation Visits and Site

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Qualification Visits be done remotely via video conference or teleconference as well.

2. CCCTO staff are required to work remotely until further notice and will be screened for COVID-19 symptoms if the need to visit campus arises, according to Froedtert policy. While working remotely, study staff will attempt to complete data entry in a reasonable amount of time. Staff will make every effort to adhere to the timelines outlined in the study contract, however technical considerations may prevent this from occurring at times.
3. The MCW CCCTO Administrative Director must approve any visitors requesting to visit the MCW CCCTO for professional purposes. Visitors/vendors are no longer allowed on campus except for certain limited circumstances.
4. All approved visitors will be screened within 3 days prior to their visit to the MCW CCCTO for COVID-19 symptoms or risk factors.
5. Visitor Screening Form:
 - a. All visitors approved by the MCW Cancer Center CTO Administrative Director will be required to complete the COVID-19 Visitor Screening Form, via email, within 3 days of their scheduled visit to the MCW CCCTO. An MCW CCCTO staff member will email the form to the potential visitor. (See Appendix 1)
 - b. Failure to complete the above form within a 72 hour timeframe will result in the following actions:
 - An MCW CCCTO Staff member will place a follow up email to the monitor and/or a phone call to complete a verbal screening.
 - If a written or verbal screening cannot be obtained prior to the visit, the visitor will be notified via email that the visit will be postponed or cancelled.
 - c. Upon receipt of the successfully completed form, the form should be filed in the study folder in the shared drive.
 - d. If a visitor presents to the CCCTO showing signs of a suspected illness, the CCCTO reserves the right to check the visitor's temperature and ask them to leave the office if it is above 100.4°F.
6. MCW Cancer Center CTO Staff will be kept aware of any institutional requirements regarding COVID-19 which may override this SOP.

6.0 REFERENCES

Centers for Disease Control and Prevention Coronavirus Disease 2019 (COVID-19) Website: <https://www.cdc.gov/coronavirus/index.html>

Medical College of Wisconsin Infoscope 2019 Novel Coronavirus (COVID-19) information Website. <https://infoscope.mcw.edu/Coronavirus.html> (Only available on campus.)

Froedtert Health Intranet Infection Prevention and Control Website. (Only available on campus.) <http://intranet.froedtert.com/?id=7860&sid=1>

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Department of Health and Human Services, “Safer At Home” Information:
<https://www.dhs.wisconsin.gov/covid-19/prepare.htm>

7.0 APPENDICES

APPENDIX 1: COVID-19 VISITOR SCREENING FORM

MEDICAL COLLEGE OF WISCONSIN CANCER CENTER CLINICAL TRIALS OFFICE COVID-19 VISITOR SCREENING FORM			
Visitor Name:			
Sponsor:			
Study Short Title (Oncore Title):			
<p><i>Although Medical College of Wisconsin has not implemented any formal travel/visitor restrictions at this time, we are attempting to limit visitors by encouraging study visitors to use the remote access option (EpicCare PhysicianLink) and are screening other potential visitors. We are asking visitors to complete the following screening questionnaire within 72 hours prior to your visit. If this questionnaire is not completed or any of the answers below are yes, your visit will be rescheduled.</i></p>			
<input type="checkbox"/> Yes <input type="checkbox"/> No	Fever (> 100.4) or signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath)	AND	Close Contact with a COVID-19 patient within 14 days of symptom onset
<input type="checkbox"/> Yes <input type="checkbox"/> No	Fever (> 100.4) and signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization	AND	A history of travel from affected geographic areas (China, Japan, Iran, Italy or South Korea) within 14 days of symptom onset
<input type="checkbox"/> Yes <input type="checkbox"/> No	Fever (> 100.4) with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without alternative explanatory diagnosis (e.g., influenza)	AND	No source of exposure has been identified
<p><i>Failure to complete the above form or if any of the above answers are YES, your visit will be postponed or cancelled. You may be asked to have your temperature checked upon arrival and if you have a fever above 100.4°F you will be asked to leave the office.</i></p>			

Authorized by:


James Thomas, Medical Director


Betty Oleson, CTO Administrative Director

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