WSU IRB
Investigator Guidance for Conducting Human Subject Research During the Novel Coronavirus Emergency – May 2020 Update

As of March 18, 2020, Wright State University (WSU) put the following restrictions in place to minimize the risk of contracting or spreading COVID-19 in human subject research interactions and to best utilize limited university resources. Most of these restrictions have been extended due to Ohio's Stay-at-Home Order until May 29, 2020 (see below).

However, to begin to move forward in "opening up" the human subject research program, the WSU IRB will begin reviewing all new study submissions regardless of whether the proposed research exceeds the limitations described below in "Which studies may continue?" The following are changes to the restrictions that will be implemented as of May 4, 2020:

- The WSU IRB will begin reviewing all submissions, regardless of conduct restrictions.
- New IRB-approved research that involves face-to-face interactions to be conducted outside of WSU campus (i.e. Premier, Dayton VA) must not commence until the external entity has also given approval to conduct such activities. WSU IRB approval does not override local facility, sponsor, state requirements/prohibitions.
- New research that involves face-to-face interactions to be conducted on campus remains prohibited and will not receive final WSU IRB approval until campus restrictions are lifted/revised. The University will continue to monitor and evaluate this timeframe and make changes, as needed.

It is important to note that Wright State undergraduate students are still prohibited from participating in any face-to-face human subject research that is part of their educational program at Wright State University.

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 (see below for guidance on developing plans). 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 follow 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.

Questions to Assist in Creating Study-Specific Plans

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 on-going 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 a study-specific plan** 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
    - 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.