Ramp Up Plan (Phase 2) During COVID-19: Human Subjects Research
Version 1, August 10, 2020

The IRB office is fast-tracking new COVID-19 related IRB protocols, as well as modifications to utilize remote procedures in currently approved research. It is important to ensure that this work proceeds in as timely a manner as possible.

In addition to this Ramp Up plan, the Guidance for Clinical Trial Research & COVID 19 must be followed, as applicable, which provides general requirements and considerations with respect to patients enrolled, or being considered for enrollment and the management of USA Health Clinical Trials.

Minimum Requirements for Human Subjects Research:

- Limited, lower-risk human subjects’ activities may be allowed. The preference is for remote interactions whenever possible, for safety.

- If activities are approved by the IRB to be conducted in person, additional precautions to protect both research teams and subjects will apply.
  - Social distancing must be maintained. If procedures require less than 6ft of distance, the project must take additional precautions including masks and other personal protective equipment.
  - Schedule appointments to not overlap with other subjects
  - Research areas/equipment must be sanitized between subject visits.
  - Research personnel and subject must wear masks provided by the research team. Subjects should be provided options to wear gloves.
  - For individual contact tracing purposes, maintain a list of all subjects who come on-site and who interacted with them.

- Pre-screening is required prior to subject/visitor coming on campus by completion of a health screening survey for potential exposure to and risk of the COVID-19. See Appendix 1 “COVID-19 Screening Measures” for additional detail. This requirement ensures subject:
  - Has not received a diagnosis of COVID-19 in the past fourteen days,
  - Has not had known close contact with a person who is lab confirmed to have COVID-19 within 14 days,
  - Does not exhibit any of the COVID-19 symptoms, beyond recurring or chronic symptoms:
    - Temperature greater than or equal to 100.4 F
    - Cough
    - Shortness of breath or difficulty breathing
    - Rhinorrhea
    - Myalgia (muscle pain)
    - Unusually severe headache
    - Sore throat
    - Loss of taste or smell
    - Diarrhea

Unless the above data will be analyzed as part of the research or required by the study sponsor, the information does not need to be part of the research record.
• Do not invite subjects in known high risk groups (COVID-19 vulnerable) to campus

• Online Zoom platform
  o Online interviews that require HIPAA or other healthcare privacy compliance must utilize the USA Health Systems HIPAA-compliant ZOOM portal.

**Engagement in the following activities:**

• Online interviews, surveys, and focus groups may continue.

• IRB protocols transitioning to online methodologies (highly encouraged) is permissible after IRB review and approval.

• Research conducted in external clinics/other institutional settings such as schools and prisons is permissible, providing that the external site allows such engagement during the pandemic.

• Research in community settings, including nursing homes, is not permissible during this time. Additionally, face-to-face focus groups are not permissible at this time.

• If you have an IRB protocol that requires the testing of human subjects for research purposes with an FDA approved COVID-19 test, both positive and negative cases must be reported to state/local health authorities. This must be disclosed in the consent form.

• The IRB must be notified and approve change in practices from the originally approved protocol prior to engagement in activities

**USA IRB:**

• The USA IRB will continue to consider the risk/benefit ratio for subject’s participating in research.

• Until further notice, as part of continuing review for existing studies, the IRB will assess the safety of subject’s and the research team in terms of compliance with this plan. In addition to this plan, all human subjects’ research must also comply with guidance provided in the University Research and Scholarship Ramp-Up Plan, as applicable.

• See IRB Review and Research Guidance COVID 19, March 12, 2020 for when and how the IRB must be notified of changes to approved research and other regulatory activities.

**Contact for Additional Questions:**
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APPENDIX 1: COVID-19 Screening Measures

1. Body temperature of subject/visitor must be taken upon site arrival. The measured temperature must be less than or equal to 100.4 degrees F.

2. When subject/visitor appointments are scheduled, the individual will be required to acknowledge that they will only report to the research site if they are well and are not exhibiting symptoms associated with COVID-19 as identified by the Centers for Disease Control (CDC). At the time this policy was approved, these symptoms include fever (over 100.4 degrees F), cough, unusual congestion, shortness of breath, fatigue, muscle or body aches, new loss of taste or smell, sore throat, nausea or vomiting, diarrhea. Further, research subjects will be instructed to contact the research site to reschedule their appointment if symptoms are experienced prior to their scheduled campus visit.

3. A COVID-19 screening questionnaire will be administered to each subject/visitor upon arrival at the research site. Individuals who respond affirmatively to questions regarding exposure and/or symptoms will not be allowed to participate in the research study and will be directed to contact their Primary Care Provider who will determine the need for COVID-19 testing.

4. The research site may consider rescheduling the subject/visitor.
Screening Tool for Coronavirus Disease 2019 (COVID-19)

Name: ____________________________________________________________

Date of Visit: ______________

Study Team member to see subject will verbally ask BOTH of the following questions:

CLINICAL FEATURES

STEP 1

Have you had a fever within the last 14 days?  

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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Have you had symptoms of a lower respiratory illness (cough, difficulty breathing, etc.) within the last 14 days?  

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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If the patient answers YES to EITHER of the above questions, proceed to Steps 2 and 3.

STEP 2

Ensure subject (and any guests accompanying subject) is wearing a mask that covers both nose and mouth.

If the patient answers NO to BOTH of the above questions, subject may proceed with study procedures.

Verbally ask subject BOTH of the following questions:

EPIDEMIOLOGIC RISK

STEP 3

Have you traveled to one of the affected geographic areas* in the past 14 days? (Refer to https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html for updated list; check the list at least daily since the situation continues to change.) *China, Iran, Japan, and Italy are the main countries.

<table>
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<tr>
<th>YES</th>
<th>NO</th>
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Have you had close contact with a person who has a confirmed case of COVID-19 disease? Or have you had close contact with a person while they were ill, and their healthcare provider is working to determine if they have COVID-19?

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<tr>
<th>YES</th>
<th>NO</th>
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If you check YES for any of the above, notify primary care physician (PCP) and / or reschedule study procedures.

If you check NO for any of the above scenarios, proceed with normal research activities.

*Affected areas are defined as geographic regions where sustained community transmission has been identified.