CDC Institutional Biosafety Committee (IBC) Meeting Minutes

Date: December 19, 2025
Time: 10:30 AM – 12:00 PM
Location: MS Teams meeting

Member	Attendance	Member	Attendance
1. NCEZID/DVBD1	☐	13. NCEZID/DCLSR2	☐
2. NCIRD/DVD	☒	14. IOD/OLSS3	☐
3. NCEZID/DHCPP1	☒	16. NCEZID/DCLSR3	☒
4. IOD/OLSS1	☒	17. NCEZID/OD	☒
5. OCOO/OSSAM/OHC	☐	18. IOD/OLSS4	☒
6. NCEZID/DVBD2	☒	19. NCHHSTP/DHP2	☐
7. IOD/OLSS2	☐	20. Outside Member/Atlanta1	☐
8. NCHHSTP/DHP1	☒	21. Outside Member/Atlanta2	☐
9. NCHHSTP/DTE	☐	22. Outside Member/Fort Collins	☐
10. NCIRD/ID	☒	23. Outside Member/Puerto Rico	☐
11. NCIRD/CORVD	☒	24. CDC/GHC/OD	☒
12. NCEZID/DCLSR1	☒	**Visitor(s) 5**	

Agenda

- **10:30 am EST- Welcome**.
- **OLSR Director Brief:** NOT-OD-25-082: Implementation Update: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
- Review and approval of **September 19, 2025,** Meeting Minutes.
- Review of IBC registrations.
- Other Business: Lab incident report and IBC Charter update

Principal Discussion

- Quorum confirmed.
- Meeting called to order at 10:31 am
- **OLSR Director Brief:** The OLSR Director thanked the members for their contributions and provided briefing on the new NIH memo regarding promoting maximal transparency. CDC will voluntarily comply with the NIH memo. To implement this policy, the following actions will be taken:
    - The CDC IBC will continue to provide annual updates on the IBC membership roster through the NIH-IBC Registration Management System (RMS).
    - The IBC Administrator prepares meeting minutes in accordance with the established SOP.
    - The CDC IBC reviews and approves the meeting minutes at the subsequent IBC monthly meeting
    - The IBC-approved meeting minutes are routed to the ADC and the OLSR Director for review and approval.
    - If revisions are requested, the document is returned to the IBC for revision and then submitted to the OLSR Director for approval, as needed.

- Once final approval is obtained, the IBC Administrator submits an eTicket through the OLSR web ticket system for publication.
- CDC will continue to communicate with the NIH Office of Science Policy (OSP) in receiving updates in the NIH Guidelines and reporting relevant Labortory incidents.

- Review and approval of **September 19, 2025,** Meeting Minutes.
- Review of IBC Registrations.
- Other Business: Lab incident report and IBC Charter update.

Review of IBC Registrations

1. **IBC-2025-271 Renewal**

General Project Description: This protocol covers the steps performed by personnel in the Arboviral Diseases Branch (ADB), Diagnostic & Reference Team, to store, propagate, and use chimeric Tickborne encephalitis virus/Dengue 4 Δ30 for diagnostic testing of TBEV infections using plaque reduction neutralization tests, ELISA, and molecular tests. In addition, to produce and use non-infectious reagents: RNA control for molecular assays, antibody and antigen for serological assays. This protocol also covers other staff within ADB for using the viruses.

Approximate percentage of the viral genome used: <1/2

Applicable Sec of NIH Guidelines: III-D-1-a, III-D-3-a, III-D-3-e, III-D-4

Required biological containment level for the work to be implemented: BSL-2

General points discussed: N/A

Committee Action: Approve as written

2. **IBC-2025-272 Renewal**

General Project Description: We propose to use well established plasmid-based reverse genetics systems to generate reassortant and mutant influenza viruses for the purpose of identifying molecular markers of virulence and transmission. Recombinant viruses will be evaluated in vitro and in vivo for infectivity, virulence and transmissibility. All proposed recombinant viruses are expected to be attenuated compared to their wildtype counterpart.

Approximate percentage of the viral genome used: >2/3

Applicable Sec of NIH Guidelines: III-D-2-a, III-D-3, III-D-4-a, III-D-4-b, III-D-4-c(1), III-D-4-c(2), III-D-4-c(3), III-D-7-a, III-D-7-b, III-D-7-c, III-D-7-d, III-D-7 None of the Above.

Required biological containment level for the work to be implemented: BSL-2, BSL-2E, BSL-3E

General points discussed:

- **Section 3**
  i. IBC noticed that IACUC Protocol #3347MAIFERC will expire at the beginning of February 2026.
- **Section 4.3**
  i. Please upload a Biorisk Assessment (BRA) form to cover additional details regarding the procedures below –
    - The specific influenza strains/variants and their RG classifications
    - A clear description of the aerosol-generating procedures involved
    - The engineering controls that will be used (e.g. Class II BSC, sealed centrifuge rotors)
    - The PPE required, including respiratory protection if applicable
    - Any additional safety measures associated with institution's BSL-2E designation

    Note: The information above will help verify that the proposed work and procedures align with BMBL guidance for aerosol-generating activities with RG2 influenza viruses.

Committee Action: Approve with changes

3. **IBC-2025-274 Renewal**

General Project Description: This is a project that will generate various E. coli expression clones for the production of soluble hemagglutinin and neuraminidase fragments from human, avian and swine influenza viruses (seasonal, zoonotic and pandemic potential) for use as reagents in vaccine studies, development of novel assays, antibody epitope studies and receptor interactions and enzyme activity studies. Studies will include mutational studies to assess effects of mutations on protein stability, receptor specificity.
Approximate percentage of the viral genome used: <1/2
Applicable Sec of NIH Guidelines: III-D-2-a, III-F-8
Required biological containment level for the work to be implemented: BSL-2
General points discussed: N/A
Committee Action: Approve as written

4. **IBC-2025-275 Renewal**
General Project Description: This renewal is for a project that will generate various insect cell expression clones for the production of soluble hemagglutinin and neuraminidase ectodomains from human, avian and swine influenza viruses (seasonal, zoonotic and pandemic potential) for use as reagents in biosensor assays, enzyme/antiviral assays, antibody epitope studies, enzyme assays, receptor interactions and enzyme activity studies. Studies will include mutational studies to assess effects of mutations on protein stability, receptor specificity, as well as Neuraminidase activity and antiviral susceptibility.
Approximate percentage of the viral genome used: <1/2
Applicable Sec of NIH Guidelines: III-D-2a, III-F-8
Required biological containment level for the work to be implemented: BSL-2, BSL-2E, BSL-3E
General points discussed: N/A
Committee Action: Approve as written
Approve as written

5. **IBC-2025-276 Renewal**
General Project Description: This project will express influenza reactive monoclonal antibodies in mammalian 293T cells. Expression vectors will be transfected and the monoclonal antibodies will be secreted and purified from the culture supernatant by regular antibody purification strategies.
Approximate percentage of the viral genome used: N/A
Applicable Sec of NIH Guidelines: III-E, III-F-8
Required biological containment level for the work to be implemented: BSL-2
General points discussed: N/A
Committee Action: Approve as written

6. **IBC-2025-277 Renewal**
General Project Description: Internal nucleoprotein and polymerase subunit proteins from human, swine and avian influenza A and B viruses will be cloned for expression in a baculovirus expression system. Proteins will be used as reagents in assay development, and antibody production.
Approximate percentage of the viral genome used: <1/2
Applicable Sec of NIH Guidelines: III-D-2a, III-D-3e, III-F-8
Required biological containment level for the work to be implemented: BSL-2
General points discussed: N/A
Committee Action: Approve as written

7. **IBC-2025-278 Renewal**
General Project Description: This is a renewal for a project that generates various baculovirus expression clones for the production of soluble hemagglutinin and neuraminidase ectodomains from human, avian and swine influenza viruses (seasonal, zoonotic and pandemic potential) for use as reagents in vaccine studies,

development of novel assays, antibody epitope studies and receptor interactions and enzyme activity studies. Studies include mutational studies to assess effects of mutations on protein stability, receptor specificity, as well as neuraminidase activity and antiviral susceptibility.
Approximate percentage of the viral genome used: <1/2
Applicable Sec of NIH Guidelines: III-D-2a, III-D-3e, III-F-8
Required biological containment level for the work to be implemented: BSL-2
General points discussed: N/A
Committee Action: Approve as written

8. **IBC-2025-279 Renewal**
General Project Description: This project will generate various baculovirus expression clones for the production of soluble ectodomains from human respiratory viruses for use as reagents in current assays and in the development of novel assays.
Approximate percentage of the viral genome used: <1/2
Applicable Sec of NIH Guidelines: III-D-2a, III-D-3e, III-F-8
Required biological containment level for the work to be implemented: BSL-2
General points discussed: N/A
Committee Action: Approve as written

9. **IBC-2025-280 Renewal**
General Project Description: Influenza vaccines include neuraminidase (NA), but it is not antigenically characterized. Vaccine's effectiveness can be improved by achieving NA antigenic match to circulating viruses. NA antigenic analysis requires the use of a different hemagglutinin (HA) in the virus to avoid interference from HA-specific antibodies. To generate reassortant viruses, a reverse genetics technique based on the vaccine donor virus A/PR/8/34 (H1N1), will be used. HA and NA substitutions identified via surveillance will be introduced to determine their role in antigenicity. These experiments will be performed in compliance with BSL-2 or BSL-2E guidelines.
Approximate percentage of the virtual genome used: >2/3
Applicable Sec of NIH Guidelines: III-D-1a, III-D-1-b, III-D-3a, III-D-7, III-F-8
Required biological containment level for the work to be implemented: BSL-2, BSL-2E
General points discussed:
Section 3: Please add microorganism or influenza viral strains used in the protocol
Committee Action: Approve with changes

Other Business

- **Lab Incident Report discussion** – The Alternate BSO briefed the Committee on a laboratory incident involving Recombinant reverse genetics influenza A(H1N1) pdm09 virus based on cold-adapted A/Florida/62/2014 live attenuated influenza vaccine. The incident occurred on November 28, 2025. A preliminary report was submitted to the NIH OSP on December 1, 2025. Upon completion of the incident investigation, a formal report was submitted on December 22, 2025. The investigation found no departures from established procedures. Work was conducted in accordance with the IBC registration and risk assessment. The risk of exposure was deemed low due to immediate implementation of post-exposure procedures, the employee's vaccination status, and the absence of viable virus in the dilution associated with the needlestick. Additional training has been implemented as a corrective action.

- **IBC Charter Update -** The IBC Charter Working Group has completed the draft revision. A full draft will be shared with the committee for feedback before routing to the OLSR Director for review and approval.
- Meeting adjourned at 12:00pm

REYNOLDS M. SALERNO - S

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