WSU IRB
Investigator Guidance for Conducting Human Subject Research
During the Novel Coronavirus Emergency

To minimize the risk of contracting or spreading COVID-19 in human subject research interactions and to best utilize limited university resources, Wright State University is placing temporary restrictions on human subject research effective Wednesday, March 18 and continuing through May 1. The University will continue to re-evaluate this timeframe and make changes, as needed.

Which studies may continue?

1. On-going studies which offer direct therapeutic benefit (drug or device) to participants
   - Studies that involve the administration of drugs or monitoring of devices that provide direct therapeutic benefit (drug or device) to study subjects may continue. For the purpose of the pause, it is assumed that trials with investigational treatments, including drugs and devices, provide the potential for therapeutic benefit (drug or device) and should continue. To the extent possible, study activities that can be done remotely by telephone or electronically, such as screening or follow-up, should be done in this way. For health and safety, these changes can be instituted immediately; please submit an amendment to the WSU IRB to indicate the temporary modifications.

2. On-going studies that do not involve face-to-face interactions with subjects
   - Studies conducted electronically or via telephone or involving secondary data analysis may continue. Note that both biomedical and social-behavioral research involving face-to-face interactions must be paused unless it meets Criteria 1 described above.

All investigators should evaluate each active study and develop study-specific plans for continuity of operations. These plans should consider the necessity of continuing the research (direct benefit to participants and/or risks of discontinuing the research) and any necessary modifications to study procedures. Use the information below to guide development of the plan. The external Sponsor (for sponsored research) and/or the coordinating center should be contacted as appropriate.

Most minimal risk, short-term, non-clinical treatment studies can be paused until the emergency is lifted without notifying the IRB except for maintaining continuous study approval via continuing review.

However, it is important to note that in accordance with federal regulations, ongoing research must continue to be conducted in accordance with the IRB-approved protocol unless an amendment is approved by the IRB or without IRB approval when necessary to
eliminate apparent immediate hazards to the subject (45 CFR 46.108(a)(3)iii and 21 CFR 55.108(a)).

IT IS IMPORTANT TO UNDERSTAND THE FOLLOWING - If an investigator changes study activities approved in the protocol (i.e. eliminates study visits, clinical testing, etc...) to eliminate immediate hazards to the subject, he/she must submit a Reportable Event Form to the IRB via the electronic submission system within 5 days of this change. If this change will be ongoing, the investigator must also submit an Amendment Form ASAP.

Note that this requirement does not include normal minor study deviations (e.g., a subject’s study visit is delayed by a week due to illness), which should be recorded and reported to the IRB at the time of continuing review. Examples of Deviation and Internal Serious Adverse Events Logs investigators can use can be found on the IRB’s website. It is very important to document all deviations from the protocol and the reasons for these deviations in order to be able to work with the IRB, sponsors and regulators now and after the emergency to meet regulatory requirements.

The WSU IRB Office is available for consultation, but investigators should independently evaluate their specific study circumstances before contacting the IRB Office. Note that IRB resources are also limited and will be focused on supporting research that has direct benefit to subjects or where discontinuation of research would involve risks to subject.

New Initial Study Submissions are strongly discouraged at this time.

Questions to Assist in Creating Study-Specific Plan

1) Contact study sponsors (e.g., federal, industry, private) and/or the coordinating center for study-specific information related to procedures to address the following as indicated:

- Anticipated delays in recruitment for new participants
- How delayed or missed participant contacts/visits for participants may impact ongoing study participation (e.g., whether a missed safety assessment might impact the ability of the participant to receive the next round of therapy)
- If the sponsor anticipates any drug shortages or delays in shipping and the subsequent impact on study conduct
- Any changes to biospecimen/sample storage and shipping requirements
- Changes in any reporting requirements to the sponsor
- Changes in monitoring (implementation of remote monitoring procedures)

2) Develop study-specific plans for each active study considering the following:

- Sponsor provided information (from prior section)
• Need for continuity of the research intervention during the study period.
• Make every effort to change from on-site visits to home visits or telemedicine (or telephone visits)
• Level of relevant pharmacy operations as applicable
• Facility availability
• Study team and clinical staff availability
• Ability to conduct research interventions in current locations per Ohio restrictions and policies
• Orderly withdrawal of subjects if indicated or necessary
• Substantive delays in the ability of the team or participant to complete study procedures
• Other treatment options for patients not able to access clinical trials (e.g., cancer, cardiac patients)
• Maintaining communication with sponsors
• Restrictions or accommodations associated with community recruitment of participants (in the event the study remains open for recruitment)

3) Study team planning

• Identify emergency contacts within the study team
• Develop a communication plan with the study team and participants (i.e., assure participants are kept informed if clinic visits or administration of study intervention is canceled or delayed)
• Prioritize work
  o Do not open new studies if there is no possibility for participant enrollment at this time

4) Continue to prepare and submit necessary IRB forms via rspgateway.wright.edu including amendments, continuing reviews and reportable events.