



Important Update: Allowable In-Person Participant Research Visits, Shipping Study Drug to Participant Home, and Use of Zoom

With the ongoing escalation of risk level in St. Louis for spread of the COVID-19 virus, the Human Research Protection Office (HRPO) and the Office of the Vice Chancellor for Research (OVCR) have recently updated Washington University's [Guidance on Clinical and Human Subject Research](#) addressing the on-campus research visits that are and are not allowable to perform in-person, along with additional procedural updates in the [IRB/HRPO FAQ document](#).

Effective March 23, 2020, whenever possible, research visits should be performed remotely. Research visits in an essential clinical and human subject research study that cannot be performed remotely and are essential to a participant's health or well-being may be performed in person by following the additional guidance below:

- The investigator has reviewed the participant's *individualized* risk profile, and determined that the risks of missing the visit are greater than the risks of attending an in-person visit (including potential exposure to COVID-19). The higher risk level for patients > 60 years old or with medical conditions that compromise immune function must be carefully weighed.
- The participants should be provided with information regarding the current COVID-19 pandemic 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.
- Prior to the visit, if possible, and with repeat screening by staff at the time of the visit, all research participants should be screened for loss of taste, loss of smell, fever, cough and flu-like symptoms, international and domestic travel history, as well as exposure to COVID-19 infected or suspected patients in the prior 14 days. Screening should be conducted according to the current Washington University [Infection Prevention guidelines](#).
- The research team has carefully planned how best to optimize the visit workflow to maximize social distancing and minimize participant risk.

Please note that in-person participant visits are no longer permitted for the sole purpose of avoiding irreparable harm to the study's goals.

Please see the [updated IRB/HRPO FAQ](#). The updated IRB/HRPO FAQ addresses the following additional questions and topics:

- Shipping investigational products to participant's homes
- Waiving modification fees for industry supported studies when the changes relate to COVID-19
- Use of Zoom as a remote option
- Alternatives for signatures on HRPO assurance documents

Additional guidance in adapting studies to the COVID-19 pandemic may be obtained by e-mailing Yi Zhang, RN, JD at yizhang@wustl.edu or Suresh Vedantham, MD at vedanthams@wustl.edu.

The updated guidance was developed only after careful consideration by research administration and infectious disease experts at WashU and BJC. We appreciate the challenges that this guidance presents to clinical studies, but these are necessary measures to reduce the spread of COVID-19 and to protect the health of our research participants and our community.

Sincerely,

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