

15. In-person research interactions in Johns Hopkins clinical facilities.

Johns Hopkins has a special duty to protect its patients, research participants, and staff when they enter non-campus facilities. Resumption of research of substantial prospective clinical benefit to participants is a priority. Importantly, for patients obtaining clinical care at Johns Hopkins facilities, the incremental increase in risk of COVID-19 associated with research participation is limited and can be managed by adherence to the health and safety practices at those clinical care sites. As clinical activity resumes at Johns Hopkins facilities, coordination between research and clinical activities is important to limit density and ensure appropriate resource allocation. Research-only visits conducted in Johns Hopkins clinical facilities and research activities conducted in ICTR clinical research units are included as “research in JHU clinical facilities.” Human subject research may restart in the below phases to facilitate a smooth resumption of the substantial research portfolio conducted in JH clinical facilities:

Phase 1: Therapeutic trials/Interventional studies, with potential for direct benefit to study participants. Observational or other minimal risk studies where ALL in-person procedures occur during routine standard of care clinical visits and have minimal participant interaction in terms of duration or activity (e.g., collection of blood or other biospecimens, research quality vital signs). Greater than minimal risk studies of limited or no direct benefit to study participants may resume in this phase, but excluded from this phase are studies that involve: 1) high risk aerosol generating procedures (such as Sputum induction, pulmonary function tests in nonclinical space, sputum culture, pulmonary exercise test) or 2) research participant group activities (greater than 1 research participants plus a parent or LAR not sharing the same household seen at one time).

Phase 2A: Observational studies or clinical trials of limited or no direct benefit to study participants that take place in JHU facilities, including greater than minimal risk studies, that involve: 1) high risk aerosol generating procedures (such as Sputum induction, pulmonary function tests in nonclinical space, sputum culture, pulmonary exercise test), 2) research participant group activities involving between 2 and 8 research participants not sharing the same household seen at one time.

Phase 3: All other protocols involving in-person interaction.

16. In-person research interactions in non-clinical Johns Hopkins-managed facilities.

When engaging research participants in JHU managed facilities settings outside of Johns Hopkins clinical facilities, faculty and research staff must consider the potential risks and benefits of in-person interaction and must follow all JHU facility guidelines on health and safety protections, as described here and in the Return to Campus Guide, as well as all applicable limitations and guidelines applicable to the location where the study takes place.

This guidance includes on-campus research activity conducted outside of facilities where clinical care is provided. Examples of such activity include research studies involving participants in the Homewood campus labs or in Hopkins managed buildings such as the JHSPH’s Lighthouse and Wood Clinic facilities that do not provide clinical care. The planned phases are:

Phase 1: Observational studies or clinical trials of limited or no direct benefit to study participants that take place in non-clinical JHU managed facilities, including greater than minimal risk studies, but excluding those that involve: 1) high risk aerosol generating procedures (such as Sputum induction, pulmonary function

tests in nonclinical space, sputum culture, pulmonary exercise test), 2) research participant group activities (greater than 1 research participant plus a parent or LAR not sharing the same household seen at one time).

Phase 2A: Observational studies or clinical trials of limited or no direct benefit to study participants that take place in JHU facilities, including greater than minimal risk studies, that involve: 1) high risk aerosol generating procedures (such as Sputum induction, pulmonary function tests in nonclinical space, sputum culture, pulmonary exercise test), 2) research participant group activities involving between 2 and 8 research participants not sharing the same household seen at one time.

Phase 3: All other protocols involving in-person interaction.

17. In-person research interactions outside of Johns Hopkins-managed facilities, in the U.S. and internationally, including community-based facilities and in participant homes.

When engaging research participants outside JHU managed facilities, faculty and research staff must consider the potential risks and benefits of in-person interaction in the context of the proposed location of that interaction.

These locations will vary by facility, participant populations, and geography. For studies that involve in-home participant visits, researchers must be prepared to provide *research staff and participants* with appropriate safety equipment (including face coverings) and information to protect them against COVID-19 exposure and transmission. Researchers must also consider risks to others who may be in the home but who are not participants in the research.

For all such in-person studies, including those involving fieldwork, researchers must consider the local epidemiology and mitigation procedures in response to the COVID-19 pandemic. University guidance to Johns Hopkins investigators does not supersede the required compliance to restrictions by local authorities, but JHU researchers may provide protections that go beyond local requirements. For international studies, investigators should consult their local, in-country partners to help guide decisions about resumption of in-person research activities. As a general guideline, research activities should minimally provide social distancing and protection procedures equivalent to those in use in ambulatory settings in their local environment. For example, if a study is occurring in a place where attending to routine outpatient care necessitates wearing a face shield and performing COVID-19 testing, then the research study should include the same protections. Researchers must also address ethical issues such as privacy, mandated public health reporting, and data management. In this climate of rapidly evolving regulatory requirements, resumption plans should address compliance with relevant regulations. The planned phases are:

Phase 1: Therapeutic trials/interventional studies, with potential for direct benefit to study participants. Observational studies or clinical trials of limited or no direct benefit to study participants, including greater than minimal risk studies, but excluding those that involve: 1) high risk aerosol generating procedures (such as Sputum induction, pulmonary function tests in nonclinical space, sputum culture, pulmonary exercise test), 2) research participant group activities (greater than 1 research participant plus a parent or LAR not sharing the same household seen at one time), 3) interventions in facilities (such as nursing homes) where the risk of COVID 19 is high. For studies that take place in international locations, this category of studies may restart subject to local infection control/public health restrictions, using risk mitigation procedures and PPE appropriate to the level of risk for COVID-19 transmission associated with the specific in-person interaction..

Phase 2A: Observational studies or clinical trials of limited or no direct benefit to study participants, including greater than minimal risk studies, that involve: 1) high risk aerosol generating procedures (such as Sputum induction, pulmonary function tests in nonclinical space, sputum culture, pulmonary exercise test), 2) research participant group activities involving between 2 and 8 research participants not sharing the same household seen at one time, 3) interventions in facilities (such as nursing homes) where the risk of COVID 19 is high. For studies that take place in international locations, this category of studies may restart subject to local infection control/public health restrictions, using risk mitigation procedures and PPE appropriate to the level of risk for COVID-19 transmission associated with the specific in-person interaction.

Phase 3: All other protocols involving in-person interaction.