

Criteria for Resuming or Beginning New Research Projects Involving Human Subjects during Research Resumption Phases 3 & 4

(This document was modified from UNH procedures).

When PSU resumes limited on-campus operations, researchers whose studies involve face-to-face data collection activities involving human subjects will need to consider implementing measures to minimize risk of possible COVID-19 exposure for both participants and research personnel before resuming existing studies or beginning new data collection. The PSU Institutional Review Board for the Protection of Human Subjects in Research (IRB) requirements below provide additional steps to protect human research subjects from exposure due to participation in research.

First, all resuming and new research studies must apply for and receive approval from the CRI, EHS, and OAA. The form may be found at https://campus.plymouth.edu/research/wp-content/uploads/sites/163/2020/07/PSU_Phased_Resumption_of_Research_Activity_2020-07-21.pdf

While implementation of some measures for existing studies will not require a modification to an IRB-approved protocol (e.g., screening, social distancing, use of PPE), others will. If contracting COVID-19 is now a potential risk as a result of participation in a research study, before resuming data collection researchers need to submit a modification request to the IRB addressing this new risk, including measures in place to minimize the risk, an updated assessment of the study's risk:benefit ratio, and updated consent/assent information. For new studies (not yet reviewed by the IRB), researchers should address possible COVID-19 exposure as a risk in their application if studies are in any of the three groups listed below.

Definition of Group according to risk:

- Group 1: Studies Involving:
 - ✓ Direct physical contact with participants, including contact for placement of research devices or handling of bodily fluids (e.g., saliva, sweat, urine, blood).
 - ✓ Physical exertion by participants (e.g., VO2 max test, lifting weights).
 - ✓ Populations at higher risk of severe illness from COVID-19 (e.g., people 65 years and older, with underlying medical conditions, or living in nursing homes or long-term care facilities).
 - ✓ Bringing non-student participants on-campus specifically to participate in research.
 - ✓ Bringing together for research purposes more than 10 people in a limited space setting (e.g., classrooms, labs).

- Group 2: Studies Involving:
 - ✓ Face-to-face data collection (e.g., surveys, interviews, focus groups, administration of instruments/measures) in limited space settings (e.g., classrooms, participants' homes, coffee shops) but with none of the attributes listed in #1 and where the use of virtual/remote options (e.g., Qualtrics, phone, Zoom) is not feasible.

- ✓ Observation or videorecording in limited space settings (e.g., classrooms, labs) where the individuals are gathered for non-research purposes (e.g., instruction).
- Group 3: Studies Involving:
 - ✓ Face-to-face data collection in the outdoors (e.g., intercept studies at state parks or other public venues) where appropriate social distance can be maintained.
 - ✓ Data collection where the use of virtual/remote options (e.g., Qualtrics, phone, Zoom) are feasible.
 - ✓ Presence of students on campus in groups, whether in classes, athletic events/competitions, or other gatherings that occur for non-research purposes.

In resuming a research study or when developing a new study that involves face-to-face data collection regardless of Group, researchers need to address 1-5 below:

1. Discuss with research personnel before resuming a study the possible risk of COVID-19 exposure as it pertains to conducting the research study, and only involve those who agree (without undue influence or coercion).
2. Change where possible study procedures (recruitment, consent, or data collection) to minimize exposure.
3. Confirm that all research personnel have been trained before commencing data collection on any new procedures adopted to prevent exposure to COVID-19.
4. Outline contingency plans for the study if studies have to stop again on short notice in the upcoming months in the event that the university stops all on-campus operations and research again due to public health concerns related to a second wave of COVID-19 (e.g., a localized outbreak, another statewide stay at home order).
5. Develop continuity plans for studies in the event that a member of the research team or a participant reports exposure to, developing symptoms associated with, or having tested positive for COVID-19 within 14 days of a data collection event (e.g., visit to a lab, interview). The plan should explain reporting procedures and the assessment of whether to continue the study and any changes or measures implemented to minimize further exposure to COVID-19 for research personnel and other participants.

Different types of studies may need different measures to prevent exposure to COVID-19. Measures to minimize the risk of COVID-19 exposure that researchers in Group 1 need to implement, and Group 2 and 3 may need to implement, as appropriate for the research setting and the study include, but are not limited to:

1. Confirm the following are in place where applicable for Group 1 studies and as appropriate for Group 2 or 3 studies, following University requirements/guidance:
 - a. Procedures for screening of research personnel and research participants for potential risk before they travel to the data collection site or before data collection and documenting such screening (not part of the research record). Screening may be necessary at the mid-point of the day if data collection will last longer than 4 hours.
 - b. Research personnel and participants have the appropriate Personal Protective Equipment (PPE) (e.g., gloves, masks) and have been trained in their use (and documentation of such).

- c. Procedures for cleaning and disinfecting surfaces, equipment, furniture, door handles, etc. regularly and between participants.
 - d. Procedures for personal hand hygiene following direct contact with participants or high touch surfaces.
 - e. Social distancing requirements among research personnel and participants except for when necessary to collect data (e.g., to draw blood, place receptors on a participant).
2. Provide participants with information about the possible risk of COVID-19 exposure as it pertains to participation in the research study.
 3. Provide research personnel and participants instructions on contacting the researcher immediately if they contract COVID-19 (including show symptoms or testing positive).
 4. Reduce number of research personnel present for data collection.
 5. Minimize and stagger participant study visits and time to reduce exposure of participants and research personnel as much as possible.

IRB staff are available remotely to answer questions or talk about studies. Please contact them as follows: Ryanne Carmichael, Director rcarmichael@plymouth.edu and Clarissa Uttley, Assoc. Director cmuttley@plymouth.edu.