INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, August 5, 2020
Time: 10:00 AM – 11:00 AM

Location: Remote via Zoom

Members Present:
1. Thea Brabb, Comparative Medicine (Animal Containment Expert)
2. Lesley Colby, Comparative Medicine (Animal Containment Expert)
3. Richard Grant, Washington National Primate Research Center
4. Kevin Hybiske, Allergy and Infectious Diseases
5. David Koelle, Allergy and Infectious Diseases
6. Stephen Libby, Laboratory Medicine (IBC Chair)
7. Susan Parazzoli (Community Member)
8. Jason Smith, Microbiology (IBC Vice Chair)
9. Eric Stefansson, Environmental Health & Safety (Biosafety Officer, Animal Containment Expert)
10. Paul Swenson, Seattle-King Co. Dept. of Public Health (Community Member)

Commonly Used Abbreviations
IBC: Institutional Biosafety Committee
BSO: Biological Safety Officer
BUA: Biological Use Authorization
BSL: biosafety level
PI: Principal Investigator
IACUC: Institutional Animal Care and Use Committee
NIH: National Institutes of Health
DURC: Dual Use Research of Concern
SOP: standard operating procedure

1. **CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:02 a.m. A quorum was present.

2. **REMINDER:** The IBC Chair reminded attendees that any notes that they retain are subject to public disclosure. A statement was also made about conflict of interest and voting on research proposals as described in the IBC Charter. This includes sharing a grant or a familial relationship.

3. **SUBCOMMITTEE REPORTS**

   a. McClelland, Scott, new, *A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19*

   - Two members of the IBC served as the Subcommittee Reviewers. A third member of the IBC had a conflict of interest and did not vote, but served to answer questions regarding the clinical trial procedures. One of the Subcommittee Reviewers presented the Subcommittee Report.
   - This multi-site, phase III study will evaluate the effectiveness of a novel vaccine to prevent COVID-19 among adults 18 years of age or older compared to a placebo. Participants will remain on the study for two years following administration of the first dose, and will participate in remote weekly checks for COVID-19 symptoms and any adverse events. Symptomatic individuals will undergo testing for SARS-CoV-2. The sites of administration will be at Harborview Medical Center as well as mobile clinic sites.
   - The IBC discussed that evidence of negative RCV testing is needed to work at BSL-1. They also discussed aerosol not being an issue in the administration of this product.
   - When evaluating the risk of the product acquiring replication competence to harm the administrator of drug, it was decided that the administrator should work with BSL-2 personal protective equipment (PPE) attire, and all waste disposal must be conducted under BSL-2 practices.
   - The UW Institutional Review Board (IRB) and The Data and Safety Monitoring Board (DSMB) are responsible for follow up and monitoring of study participants. The IBC and EH&S will consult with UW IRB and Employee Health Center infectious disease physician on their review.
   - The draft BUA letter was shown.
   - The Chair made a motion to make the draft BUA letter a conditional approval for Dr. McClelland pending use of enhanced BSL-2 PPE use at all administration sites as well as receipt and further subcommittee and ad hoc review of the following documentation:
     - RCV testing documentation demonstrating the virus cannot replicate OR documentation from the FDA to state their official judgement about RCV testing
     - FDA Investigative New Drug authorization
     - Informed consent form for study participants
     - Standard operating procedures for clinical site, including the mobile clinic site and to include waste disposal plans
     - Information on the nature of the mobile clinics
   - Approval will be granted by the subcommittee on behalf of the IBC only after all conditions are adequately addressed and documented.
   - Another member seconded the conditional approval motion made by the Chair.

- The Committee voted to conditionally approve the draft BUA for Dr. McClelland. There were two voting abstentions.

4. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

- The IBC will be reviewing their purview as it relates to human gene transfer and recombinant product administration versus IRB responsibility. Additional guidance from the NIH will be sought. This will be an agenda item at the next convened IBC meeting on August 19.

5. MEETING ADJOURNED AT APPROXIMATELY 11:22 A.M.