Submission of Proposals for COVID-19-Related Research

In order to ensure safe practices and compliance requirements are met, all COVID-19-related research proposals are currently reviewed by an Environmental Health & Safety Biosafety Officer. Depending on the nature of the proposal, additional review may also be required by either the Institutional Biosafety Committee (IBC) or a Rapid Research Review Team (RRRT) sub-committee which reviews work with human specimens. To address timely review of all proposals, the Institutional Biosafety Committee (IBC) is meeting on a modified schedule with increased frequency.

Investigators wishing to perform essential COVID-19-related research should submit for each project:

1. An Appendix A in Rascal that identifies the scope of research, any aerosol generating procedures like centrifugation or FACS, and very specifically in the General Information section, the type of SARS-CoV-2 viral material employed (see examples below).
2. Research with clinical specimens ONLY can receive expedited review by the RRRT. These material are highlighted by (*) in the examples below. As well as an Appendix A, please submit COVID-19 Application to use Human Specimens. Appendix A can be attached to the respective IRB application, or there is already an Appendix A attached, can be submitted a standalone Appendix.

- Viral culture from a repository
- Virus isolation from specimens
- Culture of cells from human specimens
- Full length viral RNA
- Pseudotyped viral vector (lentiviral, VSV)
- Viral genes in plasmids
- Respiratory specimens from COVID-19 patients (swab, BAL, endotracheal wash)*
- Clinical specimens from COVID-19 patients (blood, urine, fecal)*
- Cadaverous tissue*
- Material subjected to viral inactivation in the University’s Biobank*
- Material subjected to viral inactivation in a Columbia University research laboratory*
- Material not inactivated, processed for shipping*
- Material subjected to viral inactivation before receiving at Columbia University (non-infectious)*

In order to follow CDC and University guidance for any work with SARS CoV-2 specimens, specific protocols must be developed, reviewed, approved and then trained on, and strictly followed in order to eliminate the primary mode of SARS-CoV-2 transmission: through direct or indirect contact of mucous membranes with infectious aerosols/droplets and possibly fomites. In the research laboratory many routine procedures can potentially generate aerosols and droplets that are often undetectable. The following laboratory procedures have been associated with the generation of infectious aerosols and droplets: centrifugation, pipetting, vortexing, mixing, shaking, sonicating, removing caps, decanting liquids, preparing smears, flaming slides, aliquoting and loading specimens, loading syringes, manipulating needles, syringes or sharps, aspirating and transferring blood and body fluids, sub-culturing blood culture bottles, spilling specimens, and cleaning up spills.

Please ensure that all Appendix submissions explicitly address these and other aerosol-generating procedures, including engineering controls, administrative controls and personal protective equipment that will be used to meet applicable guidance. Please refer to the guide for enhanced work practices for specimen processing and cell culture for this purpose. Also, investigators are strongly encouraged to avoid the submission of Appendix A documents describing work at multiple levels of risk. For example, the use of non-inactivated samples should be separated from work with pseudotyped virus, or segmented RNA.

Note – Requirements related to the use of in vivo models for COVID-19 research will be forthcoming and will include submission of IACUC protocols in addition to the above.

Need assistance? Email biosafety@columbia.edu

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