Columbia University Guidelines for Resumption of Human Subjects Research: All Campuses

October 20, 2021*

The University first issued guidelines for resumption of in-person procedures for human subjects research (HSR) on campus on September 1, 2020. Those Guidelines have now been updated as follows below:

1. HSR may be conducted in accordance with an appropriate IRB approval and pursuant to plans that are developed by principal investigators to ensure compliance with critical health and safety requirements, for both staff and research participants. COVID-19 precautions must be implemented as appropriate. For example, protocols that involve handling materials or keyboards must include appropriate time to sanitize the materials in between participants.

2. HSR studies for which in-person procedures have remained paused may be restarted in phases as needed. Timelines for the restart of in-person research activities should be communicated to faculty, staff, and participants as appropriate.

3. Research participants who are University affiliates, e.g., undergraduate and graduate students, may participate in in-person HSR studies on campus in accordance with the IRB-approved protocol and all applicable campus health and safety requirements.

4. Research participants who are not University affiliates (“non-University participants”) are allowed to enter Columbia buildings as needed, subject to the following requirements:
   a) Non-University participants must comply with any University requirements for face coverings and physical distancing. Additionally, CDC and New York State guidelines require all persons in health care organizations must be masked whether or not vaccinated.
   b) All non-University affiliate participants must complete a Health Screening Form on the day of participation. A Spanish version is available.

5. HSR conducted off campus, such as community-based research, may be conducted in compliance with the University’s Guidelines for the Planning of Resumption of Field Research if permitted by the applicable school, department, center or institute. If there is an external IRB involved, approval from that IRB to start or restart in-person procedures is required in addition to University approval. If there is no external IRB involved, a Columbia IRB-approved protocol and approval by the applicable school, department, center or institute is all that is required.

6. Columbia IRBs will not re-review studies that have already received IRB approval or review plans for resumption of in-person procedures. Any required renewals or modifications, however, must be submitted and approved in accordance with Columbia’s Human Research Protection Program requirements.

*Updated Dec. 23, 2021 to add Spanish translation of Health Screening Form.

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