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RESEARCH WITH MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS (MERS-CoV)

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 using MERS-CoV in research.

These EH&S Guidelines apply to work with wild-type or recombinant strains of MERS-CoV. Before work with MERS-CoV may be approved in University facilities, the following requirements must be met.

1. SCOPE

- 1.1. **Agent** – MERS-CoV is a coronavirus, similar to bat coronaviruses, but distinct from SARS-CoV. The virus was first found in Saudi Arabia in 2012(1), and is currently believed to be circulating in the Arabian Peninsula from repeated introduction from camels to humans.
- 1.2. **Incidence** – Current retrospective analysis indicates that the first recognized cases of MERS-CoV infection may have occurred in Jordan in April of 2012. Thus far all cases of MERS-CoV infection have been linked to residence in, or travel to the Arabian Peninsula. A travel-associated case of MERS resulted in 82 laboratory confirmed infections in South Korea between May and June of 2015(2).
- 1.3. **Sequelae** – Within 14 days of potential exposure disease symptoms range from no symptoms to severe acute respiratory disease to death. A fever, cough, and shortness of breath are usually present. Gastrointestinal symptoms may also occur. The current case fatality rate is approximately 30-40% for cases of MERS reported through July 2016(1).
- 1.4. **Vaccine** – No specific vaccine for MERS-CoV is available.
- 1.5. **Laboratory Hazards and Communicability**
 - 1.5.1. The reservoir and mechanism of transmission for MERS-CoV is currently unknown, although camels may be a source of MERS-CoV infection in humans(3). MERS-CoV is known to be transmitted via close contact in families and health care facilities. Airborne transmission is suspected.
 - 1.5.2. MERS-CoV 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.

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1.5.3. 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.

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

2. GUIDELINES

2.1. All Principal Investigators (PIs) using wild-type or recombinant strains of MERS-CoV 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 MERS-CoV must be registered with the University of Pittsburgh Institutional Biosafety Committee in accordance with the NIH Guidelines.

2.3. Work with MERS-CoV shall be limited to the Regional Biocontainment Laboratory, an EH&S-approved BSL3/ABSL3 facility.

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

2.3.2. Other animals (such as ferrets) infected with wild-type or recombinant MERS-CoV 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 MERS-CoV 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 MERS-CoV, and must be approved by EH&S and the University Biohazards Committee prior to initiating research with wild-type or recombinant strains of MERS-CoV.

2.5. Laboratories shall be inspected by EH&S at least annually to verify appropriate BSL-3/ABSL-3 containment, practices, and restricted access.

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2.6. Occupational Health Requirements

- 2.6.1. All personnel entering any BSL-3/ABSL-3 facility at the University of Pittsburgh where MERS-CoV 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 MERS-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 MERS-CoV personnel shall be required to follow the post-exposure response procedures outlined in 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 MERS-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.
 - 2.13.2.1 During this period of isolation, absent any signs or symptoms of MERS-CoV infection, the employee will be given a paid, approved leave of absence by his or her supervisor.

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2.13.2.2 If personnel who have had a known exposure to wild-type or recombinant strains of MERS-CoV begin to develop signs and/or symptoms of disease (e.g. fever, cough, shortness of breath) within 14 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 MERS-CoV are used to assure that individuals handling MERS-CoV, or animals infected with MERS-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 MERS-CoV with a high risk of infection.

3. REFERENCES

- 3.1. CDC Middle East Respiratory Syndrome: About MERS.
<https://www.cdc.gov/coronavirus/mers/about/index.html>; accessed 02/15/2017.
- 3.2. Cho, SY, Kang, JM, et al. MERS-CoV outbreak following a single patient exposure in an emergency room in South Korea: an epidemiological outbreak study. *Lancet* **388**: 994-1001, 2016.
- 3.3. WHO Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Fact Sheet.
<http://www.who.int/mediacentre/factsheets/mers-cov/en/>; accessed 02/15/2017.

4. INFORMED CONSENT FORM (see next page)

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University of Pittsburgh
Informed Consent for Individuals Involved in Research
with Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Print Name

2P Number

I understand that due to my potential occupational exposure to Middle East Respiratory Syndrome Coronavirus (MERS-CoV) 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 MERS-CoV in the research environment.

I have read and understand the University of Pittsburgh Standard Operating Procedures for MERS-CoV. I understand that in the event of a known exposure to MERS-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 days of a known exposure (as determined by University EH&S under the Standard Operating Procedures) to MERS-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 MERS-CoV 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 MERS-CoV at the University of Pittsburgh.

Signature of DECLINATION

Date