Aerosol Generating Procedures - Guidance Document

Biological Safety Committee Approval - 10-15-2020

For procedures that must be conducted on an unmasked research subject.

EHS Guidance for Research with Risk of Aerosol Exposure Among Participants Low Risk for COVID-19 Based on Health Screening.

Notes:

(1)These recommendations for participants considered low-risk for COVID-19 exposure or positivity based on screening and may evolve as changes occur in COVID-19 prevalence, the availability of specific types of PPE, and the development of newer diagnostic tests for SARS-COV-2. Please consult EHS if you have specific questions not addressed in these guidelines.

(2) All research participants should be screened for COVID-19 within 24 hours prior to the procedures (listed below), including temperature screening, questions about symptoms, recent exposure, and travel. Whether to require virologic testing for SARS-CoV-2 before initiating study procedures will be left to the discretion of individual investigators or the settings where the research takes place.

(3) For patients with symptoms, in quarantine, or following exposure to COVID-19, research only procedures should be postponed. The following guidance does not apply to participants who are known to have COVID-19 or considered high-risk (i.e. Persons Under Investigation).

Procedure	Environmental Mitigation	PPE	Disinfection protocol	Notes/Questions
Direct airway contact (e.g. bronchoscopy, endotracheal intubation, BVM ventilation, GI endoscopy) + NIPPV + nebulized treatments	Ventilation commensurate with Yale Facilities re-opening guidance, or a combination of additional engineering controls or PPE approved by Yale EHS has been implemented	N95, N99, N100 (or equivalent P or R respirators), or other HEPA filtered respirator without a breathing valve, face shield, gowns and gloves. Additional PPE may be required based on risk assessment.	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
Smoking and vaping	<u>Staff present</u> in the room, even briefly, to administer assessments or other activities during the vaping/smoking experiment	N95, N99, N100 (or equivalent P or R respirators), or other HEPA filtered respirator without a breathing valve, face shield, gowns and gloves. Additional PPE may be required based on risk assessment.	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
	Self-administered outside the building with staff maintaining distance or in a chamber/room with adequate ventilation and/or filtration AND staff remain outside the room with no exposure to smoke/vapors for the entire experiment	ASTM 2-3 surgical mask, gloves to	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
Pulmonary function tests; Exercise tolerance testing	Staff-administered procedure in a room with adequate ventilation/filtration, but staff are unable to maintain distance during the procedure	N95, N99, N100 (or equivalent P or R respirators), or other HEPA filtered respirator without a breathing valve, face shield, gowns and gloves. Additional PPE may be required based on risk assessment.	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
Brief assessments of exhaled CO and breath alcohol	Conduct in a room with adequate ventilation/filtration, recommend self-administration if possible, with exhalation directed away from staff, consider use of mouthpieces containing filters available for CO meters.	ASTM 2-3 surgical mask, and face shield, gown or lab coat and gloves, following EHS assessment	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
Saliva sampling	self-administered	ASTM 2-3 surgical mask, and face shield, gown or lab coat and gloves, following EHS assessment	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
Other procedures requiring removal of mask by participant (e.g., singing, speaking while videotaping facial muscles)	Staff present in the room, even briefly, to administer assessments or other activities during the procedure.	N95, N99, N100 (or equivalent P or R respirators), or other HEPA filtered respirator without a breathing valve, face shield, gowns and gloves. Additional PPE may be required based on risk assessment.	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.
	Self-administered outside the building with staff maintaining distance or in a chamber/room with adequate ventilation and/or filtration AND staff remain outside the room for the entire period	ASTM 2-3 surgical mask, gloves to disinfect room/equipment	30-60 minute rest period before accessing to disinfect based on room pressure and ventilation cycles	Wait times to clean and disinfect the room may be lowered if an N95 or equivalent respirator is worn after consultation with Yale EHS.