

## Human Subjects Research Resumption Form

The purpose of this form is to: 1) Evaluate requests to resume or begin in-person human subjects research activities at CUNY Graduate Center and 2) To ensure that all researchers have assessed their situations and have a plan for the health and safety of researchers, participants, and potentially impacted communities prior to resuming research or commencing new research.

### Basic Information

<b>Principal Investigator (PI):</b>	
<b>If PI is a student, Faculty Advisor:</b>	
<b>Protocol Number:</b>	
<b>Study Title:</b>	
<b>PI email address/phone number:</b>	
<b>Funding Source:</b>	
<b>If your research population is only available during a certain period of time please state (i.e. summer, during academic school year, the month of October):</b>	
<b>If PI is a student, state year of schooling/indicate phase of academic progression:</b>	
<b>How many researchers (including faculty, advisors, students) will be present during study procedures? Please list names and school affiliation.</b>	
<b>Abstract/Brief Description of Research Activities:</b>	

<b>COVID-19 Exposure Risk Level (defined on table below) to research participants:</b>	
<b>COVID-19 Exposure Risk Level (defined on table below) to researchers and staff:</b>	

**Study Site/Location Information**

<b>Research Location(s) On-Campus (Specify school and labs, classrooms, other):</b>	
<b>Research Location(s) Off-Campus (Specify site and location type, in-home, public venue, clinic, external lab, business or office space, etc.):</b>	
<b>International site location(s):</b>	
<b>Planned mode(s) of transportation to study site for researcher:</b>	
<b>Expected mode(s) of transportation to study site for participants:</b>	

**Exposure Risk Mitigation Preparedness**

<b>How and when will research personnel be trained on handwashing, face covering, disinfection protocol?</b>	
<b>How will social distancing be maintained?</b>	

<b>How will cleaning be conducted between research activities and visits/interactions?</b>	
<b>What information source will you use to assess local conditions and their plan for changing/suspending research if conditions substantively change?</b> <b>(Example: Researchers in New York City would be expected to routinely monitor updates to local coronavirus conditions and virus-spread mitigation guidelines at <a href="https://coronavirus.health.ny.gov/">https://coronavirus.health.ny.gov/</a>; other states and foreign countries maintain their own equivalent sites.)</b>	
<b>If in the US but outside of NYC, what is the location's current rule on in-person meetings and gatherings?</b>	
<b>If international, what is the location's current rule on in-person meetings and gatherings?</b>	
<b>If international, did you purchase CUNY travel insurance or an equivalent level of coverage? If choosing the non-CUNY policy, please include details of coverage.</b>	
<b>If international, did you obtain approval to travel from the GC?</b>	
<b>Share here if there is any additional information you want to share about your plans/study sites/timeline/requirements and risk</b>	

**mitigation (including added protections, vaccination status, protective gear, time of exposure to participants, etc.):**

COVID-19 Exposure Risk	Study Activities and Examples
<b>NONE</b>	<p>Studies conducted using fully online/distance methods or remote activities</p> <p><b>Example Activities:</b> Online surveys, web-based experimental tasks, virtual interviews and focus groups, phone interviews, telehealth, remote records review, digital archival research, online ethnography (including on social media platforms)</p>
<b>LOW</b>	<p>In-person interactions and procedures that require no physical contact and that can maintain social distancing between all individuals; Can be conducted with limited number of research team members (max 2)</p> <p><b>Example Activities:</b> Behavioral experiments or clinical interventions without physical contact, computerized tasks, observational research in public setting adhering to social distancing guidance, socially distanced interviews and survey completion, library and records reviews involving in-person visit to library or records space</p>
<b>MEDIUM</b>	<p>In-person non-invasive interactions and procedures that require minimal physical contact less than 15 mins but can otherwise maintain social distancing; Physical contact with the participant limited to one research team member; Can be conducted with limited number of research team members (max 2)</p> <p><b>Example Activities:</b> short duration/maximal distancing EEG, EKG, fMRI, Instrument setup including MRI, TMS, DEXA, eye tracking, physical examinations such as balance testing and neurological exam, blood pressure measurements, sleep evaluations, audiology assessment, studies with infants and young children that are not anxiety-provoking resulting in higher than normal concentrations of aerosols/droplets via laughter, crying, screaming, playing, in-person ethnographic and participant observational research that requires brief periods of minimal physical contact and/or proximity (but which otherwise will maintain social distancing)</p>
<b>HIGH</b>	<p>In-person interactions, interventional activities and procedures that require physical contact more than 15 mins or involve collection of biofluid samples through non-aerosolizing methods</p> <p><b>Example Activities:</b> long duration/minimal distancing EEG, EKG, fMRI, MRI, ENG testing, Collection of blood, urine, saliva samples, contact with bodily fluids, interventional activities involving children, in-person ethnographic and participant observational research that requires prolonged (longer than 15 minutes continuous) physical contact and/or proximity (closer than 6 feet)</p>
<b>HIGHEST</b>	<p>In-person interactions, interventional activities and procedures that may or may not require physical contact but likely produce aerosols; Activities and procedures that require direct or close physical contact lasting more than 15</p>

	<p>mins; COVID-19 studies involving patients with current diagnosis, under investigation, or those with active symptoms consistent with COVID-19</p> <p><b>Example Activities:</b> Studies involving exercise, cardiovascular stress testing, pulmonary function tests, infant-child studies that may induce crying, medical procedures including but not limited to intubation, anesthesia, interventional and basic research studies involving COVID-19 patients, participant observation in prolonged group activities (e.g. choral groups, sports teams, religious chanting) where aerosols are being continuously produced <i>and</i> social distancing is not possible</p>
<b>INTERNATIONAL</b>	<p>In the case of international projects, the exposure risk level could fit any of the categories LOW-HIGHEST. However, there are extra considerations that need to be made for research activities outside of the US.</p>

**Required Training**

1. **NYS Blackboard Covid-19 Training**
2. **CITI Program Online Covid-19 Training**  
<https://about.citiprogram.org/en/homepage/>

**Completion Certificates must be submitted along with this form.**