

Temporary UNC Policy on Human Subjects-Related Research Visits at UNC-Chapel Hill during COVID-19 Outbreak Effective March 13th, 2020

In light of recent State of North Carolina and University statements on COVID-19 and the rapidly evolving outbreak, UNC-Chapel Hill is issuing a temporary policy related to human subjects-related research visits. This policy is being implemented to protect research participants, researchers, and the larger UNC community from risk of infection from COVID-19 as well as to ensure ongoing access to research which may provide essential support and care to participants.

This policy does not apply to IRB-approved study activities that do not involve direct subject contact (e.g., chart review, Qualtrics surveys, and remote interviews). Please refer to the Office of Human Research Ethics (OHRE) website and previous communication for submission requirements regarding protocol deviations, exceptions, and emergency use: <https://research.unc.edu/2020/03/10/ohre-irb-covid-19-update>.

This policy will be revised weekly or when appropriate based on new information and circulated to the UNC research community.

- Please send questions and comments on this policy to Andy_Johns@unc.edu.
- More information about the University's response to coronavirus can be found at <https://www.unc.edu/coronavirus/>.

Temporary Policy (Effective March 13th, 2020)

Participants

- Participant research visits should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible. Any deviation from an approved IRB protocol must be approved by the IRB unless such change is necessary to eliminate an apparent immediate hazard. Please see the OHRE website and communication: <https://research.unc.edu/2020/03/10/ohre-irb-covid-19-update>
- Research visits that cannot be performed remotely and do not provide an immediate benefit to a participant's health and/or well-being should be postponed until further notice.
- Currently, the determination of whether or not a research visit provides an immediate benefit 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.
- Research visits that cannot be performed remotely and are essential (provide immediate benefit) to a participant's health and/or well-being may be performed in person, with the following additional guidance:
 - Participants should be provided with information regarding the current COVID-19 epidemic 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>.
 - All research participants should be screened for fever, cough and flu-like symptoms (also inquiring about current season flu and flu vaccine history) by research staff prior to the research visit if possible, with repeat screening by research staff at the time of an in-person visit before being cleared to participate in an in-person research visit. If a participant has fever or symptoms of respiratory illness, they should not come to UNC Hospitals or UNC Health clinics for a research visit and should only come if they are in need of clinical care. More information on screening and triage is available on the UNC Health website (<https://www.unchealthcare.org/coronavirus>).

- Enrollment of new patients on a clinical trial or other human subject-related research should be allowed only if:
 - Participation in the trial is essential to a participant's health and/or well-being, as determined as above; or
 - The enrollment and longitudinal participant management can be conducted remotely for the duration of the COVID-19 outbreak.
- Research studies may be halted if staff, protective equipment, or other required equipment is unavailable.

Research Personnel

- All study personnel (faculty and staff) should receive appropriate training regarding proper research participant screening (e.g., masking protocols) and participant triage should a research participant be deemed at risk for COVID-19 infection during an in-person research visit screening.
- UNC Health is temporarily allowing Remote Research Monitor Visits through EpicCare Link for select cases. EpicCare Link is a view only, web-based view of Epic.
- If your research monitor has requested a remote visit for an upcoming visit, please follow the SOP for Requesting Research Monitor Access and complete the necessary forms as described. In addition, please complete the “Research Monitor Visits during Travel Restrictions” questionnaire. Each request for a remote research monitor visit in Epic will be reviewed and you will be contacted with an approval or denial of the request.

| For these study designs: | Does the specific research visit <u>'provide an immediate benefit to a participant's health and/or well-being,'</u> thus supporting in-person visits? | | |
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| | These visit types LIKELY "provide immediate benefit" (supports an in-person visit) | These visit types MAY OR MAY NOT "provide immediate benefit" (Support for in-person visit will depend on specifics of the study) | These visit types LIKELY DO NOT "provide immediate benefit" (does not support an in-person visit) |
| Randomized controlled efficacy trial (e.g., phase IIb or III) of a potential drug or device or other intervention | <ul style="list-style-type: none"> • New enrollments • Follow ups | | |
| Post-approval trial (e.g., phase IV) of a therapeutic drug, device, or other intervention to assess tolerability and/or long-term benefit | <ul style="list-style-type: none"> • Follow ups | <ul style="list-style-type: none"> • New enrollments | |
| Early phase (e.g., phase I or IIa) pharmacodynamic, safety, tolerability or feasibility trial a potential drug or device or other intervention | <ul style="list-style-type: none"> • Follow ups | <ul style="list-style-type: none"> • New enrollments | |
| Non-randomized interventional trial of a drug, device, or other intervention requiring safety monitoring | <ul style="list-style-type: none"> • Follow ups | <ul style="list-style-type: none"> • New enrollments | |
| Non-randomized interventional trial of a drug, device, or other intervention <u>not</u> requiring safety monitoring | | <ul style="list-style-type: none"> • New enrollments • Follow ups | |
| Comparative effectiveness studies or other study types describing the natural history of disease or other clinical outcomes | | <ul style="list-style-type: none"> • Follow ups | <ul style="list-style-type: none"> • New enrollments |
| Non-interventional qualitative study | | | <ul style="list-style-type: none"> • New enrollments • Follow ups |
| Non-interventional study with collection of clinical data and/or biological specimens for future research | | | <ul style="list-style-type: none"> • New enrollments • Follow ups |