Columbia University COVID-19 Guidelines for Human Subjects Research:
All Campuses

Updated March 9, 2022; effective March 14, 2022

These Guidelines are University-wide and are regularly updated\(^1\) in response to changing COVID-19 circumstances.

Current Guidelines:

1. Human Subjects Research (HSR) may be conducted in person, in accordance with an IRB-approved protocol and applicable University COVID-19 health and safety requirements, including those set forth in these Guidelines.

2. Research participants and potential research participants who are University affiliates, e.g., undergraduate and graduate students, may participate in in-person HSR studies on campus in accordance with all applicable campus health and safety requirements. They must wear a non-cloth mask as described in paragraph 4 below.

3. Research participants and potential research participants who are not University affiliates may participate in in-person HSR studies on campus in accordance with the following requirements:
   a) They are allowed to enter Columbia buildings as needed for research or clinical care purposes only;
   b) They must wear a non-cloth mask as described in paragraph 4 below;
   c) They must complete a Health Screening Form on the day of participation. A Spanish version is available;
   d) They are not required to comply with the University’s vaccine policy.

4. All HSR conducted on campus and in the community is subject to the two-way face covering requirement, i.e., both members of the research team and all research participants or potential participants must wear a non-cloth mask at all times while participating in research.
   a) The research team should provide research participants and potential participants for research with non-cloth masks if they do not have one.
   b) Exceptions to this two-way face covering requirement apply only when the research participants are young children less than two years of age or the research project requires unmasking, e.g., to assess interactions between child/adolescent and parent, interactions between child and books/toys, or similar research projects. In such cases, the masking requirement remains for the research team.

\(^1\) Guidelines originally issued on Aug. 26, 2020; previous updates issued on Oct. 20, 2021 and Dec. 23, 2021 (to add Spanish translation of Health Screening Form).
5. HSR conducted off campus, such as community-based research, may be conducted in compliance with the University's Guidelines for Field or Community Research.

6. Federal regulations allow for implementation of changes without prospective IRB approval when it is necessary to avoid imminent harm to participants, e.g., revising in-person procedures to be remote during the COVID-10 pandemic. Such changes should be reported to the IRB at the time of renewal, so the IRB file is complete. Columbia IRBs will not review plans for resumption of in-person procedures.