

University of Notre Dame Biosafety Information Regarding COVID-19 Research Projects

Dear Researcher,

With the emergence of SARS-CoV-2 (COVID-19), there is a significant need for research on diagnostics, treatment, epidemiology, and basic biology. Numerous agencies, both government and private, have begun soliciting research proposals for work related to COVID-19. As a prominent research institution with a mission to be a force for good in the world, we anticipate that many researchers will begin to plan experiments related to this field.

We are writing to inform the research community of important biosafety regulations pertaining to work with SARS-CoV-2. While data about the characteristics of the virus are still being collected, the CDC has provided [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19](#).

The NIH Office of Science Policy has issued [Frequently Asked Questions \(FAQs\)](#) regarding this guidance document and relevant Institutional Biosafety Committee (IBC) requirements under the NIH guidelines.

Appendix B-II-D of the NIH Guidelines states:

“Coronaviruses other than SARS-associated coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are classified as RG2 agents. SARS-CoV and MERS-CoV are listed as RG3 agents. RG3 agents are those that are associated with serious or lethal human disease for which preventative or therapeutic interventions *may* be available.”

In keeping with the CDC and NIH guidance, the IBC is requiring that all work with viable SARS-CoV-2 virus be performed at BSL-3 containment. NIH Guidelines also require IBC approval before any BSL-3 work can begin. Additionally, there are training requirements and facility inspections that must be completed before BSL-3 work can begin. Please contact the biosafety officer, Jason DeWispeleare, for guidance if you are proposing work with SARS-CoV-2 that requires a BSL-3 facility.

All other research that does not involve intact, viable SARS-CoV-2 virus, such as work with virus fragments, collection, and analysis of biospecimens and the use of recombinant/synthetic nucleic acids, must also receive IBC approval before work can begin. The biosafety level of containment will be determined by a risk assessment of the materials and procedures listed in the protocol. Please be aware that as more data on the SARS-CoV-2 virus emerges, the CDC and NIH guidelines may be modified. We will keep our research community informed of any such changes.

Below are useful links to relevant sites:

- [CDC Interim Laboratory Biosafety Guidelines](#)

- [NIH FAQs on Interim Laboratory Biosafety Guidance](#)
- [Notre Dame IBC](#)
- [Notre Dame Risk Management & Safety](#)