

Guidance for Human Subjects Research

Pausing Select Human Subject Research Studies at UB and affiliated institutions

The health and safety of our community is of paramount importance during the COVID-19 emergency. To this end, the University at Buffalo will be temporarily pausing select human subject research activities. This pause will not affect human subject research that includes therapies or procedures directly benefiting study subjects (e.g. clinical trials). The following provides guidance regarding specifics:

Which human subject research studies will this affect?

Studies that involve direct contact with study subjects but have no direct benefit to the subject will be paused until further notice with the exception of studies where study visits can be done remotely and do not use healthcare facility resources (personnel, space).

Some examples of *paused studies* include:

- Studies collecting human samples or imaging that require study subject contact (e.g. phlebotomy, surveillance biopsy, radiographic imaging, physical examination) without direct diagnostic or therapeutic benefit
- Interview studies
- Observational studies involving group gatherings
- Community studies
- Studies involving laboratory analysis of existing studies if the laboratory is temporarily closing (see Laboratory Guidance section).

Examples of studies ***not*** included in the pause:

- Clinical trials with treatment arms (e.g. oncology clinical trials, interventional studies for devices or therapies with significant benefit to subjects). For purposes of the pause, it is assumed that trials with investigational treatments, including drugs and devices, provide the potential for benefit and should continue.
- COVID-19 studies, observational or interventional
- Data analysis only that can be conducted remotely (e.g. EMR, previously collected)
- Studies that do not involve any subject contact (e.g. internet, tele-research, remote device/app)

Can I still enroll patients in clinical trials?

Enrollment in clinical trials should be placed on hold immediately, except where treatment during a clinical trial is medically necessary for the patient, such as some oncology studies and device studies; clinical trials with investigational drugs. Trials with drugs or devices should continue to enroll new subjects only if there are no other treatments available and the subjects would be placed at risk without treatment. Clinical trials with placebo arms should be placed on enrollment hold.

Study staff should contact sponsors of these trials immediately and inform them that enrollment for their study is on hold or will experience limited enrollment for up to 90 days. Document this communication with the sponsors.

Can I get help deciding if my study needs to be paused?

Yes. For clinical trials, please contact the Clinical Research Office (<mailto:ubcro@buffalo.edu>) For other human subject research, please contact the UB IRB (<mailto:karalus@buffalo.edu> or <mailto:ubirb@buffalo.edu>) Indicate what you think is the ethical basis for pausing or continuing the study.

Can studies being conducted entirely during an inpatient admission continue?

Inpatient studies that do not involve direct patient benefit, or that are not part of COVID-19 research efforts, should be paused. Clinical care of our patients with COVID-19 and other conditions is now the priority. The goal here is to free up all staff to respond to this and to minimize patient contact by non-essential personnel when possible. Examples of inpatient studies that should be paused include:

- Comparative effectiveness studies randomizing patients to a placebo/non-intervention arm versus alternative clinical management
- Implementation science trials looking at changes in clinical management
- Survey research on patient perceptions

Do I need to notify the IRB to pause recruitment?

No. To pause recruitment of new study subjects, **you do not need to notify the reviewing IRB.** This is not a change to the protocol, but a temporary halt in enrolling additional subjects, so notification is not required. You do need to notify the study sponsor (see below). You should document the pause in your study files.

- **For research approved by the UBIRB:** If study visits can be conducted virtually (e.g. zoom or telephone), the study teams should document what protocol-specific visits took place by this manner and any missed assessments or items that could not be performed because it was a remote visit. They **should not** submit modifications to add this possibility of remote research visits, as we expect this to be a temporary situation. In addition, these do not need to be submitted as Reports of New Information(RNIs) at this time, we will provide further guidance about how and when to submit this documentation.
- **For research approved by WIRB:** Please note the [WIRB-Copernicus IRB has issued the following guidance.](#)
- **For research approved by another IRB:** Please contact the IRB for their instruction.

Do I need to notify the IRB if all study activities are paused?

Yes, eventually. You must notify the study sponsor (see below). Please track and document all missed visits, procedures, appointments, and other relevant study activities. We are working on a mechanism to report these in aggregate at some point in the near future, rather than reporting each event individually.

Do I need to notify my study subjects of the pause?

Yes. All active study subjects need to be notified of the pause, and what it means for them. We recommend that you do this by phone, but mail and e-mail (if you have consent for email contact) may also be used if needed under these circumstances. You do not need an IRB amendment for this notification.

What should I tell study subjects?

We suggest the following script, which may be adapted to fit your particular study:

Hello, <subject name>. I am calling you today to let you know that several actions have been put into place regarding clinical trials at the UB and all of its locations. Some of these may affect you. These include:

- New enrollment in clinical trials will be severely limited for the next 90 days. If you are screening or have recently consented to participate in a clinical trial, please contact _____.
- If you are in treatment on a clinical trial, you may continue treatment, although the study visit schedule may change. When you come for your treatment, please be prepared to answer questions about your recent trips and health. This screening is intended to protect you, your family, and our healthcare workers, from coronavirus infection. If you are sick, have symptoms, or significant exposure to somebody who is infected with coronavirus, your visit may be rescheduled. We will do everything we can to maintain your treatment schedule.
- If you are having follow up visits, we may reschedule or cancel these visits during the next 90 days. These are not treatment visits. A research team member will contact you to discuss these visits prior to your next visit.

We understand that you may have concerns about your participation in clinical trials. Please contact study coordinator for specific concerns. If you are experiencing adverse events, or have been diagnosed with coronavirus infection, please contact your study team immediately using the 24-hour contact number in your consent form for the study team. Do not call the IRB or the research advocate line unless you cannot reach the study team. Be prepared to provide the name of the study you are in and the Investigator conducting the research.

Document what you have communicated to your study subjects, and when it was communicated.

Do I need approval from the IRB for communications to study subjects explaining the pause in activities?

No. It is not necessary to submit a modification. Keep documentation of dates, times and subjects who were contacted.

Do I need to notify the industry sponsor of my clinical trial?

Yes. If the study is paused, the sponsor will need to be notified.

- *For industry-funded trials*, it is critical for the study coordinators/PIs to be in direct contact with their study monitors, and they should follow up with the Clinical Research Office to determine who else needs to be contacted via the contract.
- *With the federal studies*, study monitors/PI should also continue to communicate with program managers, but official notice has to come from the Sponsored Projects Services. Document the notification and the sponsor's response. The Clinical Research Office and SPS can provide guidance if needed.

Do I need to notify the FDA?

Yes. The FDA will need to be notified if you are considered the sponsor of the study.

Should NIH or other study sponsors (government, foundation, department, UB internal sponsor) be notified?

Yes. The Sponsored Projects Services will be issuing an initial institutional notification to NIH and other sponsors, as suspension of a study represents a major deviation from the program plan. Please reach out to your SPS Agreement Administrator to initiate that communication. Sponsors will be lenient. Any follow-up communications will be sent by your SPS Agreement Administrator for all impacted grants. SPS will notify each PI prior to issuing a follow-up notification to a sponsor. All communication to external sponsors must be issued from SPS. For questions concerning your NIH- and other government- or foundation-sponsored studies, please contact your SPS representative.

Has the NIH issued any formal guidance on clinical trials or other human subjects research activities?

Yes, "Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19"

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>

Additional guidance provided is somewhat broad and more administrative but referenced below. Guidance can be found on the NIH web page for Natural Disasters:

https://grants.nih.gov/grants/natural_disasters.htm

How can I get help addressing ethical issues for a study pause?

Assistance with ethical issues can be obtained from the UB IRB.

What should I do to ensure that subjects in clinical trials remaining open have an adequate supply of study drug?

For clinical trials with investigational drugs, devices and biologics, please confirm with the sponsor that this supply is not at risk. Please review investigational supplies and identify any that will expire within the next 90 days and communicate with the sponsor regarding resupply measures.

What should I do to screen subjects who need to come to UB or its affiliates for a study treatment?

For subjects already enrolled in clinical trials, in-person visits to a UB or affiliate facility should be reduced to the minimum necessary. Subjects who are receiving study treatment should continue treatment according to the protocol unless they fail COVID-19 screening (see screening protocol below). Study visits for subjects who are in follow up, non-treatment phases of clinical trials should be done remotely or by phone if possible; safety follow-up visits should be conducted as medically necessary. All non-treatment clinical trial visits during the next 90 days should be evaluated and conducted if necessary for the safety of the subject. Visits may need to be rescheduled or missed. Contact sponsors immediately to discuss and plan for these scenarios. Document these discussions and decisions. Protocol deviations due to missed visits are highly

likely and should be planned for and documented in accordance with IRB guidance and the protocol.

What is the suggested COVID-19 screening protocol for study subject visits?

Call every subject the day before a UB site or home visit and ask the following travel screening questions:

- *Have you or your family members traveled in the last 14 days?*
If yes, ask for dates and locations of travel. If travel was outside of the local WNY region you may elect to postpone the visit by two weeks.
- *Do you or anyone in your home have any of the following symptoms: cough, fever, shortness of breath? Have you or anyone in your family had any contact with a confirmed COVID-19 patient?*
If yes to either question, then postpone the in-person visit for at least two weeks and make sure they have spoken with a health care professional.
- *All subjects should be re-screened when they arrive for their visit.* If a subject presents with the symptoms listed above at their study visit, terminate the visit and have them contact their primary provider.

How can I switch to performing research visits remotely?

Contact your study sponsor and the reviewing IRB to discuss how best to move forward with performing remote research visits, when possible. Given that we expect this to be a temporary situation, a protocol modification may not be necessary. Sponsors may grant protocol waivers to conduct research in this manner and IRBs may allow for missed assessments and missed visits to be documented and submitted as protocol deviations as this is a required change to research to eliminate apparent hazards to research subjects. The most important aspect is to discuss these issues with both parties. For those studies where WIRB is serving as the IRB of record, please see the [guidance on study modifications and documentation](#). Telephone conferencing can be used to communicate with subjects, depending upon the subject's resources.

What should I do about missed visits for trials that remain open?

If a subject misses a scheduled visit during this period, it should be documented. Contact the study sponsor for guidance on how they would like such notifications and documentation handled. It is likely, given that this will be common during this national emergency, that notification requirements will be given to all study sites.

What should I do to prepare for study subjects being removed from active protocols due to COVID-19 infection?

Review each clinical trial protocol for drug reductions or holds due to serious adverse events or for other reasons. Subjects who are diagnosed with COVID-19 will likely be removed from study treatment by the sponsor or investigator. Treatment schedule modifications or removal from the study for subjects who are in quarantine should be discussed with the sponsor. Items should be reported consistent with the reviewing IRB reporting policies.

The UB IRB would like to be made aware of any subject withdrawals related to a COVID-19 diagnosis. For studies reviewed by the UB IRB or an external IRB, please submit a Report of New Information (RNI) to document the subject withdrawal. Use these templates for documentation of [adverse events](#), [serious adverse events](#) and a [study pause](#) due to COVID-19.

Should I modify my study protocol to reduce risk to my study subjects?

When possible, you should consider such modifications, after speaking with the sponsor and the reviewing IRB (see the [WIRB-Copernicus IRB issued guidance](#)). Eliminating immediate risks may include actions to reduce potential exposure to COVID-19 or to continue to provide medically necessary study care (including study drug) to subjects who have been placed in isolation or quarantine because of suspected or known exposures. We encourage investigators to take necessary steps to eliminate additional risks to subjects.

Depending on the protocol, exposure or a positive test for COVID-19 could be classified as an adverse event, and could also cause a protocol-required reduction or temporary or permanent discontinuation of investigational drug. Giving study drug to isolated or quarantined subjects will also be situational. For example, IV infusions could pose a serious problem if given outside the clinic. The protocols will often indicate under which conditions drugs should be discontinued and how. Death during a study is a serious adverse event. We recommend that study teams communicate with sponsors/clinical research organizations about these scenarios and document the responses.

What if the sponsor issues new guidance or information about COVID-19 risks for my study?

You will need to submit a Report of New Information (RNI) to document this new information. Your study may be paused if the sponsor, Data Safety Monitoring Board (DSMB) or you identify any new increased risk to study subjects related to the protocol. Please contact your UB IRB Representative immediately.

What should I do about study monitor visits?

All monitoring visits, site initiation visits, site qualification visits, should be cancelled immediately and for the next 90 days. To the extent possible, these visits should occur remotely. Contact the study sponsor and/or clinical research organization to communicate this information, and to make arrangements or reschedule. Document the contact in the study documentation.

What facilities exist for virtual visits with study subjects or study monitors?

Telephone conferencing can be used to communicate with subjects, depending upon the subjects' resources.

What should I do about study samples that need to be shipped to the sponsor?

We recommend contacting the sponsor to delay the shipment, unless the samples cannot be stored.

I am concerned about keeping my study coordinators employed. What should I do?

There is probably other work that your study coordinators can be doing (e.g. telephone screening of potential new subjects, OnCore implementation tasks). Many coordinators are also clinically licensed, and you may wish to discuss re-deployment to patient care areas in critical need within your department or other areas. More detailed guidance will be available in the coming weeks. For now, please contact your department administrator for guidance.

How should I handle budget modifications?

Any budget modifications to incorporate costs for remote visits should be sent to the study sponsor's grant/contract representative by your CRO contract administrator or SPS Agreement Administrator.

The study pause could lead to delays in completing my study by the end of the project period. What should I do?

Most federal sponsors, including NIH, allow for a one-time no cost extension for 12 months at the end of the project. Please discuss your specific project with your SPS representative and/or NIH Program Officer, who will provide guidance on the options available to you.

In view of rapidly changing conditions related to the coronavirus outbreak, guidelines may change based on local and national conditions. These guidelines will be updated as needed.