University of Rochester Institutional Biosafety Committee

Form

**HSP**

# *Human Subjects Research - Pandemic Respiratory Aerosols and Droplets*

HSP-(PI last name or lab name)-YY

Principal Investigator: Dept: Phone:

Alternative Contact: Phone:

All RSRB projects that perform respiratory aerosol-generating procedures during the COVID-19 pandemic must:

1. Protect UR personnel from ALL study participants using engineering controls, work practice controls and PPE.
2. Verify SMH Infection Prevention approved procedures and facilities are used.
* RSRB studies

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| --- | --- | --- |
| **RSRB number** | **Known COVID-19?** | **Complete study title**  |
| STUDY0000 |  |  |
| STUDY0000 |  |  |
| STUDY0000 |  |  |

* Personnel and MyPath Training dates
* COVID-19 Safety Training – all personnel must take at least 1 of the 3 courses available

COVID-19 **E**ducation – clinical personnel

COVID-19 **S**afety Training – non-clinical personnel

COVID-19 **L**aboratory Specific Training – clinical or non-clinical personnel working in labs

* Respirator training – all persons wearing N95s or PAPRs (COVID-19 positive or untested participants)

PPE **M**ask Fit Check, and Face Shield – clinical personnel wearing N95s or wearing face shields from Orthotics

EHS **G**eneral Respiratory Protection – non-clinical personnel

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title/Role** | **COVID-19 Safety Training** | **Respirator Training** |
| **Course (E/S/L)** | **Date** | **Course (M/G)** | **Date** |
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* **Aerosol Generating Procedures (AGPs)**

Notes: 1. For checkboxes [ ] , double-click and then select Default Value – Checked or Not Checked. Or, use an X adjacent.

2. COVID-19 test guidance: <https://sites.mc.rochester.edu/departments/infection-prevention/public-health-information/covid-19-2019-novel-coronavirus/covid-19_testing/>

|  |  |
| --- | --- |
| **Aerosol Generating Procedure (AGP) or study participants that may require AGP** | **Negative COVID-19 test (as per IP schedule)?** |
| [ ]  Moderate sedation or general anesthesia  |  |
| [ ]  Airway endoscopies/procedures: **Bronchoscopy, laryngoscopy, upper GI endoscopy** |  |
| [ ]  Pulmonary function testing (PFTs) – Spirometry, **Plethysmography, any forceful expiration with often violent coughing in a tight space** |  |
| **[ ]** Non-invasive positive pressure ventilation (e.g., BiPAP, CPAP) |  |
| [ ]  Cardiac: Exercise stress testing or vigorous exercise, trans-esophageal echo |  |
| [ ]  Other procedures where the study group feels N95s may be required without participant testing (e.g. nasal/sinus visualization, studies involving participants with tracheostomies or chronically ventilated patients, dentistry without sedation, breathalyzers, playing wind instruments, singing) – list: |  |

* Engineering and Environmental Controls (for non-Clinical Spaces, i.e. UR VTEU, HIV CTU)

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| --- | --- | --- | --- | --- | --- | --- |
| **Facility Name or Building, Room Number** | **Aerosol Generating Procedure (AGP) or study participants that may require AGP** | **Airflow direction into/out of room?** | **Room Air Changes per Hour (ACH)** | **% room exhaust** | **Local Ventilation or HEPA?** | **Sink? Eyewash?** |
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CDC room clearance chart [www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1](https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html)

* Work Practices/Administrative Controls
* SMH Infection Prevention - 2019 Novel Coronavirus Disease (COVID-19) (SARS-CoV-2) <https://urmc-smh.policystat.com/policy/8020708/latest/>
* Guidance for Human Subject Research – URMC Operations <https://sites.urmc.rochester.edu/urmc-operations/urmc-redesigned/guidance-for-researchers/human-subject-research/>
* Additional:
	+ For healthy subjects: Normal trash for disposable gowns. Normal linen processing for reusable gowns.
	+ Wash your hands with soap and water when visibly soiled, after body fluid exposure, and after using the restroom. Hand sanitizer is recommended when not visibly soiled.
* Disinfection:
	+ Items that come into contact with mucous membranes require high level disinfection (HLD). Items that come into contact with intact skin require low level disinfection, such as a bleach wipe or CaviWipe.

|  |  |  |
| --- | --- | --- |
| **Disinfectant – Surfaces, Equipment** | **Contact Time** | **Safety/PPE** |
| [ ]  Oxivir 1 or Oxivir TB | 1 minute | None required |
| **[ ]** Spartan TB | 2 minutes | Nitrile gloves and eye protection |
| **[ ]  Wipes – CaviWipes, Clorox** | 3-5 minutes | Dependent on wipe |
| **[ ]  HLD (list):** |  | As per Lab Safety Unit  |

Disinfectants approved by NYS for COVID-19 <https://data.ny.gov/Energy-Environment/New-York-State-Registered-Disinfectants-Based-on-E/t3kw-56y6>

HLDs: <https://sites.mc.rochester.edu/departments/infection-prevention/policy-manual/high-level-disinfection/>

* Personal Protective Equipment (PPE)

<https://sites.mc.rochester.edu/departments/infection-prevention/public-health-information/covid-19-2019-novel-coronavirus/covid-19_masking-ppe/>