GUIDELINES FOR RESEARCH WITH NOVEL CORONAVIRUSES, INCLUDING SARS-CoV-2 (2019-nCoV)

The University of Pittsburgh has developed guidelines to establish a system of education and safeguards to ensure that all Federal, State, and Local regulations and guidelines are met when performing research with novel coronaviruses (n-CoV), including the 2019 novel coronavirus, SARS-CoV-2.

These EH&S Guidelines apply to work with wild-type or recombinant strains of uncharacterized coronavirus, including SARS-CoV-2. Before work with an emerging novel coronovirus may be approved in University facilities, the following requirements must be met.

1. SCOPE

1.1. **Agent –** Coronaviruses are medium-sized enveloped positive stranded RNA viruses in the order of Nidovirales. The viruses' envelope creates a distinctive crown like appearance under the electron microscope. Coronaviruses were identified in the mid-1960s and infect both humans and a variety of animals. Epithelial cells of the respiratory and gastrointestinal tract are the primary target cells. During outbreaks they are the cause of up to one third of community acquired upper respiratory tract infections in adults and may also cause severe respiratory infections in both children and adults. Zoonotic coronaviruses have become cause of recent emerging disease outbreaks in humans and animals. Commonly cited examples are SARS-CoV, MERS-CoV, and porcine epidemic diarrhea virus (PEDV).

Coronaviruses fall into four distinct genera. There are five non-SARS coronavirus serotypes that have been associated with disease in humans. HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, and a novel coronavirus (MERS-CoV) that emerged in 2012.

1.2. **Incidence** – Community acquired coronaviruses are ubiquitous, and outbreaks may happen in any season and can be unpredictable. Annual incidence rates depend on which virus is involved. Urbanization and frequent mixing of different animals in densely populated areas may facilitate emergence and reemergence of some of these viruses. Coronaviruses are known to have high mutation and recombination rates which may allow them to cross species barriers and adapt to new hosts.

1.3. **Sequelae –** Human infections with human coronaviruses are mostly mild and asymptomatic. Severe and fatal infections are sometimes seen in immunocompromised individuals and children. Novel coronavirus-associated disease ranges from asymptomatic to severe disease (MERS), and lower respiratory tract infections are more likely in immunocompromised individuals. The incubation period for coronaviruses varies from 2 to 14 days, with some preliminary research indicating that the incubation period may last as long as 21 days (SARS-CoV-2).

Symptoms of disease include fever, cough, and shortness of breath. Pneumonia is often a common clinical diagnosis. In severe cases of acute respiratory distress syndrome septic shock and multiorgan failure resulting in death may occur. Coronaviruses may also cause gastrointestinal symptoms such as diarrhea.

1.4. **Vaccine** – No specific vaccine for novel coronaviruses is available.

1.5. **Laboratory Hazards and Communicability**

1.5.1. Coronaviruses may be transmitted in the laboratory via animal bite or scratch, percutaneous exposure such as a needlestick or cut, a splash to an open cut or wound, mucous membrane exposure, or possibly by inhalation of an aerosol.

1.5.2. Person-to-person transmission in close contacts (e.g. family members and health care workers) has occurred, and it is thought that person-to-person transmission is limited to these close contacts. However, the potential public health impact of the person-to-person airborne transmission route is of great concern. Transmission may also occur from exposure to body fluids, fecal oral route, and environmental fomites.

1.6. **Employees at Risk**- Handling of wild-type or recombinant strains of coronaviruses or animals infected with wild-type or recombinant strains of these agents, poses a risk of exposure to personnel.

2. GUIDELINES

2.1. All Principal Investigators (PIs) using wild-type or recombinant strains of novel coronavirus (n-Cov) that have not been well described and/or any Group 3 coronaviruses must be registered with the Biosafety Officer/EH&S. Information regarding registration of biological agents may be obtained from the web site www.ehs.pitt.edu.

2.2. All PIs using recombinant strains of any coronavirus must be registered with the University of Pittsburgh Institutional Biosafety Committee in accordance with the NIH Guidelines.

2.3. Work with either Risk Group 3 and/or n-CoV obtained from a human or animal disease outbreak shall be limited to the Regional Biocontainment Laboratory, an EH&S-approved BSL-3/ABSL-3 facility.

2.3.1. Small animals (rodents) infected with wild-type or recombinant coronavirus shall be housed in individually vented caging systems for primary containment.

2.3.2. Other animals (such as ferrets or non-human primates) infected with wild-type or recombinant coronavirus shall be housed in primary containment caging.

2.3.3. Investigators shall notify the Biosafety Officer/EH&S if work with wild-type and recombinant coronavirus is planned in animal species that cannot be housed in primary containment caging as additional facility, work practice, and administrative controls will be required.

2.4. An investigator-specific Biosafety Level 3 Manual is required for all research with wild-type or recombinant strains of n-CoV, and must be approved by EH&S and the University Biohazards Committee prior to initiating research with wild-type or recombinant strains of coronavirus.

2.5. Laboratories shall be inspected by EH&S at least annually to verify appropriate containment, practices, and restricted access.

2.6. Occupational Health Requirements

2.6.1. All personnel entering any BSL-3/ABSL-3 facility at the University of Pittsburgh where coronavirus is in use must be enrolled in the University's Respiratory Protection Program, and must wear a Powered Air-Purifying Respirator (PAPR).

2.6.2. All personnel entering BSL-3/ABSL-3 facilities must have undergone a BSL-3 Worker Health Screening from Employee Health Services in the previous twelve months.

2.11 Laboratory personnel must wear personal protective equipment when handling n-CoV to include at a minimum a full clothing change, facility dedicated scrubs, liquid-barrier coverall suit, a powered air-purifying respirator (PAPR), double gloves, and shoe covers over facility dedicated shoes or liquid impervious boots. All personnel entering BSL-3/ABSL-3 containment facilities must abide by the garbing requirements for the specific facility as established by EH&S. Refer to the University of Pittsburgh Safety Manual Section V, Guidelines 05-003 and 05-023 for more details on Biosafety Level 3 requirements.

2.12 In case of a potential exposure to wild-type or recombinant strains of n-CoV personnel shall be required to follow the post-exposure response procedures outlined in in this University Guideline, the PI's incident response plan, and/or biosafety manual. Risk assessment regarding the exposure will be performed collectively by the Employee Health Services Medical Director, PI, and EH&S.

2.13 In case of a known exposure to wild-type or recombinant strains of n-CoV with a high risk for infection, the exposed individual shall be required to:

2.13.1 Report to Employee Health Services for a clinical assessment, which shall be coordinated with the Allegheny County Health Department. Employee Health Services will make arrangements for the exposed individual to self-isolate at home, and

2.13.2 Remain in self-isolation at home until Employee Health Services and/or the Allegheny County Health Department give permission for individual to return to work (up to 14-21 days post potential exposure).

2.13.2.1 During this period of isolation, absent any signs or symptoms of N-CoV infection, the employee will be given a paid, approved leave of absence by his or her supervisor.

2.13.2.2 If personnel who have had a known exposure to wild-type or recombinant strains of n-CoV begin to develop signs and/or symptoms of disease (e.g. fever, cough, shortness of breath) within 14-21 days of exposure they shall immediately notify Employee Health Services.

2.14 It shall be the responsibility of the Principal Investigator and/or individuals responsible for control of access to a facility where wild-type or recombinant strains of n-CoV are used to assure that individuals handling n-CoV , or animals infected with n-CoV are enrolled in the occupational health requirements of this Guideline; are listed on any relevant IBC and/or IACUC protocol; and have signed an informed consent form agreeing to meet the public health requirements in the event of a known exposure to wild-type or recombinant strains of n-CoV with a high risk of infection.

3. REFERENCES

Lau, S.K.P., Chan, J.F.W. Coronaviruses: emerging and re-emerging pathogens in humans and animals. *Virol J* **12,** 209 (2015). https://doi.org/10.1186/s12985-015-0432-z

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https://www.uptodate.com/contents/coronaviruses accessed 2/13/2020

https://www.cdc.gov/coronavirus/2019-ncov/index.html accessed 2/13/2020

https://www.ecdc.europa.eu/en/factsheet-health-professionals-coronaviruses accessed 2/13/2020

4. INFORMED CONSENT FORM (see next page)

University of Pittsburgh
Informed Consent for Individuals Involved in Research with Novel Coronaviruses Including SARS-CoV-2

_____ _____
Print Name **2P Number**

I understand that due to my potential occupational exposure to novel coronaviruses (n-CoV) including 2019 novel coronavirus (SARS-CoV-2) that I may be at risk of acquiring a serious infection. This infection could be fatal and/or have potential public health consequences. Due to the potential consequences associated with infection, specific control measures are required by Federal, Allegheny County Health Department (ACHD) and/or University guidelines in the event that I have a known exposure to (n-CoV) in the research environment.

I have read and understand the University of Pittsburgh Standard Operating Procedures for (n-CoV), including SARS-CoV-2. I understand that in the event of a known exposure to (n-CoV) in the research environment that I may be required by Federal, ACHD, and/or University guidelines to self-isolate from the general public until Employee Health Services and/or the ACHD clear me to return to work.

I further understand that if flu-like symptoms develop within 14-21 days of a known exposure (as determined by University EH&S under the Standard Operating Procedures) to (n-CoV) in the research environment that I am required by Federal, ACHD and/or University guidelines to report the symptoms immediately to my supervisor and Employee Health Services.

I acknowledge and accept these conditions for working with n-CoV, including SARS-CoV-2 virus at the University of Pittsburgh.

_____ _____
Signature to ACCEPT **Date**

OR, I cannot accept the conditions as described above. I understand that by declining to accept these conditions, my supervisor and/or investigator will be notified of my restriction from handling n-CoV including SARS-CoV-2 at the University of Pittsburgh.

_____ _____
Signature of DECLINATION **Date**