SARS-CoV-2 (COVID-19) Research Laboratory Biosafety Guidelines

<table>
<thead>
<tr>
<th>Research Activities with Known or Likely Infected Specimens from Humans or Animal Models</th>
<th>Assigned Biosafety Level</th>
<th>Contact for Help, Approvals &amp; Access to Appropriate Laboratory Facilities</th>
</tr>
</thead>
</table>
| • Storage and laboratory work with seed stocks, working stocks or specimens\(^1\) with the intent to grow or use live virus at Duke.  
  • Virus isolation, characterization and/or expansion  
  • Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans" \(^2\)  
  • Use of live SARS-CoV-2 virus in functional assays:  
    • Plaque/Focus Forming Unit assays  
    • Serologic virus capture/binding assays  
    • Therapeutic MIC assays  
    • Live cell sorting with intact virus  
  • Use of live SARS-CoV-2 virus in animal | BSL-3/ABSL3\(^3\) | Gregory D. Sempowski, Ph.D.,  
  Director, Duke Regional Biocontainment Laboratory  
  Duke Human Vaccine Institute  
  Phone: 919-684-4386  
  greg.sempowski@duke.edu  
  https://shared-resources.dhvi.duke.edu/rbl |
| • Processing, aliquoting or preparing specimens\(^1\) for research use and storage  
  • Preparation of chemical- or heat-fixed specimens\(^1\) for microscopic analysis  
  • Nucleic acid extraction of specimens\(^1\) for molecular analysis  
  • Preparation of inactivated specimens for other laboratory assessments  
  • Performing diagnostic tests (e.g. serology) that do not involve activities with the potential to propagate virus  
  • Inoculating bacterial or mycological culture media | BSL-2 with enhancements\(^4\) | Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)  
  Director, Biological Safety / BSO / RO  
  Occupational and Environmental Safety Office  
  Phone: 919-684-8822  
  antony.schwartz@duke.edu  
  https://www.safety.duke.edu/biological-safety |
| • Molecular analysis of already extracted nucleic acid preparations  
  • Analysis of specimens\(^1\) that have been inactivated by a method approved by Duke Biological Safety.  
  • Final packaging of specimens\(^1\) already in a sealed, decontaminated primary container for transport to collaborating laboratories for additional analyses  
    • Specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance, Category B"  
    • Pathologic/microscopic examination of fixed specimens\(^1\) (e.g. formalin-fixed tissues or glutaraldehyde-fixed grids).  
    • Routine staining and microscopic analysis of fixed smears  
    • Routine examination of bacterial and mycotic cultures | BSL-2 | Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)  
  Director, Biological Safety / BSO / RO  
  Occupational and Environmental Safety Office  
  Phone: 919-684-8822  
  antony.schwartz@duke.edu  
  https://www.safety.duke.edu/biological-safety |

\(^*\)Please note that all proposed research with SARS-CoV-2 (COVID-19) requires review by the Biological Safety Division of OESO and will require approval of a Standard Operating Procedure (SOP) for the research. In addition, some research will also require approval by the Institutional Biosafety Review Committee (IBRC) and/or the Institutional Biosafety Committee (IBC), which will be coordinated by Biological Safety Division, biosafety@duke.edu.

\(^1\)Specimens are defined as, but not limited to, blood, serum, plasma, tissues, feces, urine, sputum, mucosal swabs or washes/secretions collected from any species.

\(^2\)For assistance with required import permits and export licenses contact Duke Office of Export Controls (export@duke.edu; 919-613-6800).

\(^3\)Animal Biosafety Level-3 (ABSL-3)

\(^4\)Required Enhancements to standard BSL-2:
  • Any procedure with the potential to generate aerosols or droplets (e.g. vortexing, cell sorting, ELISA plate washing) will be performed in a certified Class II Biological Safety Cabinet (BSC). BSC must be decontaminated with an EPA approved disinfectant for coronavirus.
  • Personnel will wear a closed front gown, mucous membrane splash protection (e.g. full-face shield or surgical mask with safety glasses or surgical mask with goggles) covering the eyes, nose, and mouth and double pair of gloves.
  • Centrifugation of specimens must be performed using sealed centrifuge rotors or sample cups.
  • The use of sharps should be eliminated wherever possible.