Updated 05/06/20

COVID-19 Guidance for clinical and human subjects researchers:

Clinical and human subjects research occurring at Washington University is highly variable in scope and ranges from observational studies to research on investigational new drugs or devices which may be critically important for patient treatment. To reduce the risk of COVID-19 transmission and promote social distancing, all clinical research visits that can be postponed or performed remotely (e.g. by phone, HIPAA-compliant version of Zoom, local lab or other means) **should continue to be conducted this way whenever possible**. Research that does not explicitly improve or protect the lives of its participants, by providing treatment or otherwise providing medical care, should be regarded as **non-essential.** For non-essential studies requiring direct participant contact, which do not provide a benefit to the participant, new participant recruitment and in-person research visits must be postponed, unless they can be done remotely, **until further notice**. Clinical trials where participation is instrumental in providing care, or for interventional studies where participants have already received an intervention and require ongoing monitoring and follow up for safety reasons should be considered care-related clinical research and many of these visits may be regarded as **essential**.

For additional questions regarding which electronic or telecommunication means to use to communicate with research participants remotely, please refer to the HRPO/IRB FAQ document.

Non-Essential Research Visits
All in person research visits that are not essential to a participant's health and/or well-being must be postponed until further notice. Non-essential research visits may be conducted remotely via telecommunication. Currently, the determination of whether or not a research visit is "essential to the health and/or well-being of a participant" is determined by the principal investigator of the research study, the participant, and the participant's care provider, and should be informed by current public health guidance regarding the COVID-19 outbreak.

Essential Research Visits
Research visits that cannot be performed remotely and are essential to a participant's health and/or well-being may be performed in person, with the following additional guidance:

a) Participants should be provided with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection. This information may be provided in multiple forms suited to the type of contact, including a website link, a telephone script and an in-person handout. If possible, this information should be shared before the research visit. See the following CDC COVID-19 link for reference and materials: https://www.cdc.gov/coronavirus/2019-ncov/index.html.
b) All research participants should be screened for loss of taste, loss of smell, fever, cough and flu-like symptoms, international and domestic travel history, as well as exposure to COVID-19 infected or suspected patients in the prior 14 days by research staff prior to the research visit if possible, with repeat screening by research staff at the time of the visit. Screening should be conducted according to current Washington University

Infection Prevention guidelines: https://fpp.wustl.edu/covid-19-information/. Those who screen positive prior to on-campus, in-person visits should be referred to their primary care physician or triaged per site-specific protocol for clearance to participate in an in-person research visit.

Screening participants

In-Person Interactions with Study Participants

Research participants will be required to complete a short screening for (1) exposure to the novel coronavirus, (2) symptoms of illness, including loss of taste or smell, before they arrive for any study-related visits and in-person interactions, and (3) international and domestic travel history. Research participants with possible exposure or symptoms of illness or high-risk travel history will be scheduled (or re-scheduled) for a future appointment and monitored for illness progression. These are institutional policies rather than IRB protocols, and patients retain the right to delay appointments, or withdraw from an ongoing study at any time.

Pre-Interaction Precautions

Participants should be contacted by telephone or email to complete the questionnaire 24-48 hours prior to their scheduled visit, whenever possible. This brief screening tool should include questions about current symptoms (loss of taste, loss of smell, fever, cough and shortness breath) and potential exposures (travel, contact with known or suspected COVID-19 patient). A link to the currently recommended questions for screening patients seen in the outpatient setting is available at https://fpp.wustl.edu/covid-19-information/guidelines-for-evaluating-suspected-infection-in-the-outpatient-setting/ (Guidelines for Evaluating Suspected Infections in the Outpatient Setting).

Upon Arrival

Before intake, confirm the patient has had no change in their clinical status, no new exposure incidents or travel history since the pre-visit screening. If a participant could not be reached by telephone or email and presents for a scheduled visit, they should be instructed to immediately perform proper hand hygiene and don a mask before the screening evaluation is conducted. If a patient has symptoms, including loss of taste or smell, or experienced a new exposure, contact a clinician (principal investigator or designee) immediately for further evaluation. Based on safety monitoring requirements, the clinician will determine whether the visit should be continued.

How to manage study participants who are interview screen positive

Research participants with possible exposure or symptoms of illness should be scheduled (or re-scheduled) for a future appointment and monitored for illness progression. Future appointments should be made after the participant has clinically recovered or been medically cleared. Participants must comply with all home quarantine recommendations and requirements.

In the instance that a participant screens positive for COVID-19 exposure or potential illness and must be seen for clinical reasons or safety concerns, please follow all current infection prevention guidance, including the following:

Staff and faculty at highest risk should not come into contact with a potentially infected COVID-19 patient. High risk faculty and staff includes adults over the age of 65, and anyone with cardiovascular or pulmonary disease, or who is immunocompromised.

1. Precautions to minimize patient risk to others
    a. The patient will wear a mask
    b. If available, the patient should be isolated in a single-patient, negative pressure room, with the door closed. Otherwise, patients will be placed in a single-patient room with the door closed.
    c. Limit patient movement and transport throughout the facility. Notification and preparations for safe transport of the patient must occur prior to transport.
    d. All clinicians in contact with the patient must comply with current infection prevention precautions (i.e. gown, gloves, face mask).
2. Utilize Personal Protective Equipment
    a. Gloves
        i. Perform hand hygiene, then don clean, non-sterile gloves before entry to the patient's room. Change gloves if they become torn or heavily contaminated. Remove and discard gloves and perform hand hygiene before leaving the room.
    b. Gowns
        i. Don a clean disposable gown before entry into the patient room or area. Change the gown if it becomes soiled. Remove and discard the gown before leaving the patient room or care area.
    c. Respiratory Protection
        i. Don an "ordinary" face mask before entry into the patient room or area for routine assessments.
    d. Eye Protection
        i. Don eye protection (e.g., goggles, a disposable face shield that covers the front and sides of the face) before entry to the patient room or care area. Remove eye protection before leaving the patient room or care area.
    e. Aerosol-Generating Procedures
        i. Procedures that are likely to induce coughing; e.g., nasopharyngeal specimen collection, sputum induction, and open suctioning of airways should be performed cautiously and avoided if possible.
        ii. If these procedures must be done, they should be performed in an Airborne Infection Isolation Room. Individuals present should be limited to only those who are essential.
    f. For explicit instructions for donning and doffing PPE, follow the included links to resources provided by the CDC and BJC Healthcare.
        i. https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf
        ii. https://www.youtube.com/watch?v=YXNVcnxuMmA
3. Patient room disinfection
    a. Rooms should be cleaned using virucidal treatment, then left unoccupied with all doors closed for a minimum of 30 minutes.

b. Gowns, gloves and other PPE should be deposited into biohazard safety bags and in medical waste containers per EH&S and CDC guidelines: https://fpp.wustl.edu/covid-19-information/.

4. All equipment used in handling specimens of screen-positive patients should be disinfected, placed in a bag, and transported to processing facilities/labs using current EH&S guidance.

Advice for External Research Monitors:

Monitoring activity may be affected during this period, and should be converted to remote monitoring whenever possible. Remote access to Epic CareLink to allow remote monitoring is allowed due to COVID-19 crisis. If you have questions regarding how to provide remote access to Epic, please contact the Epic1 Research Team at hipresearchteam@wustl.edu. Monitors who require in-person visits must comply with WU and BJC policies for visitors (https://emergency.wustl.edu/coronavirus-disease-covid-19/interim-policies-on-travel-events-and-visitors/ and https://www.bjc.org/coronavirus).