Update to COVID guidance for users of YCCI Clinical Research Units (HRU, CSRU, West Campus)

If your research is being conducted outside of the YCCI space, please follow the guidance of the operating clinical entity or that of Yale Medicine.

We ask for your continued patience as we strive to support the conduct of outstanding clinical research, while we ensure the safety of our participants and research team members. If you have any questions, please feel free to contact Dr. Thomas Carpenter, Medical Director for the YCCI Clinical Research Units (Thomas.Carpenter@yale.edu) and/or Kelly Anastasio, Sr. Associate Director, YCCI Clinical Research Operations (Kelly.Anastasio@yale.edu).

To protect the health and safety of research participants and staff, the following updates to our policy will be implemented as of March 30, 2022:

- Everyone entering YCCI Clinical Research Units is required to wear a mask, even if vaccinated. Participants and medically necessary caregiver/guardian wearing a cloth mask will be given an ASTM disposable face mask.
- Symptom screening with temperature checks/questionnaires will continue.
- All participants enrolled in in-patient, non-therapeutic* research studies need to show proof of being fully vaccinated** for COVID-19 or proof of a negative PCR test taken within 72 hours of the scheduled admission. Provide confirmation of vaccination or negative test by emailing iris.montalvo@yale.edu and carmen.galarza@yale.edu. You may also ask your patient to update their vaccination status via My Chart.
- For out-patient, non-therapeutic visits of GREATER than 4 hours: Participants need to show proof of being fully vaccinated** or proof of a negative test (PCR within 3 days or rapid antigen within 24 hr) prior to the study visit. Please email confirmation of vaccination or negative test to iris.montalvo@yale.edu and carmen.galarza@yale.edu.
• For **out-patient, non-therapeutic visits of LESS than 4 hours**: unvaccinated participants can be scheduled. There is no longer a vaccination or testing requirement for visits lasting less than 4 hours.

• Children younger than 2 years old can participate in studies without testing per investigator discretion.

• Please be advised that all scheduled participants without proof of vaccination or a negative test, if required, will be canceled. Visits can be rescheduled once participants are able to adhere to the guidance.

*"Non-therapeutic" research refers to research participants who are not actively receiving a necessary therapy as part of the research. Participants in trials for COVID-19 vaccines would not be considered in this category. It is advisable that those receiving necessary therapies as part of the research adhere to this policy unless medically contraindicated.

**The CDC has updated its guidance on vaccines to indicate that being ‘up to date with COVID-19 vaccinations’ includes an additional dose of vaccine for individuals who are immunocompromised and a booster for those who are eligible.

For additional information, including Frequently Asked Questions regarding COVID-19 and Human Subjects Research, refer to following Yale Human Research Protection Program (HRPP) guidance.

Individuals conducting off-campus research or field work are required to quarantine and/or test when returning to New Haven in alignment with Yale’s travel policy for students, faculty, and staff.