

IBC Risk Assessment Guidance: Blood-based Products from Recovered COVID-19 Human Subjects

Following CDC, OSHA and international guidance, the Institutional Biosafety Committees (IBCs) of Vanderbilt University (VU) and Vanderbilt University Medical Center (VUMC) have required [BSL-2 containment with enhanced safety practices](#) for lab activities involving samples taken from patients with active COVID-19 infections. Clinical researchers wish to study samples from human subjects that have resolved their COVID-19 symptoms and presumably contain no active virus. This guidance document specifically addresses blood-based products (blood, serum, plasma) collected from human subjects that have resolved their COVID-19 symptoms, and when those samples can be considered to have no further risk than a standard patient sample.

The Biosafety Section of the Office of Clinical and Research Safety (OCRS) in conjunction with the IBC Chairs and other members of the VU and VUMC IBCs researched the criteria that have to be met for work at BSL-2 with a blood-based sample from a COVID-19 patient. At first, criteria based on RT-PCR testing of the patient or the material itself were considered. Unfortunately, current medical findings show that patients can test positive for viral RNA long after resolution of all symptoms and cannot be a reliable measure for being free of infectious virus. Similarly, requiring testing of the material is impractical due to the difficulty of obtaining tests. While criteria for release of a patient from clinical care were also considered, these criteria in and of themselves may not correlate to the presence of infectious virus in one's body fluids.

The working group next looked at the guidance in place for recovered COVID-19 patients to donate convalescent plasma for use as a treatment. According to the FDA's [Recommendations for Investigational COVID-19 Convalescent Plasma](#), a recovered COVID-19 patient is eligible to donate if they have "complete resolution of symptoms at least 14 days before the donation. A negative result for COVID-19 by a diagnostic test is not necessary to qualify the donor". Blood banks are following similar criteria for recovered donor eligibility. Accordingly, the working group reached consensus that this standard is appropriate and proposed its adoption by the IBCs. Going forward, clinical researchers wishing to work with blood-based products from human subjects recovered from COVID-19 at BSL-2 containment must submit documentation to demonstrate that those samples were collected at least 14 days after complete resolution of symptoms. Otherwise, these samples must be handled in accordance with the [Biosafety Action Grid for COVID-19/SARS-CoV-2 Materials](#).

This determination does not extend to other body fluids and tissues from recovered human subjects. OCRS Biosafety and the IBCs will monitor the development of public health agency standards related to these materials and apply these when possible to facilitate research activities involving these clinical samples.