

Regular Meeting of the WMed Institutional Biosafety Committee (IBC)
January 27, 2026
1:00pm - 2:00pm
In person Room 423

Meeting Start Time: The Chair confirmed there was a quorum and the meeting was called to order at 1:05pm.

Number of Regular members on the roster: 10; Number required for quorum: 6

1. Attendance

Voting Members Present	
Status	Initials
Chair, Member	NH
Vice Chair, Member	CJ
Member	RV
Member	RP
Member	AC
Member	JD
Member	MC
IBC Coordinator	CJK

Voting Members Absent	
Status	Initials
Community Member	SF
Community Member	RS

Non-Voting Members Present	
Status	Initials
SDRC, Ex-officio	CS
RSO, Ex-officio	PJ

2. Welcome and Updates

- NH welcomed members to the meeting.
- CJK now officially a voting member of the IBC.

3. Conflicts of Interest and Confidentiality

The Chair reminded all members present that any member of the IBC may not participate in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

4. Review of Prior Minutes

a. Approval of 11.17.2025 minutes

Discussion: No comments.

MOTION: A motion was made by RV and seconded by CJ to approve the **11.17.2025**

meeting minutes.

VOTES: Approve

# Present	Votes For	Votes Against	Abstained	Recused	Absent
7	7	0	0	0	3

5. Radiation Safety Updates - PJ

- **Dosimetry Review:** Recent dosimeter data was reviewed, and all exposure levels were within acceptable limits.
- **Annual Laboratory Review:** In December, PJ completed the required annual inspections of the isotope laboratories - one located on the 5th floor and one at the Innovation Center. No deficiencies were identified.
- **Radioactive Waste Storage:** The Innovation Center currently has a substantial volume of accumulated radioactive waste, and the storage cabinet is at full capacity. A waste pickup is being scheduled for next month.
- **CT Machine Replacement:** The CT machine on the 7th floor is being decommissioned and replaced with a new unit scheduled for installation this week. This upgrade requires an amendment to the State of Michigan radiation license, which may take approximately one month to process. As part of the amendment, room shielding must be reevaluated, and State physicists will review the updated shielding analysis and provide comments.
- **New Equipment Details:** The previous CT machine was originally provided as a gift from Stryker. The replacement device offers enhanced internal shielding and allows operation from an adjacent control room, ensuring that wall shielding will adequately protect personnel during use.

RP joined at 1:14pm during Radiation Safety Update

PJ left at 1:15pm after Radiation Safety Update

CS joined at 1:16pm

6. Research Compliance

a. Possible Noncompliance Identified

- Protocol IBC-2024-009 under HH, includes the use of diphtheria toxin and was approved by the IBC in October 2024. In early January 2026, NH completed an additional ABSA course, during which the training covered classification under the NIH Guidelines. During a mock IBC review exercise, toxins such as diphtheria were discussed, and NH realized that HH's protocol may not have been properly categorized under NIH Guidelines Section III-B-1, which requires both NIH OSP and IBC approval prior to initiation of work.
- NH emailed Dr. Kathryn Harris, Director of the NIH Office of Science Policy (OSP), providing a brief description of the protocol and requesting guidance on how to proceed.
- HH has not initiated any work, does not yet have the mice, but has purchased the diphtheria toxin.
- Under Section III-B-1, "Experiments involving the deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 <100 ng/kg" require prior NIH and IBC approval. This includes toxins such as botulinum, tetanus, and diphtheria toxin.

- While NIH OSP and IBC approvals may occur concurrently, IBC approval occurred in October 2024, and the application to NIH OSP was submitted on January 26th, 2026. Although this represents a gap between approvals, work has not begun. The committee discussed that this may be considered a near miss rather than noncompliance. The committee also thinks that the work described would not fall under Section III-B because there is not cloning of the toxin taking place.
- Dr. Harris’s initial response indicated that the work does fall under Section III-B, that an incident report should be filed, and that the PI must not begin work until NIH OSP sets containment conditions. Her email also included the Toxin FAQ and Appendix F list of previously approved toxin experiments.
- An incident report prepared by CJK was shared for committee review. Discussion focused on whether the event should be classified as a near miss, given that the IBC had approved the protocol, NIH OSP approval is now in progress, and no work has been initiated.
- The incident report includes a brief description, a timeline of events, and a Corrective and Preventive Action (CAPA) plan outlining program-level changes intended to prevent similar incidents.
- Additional discussion addressed whether the incident report should be submitted immediately, whether submission should wait until further clarification is received from NIH OSP, and whether filing the incident report would trigger additional NIH follow-up.
- Several clarification questions will be sent to Dr. Harris by NH, including:
 - How this work qualifies under Section III-B when it does not involve cloning of diphtheria toxin; Whether noncompliance occurred because NIH OSP approval was not obtained prior to IBC approval; Whether noncompliance is considered to have occurred even though no work has begun but there was a lack of prior OSP approval?

MOTION: A motion was made by RP and seconded by CJ to wait for clarification before submitting the incident report.

VOTES: Approve

# Present	Votes For	Votes Against	Abstained	Recused	Absent
8	8	0	0	0	2

7. Protocol Updates

- a. **Addition of student to Jondle Protocol – processed administratively**
- b. **Closing Li protocol 2024-005 – processed administratively**

8. Occupation Health Updates - JD

- The committee discussed whether mask fit-testing should be required for all personnel working on the 4th and 5th floors.
- Fit-testing involves a 5-10 minute process required under OSHA standards to ensure that, when respiratory protection is needed in an airborne BSL-2+ exposure scenario, appropriate PPE is provided, properly fitted, forms an effective seal, and that personnel are trained in correct use.
- The committee determined that fit-testing is not required at this time for staff on the 4th and 5th floors because no work is currently conducted on these floors that would necessitate the use of N95 respirators.

9. Biosafety Updates - AC

- **Annual Laboratory Inspections:** Inspections are currently underway and have been going well.
- **Lab Safety Coordinator Meeting:** The meeting was held on January 9th in preparation for the scheduled inspections. Follow ups from that are ongoing with floor cleaning being the main topic.
- **Use or Storage of 37% Formalin:** Formaldehyde procedures and required training materials have been updated over the past year. OSHA compliance requirements must be met for laboratories using or storing formalin. Because WMed does not have a dedicated Environmental Health and Safety (EHS) department, responsibilities are shared among Occupational Health, the Biosafety Officer, and Facilities. Additional air monitoring may be necessary in laboratories that store larger volumes of 37% formalin. The long-term goal is to reduce risk by encouraging laboratories to order smaller quantities or lower-concentration formulations whenever feasible.

10. IBC General Updates:

- **Scheduling Regular IBC Meetings for 2026:** CJK took suggestions for days or times that might work for the group to have a recurring meeting set every other month for 2026. Wednesday afternoons appeared to be the most suitable option for the majority of members.
- **Annual Exemption Form:** The annual exemption forms for all active protocols have been finalized. Only four protocols will be required to complete annual reviews.
- **Anatomy of an IBC Training:** Will take place at the next scheduled meeting.

11. Adjournment:

Meeting ended at 2:16pm.