

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, December 11, 2025
Time: 10:00 am Central Time
Location: Zoom Teleconference
Institution: HealthPartners Institute, Saint Paul, MN
Principal Investigator: Jose Orlando Maldonado-Ortiz, DDS, PhD
Project: Jose Orlando Maldonado-Ortiz, A23-114
Meeting Type: Initial Review of Project and Site
Title: Exploring Mechanisms of Hepatitis C Virus-Associated Xerostomia

1. Call to order:

The Meeting was called to order at 10:00 am Central Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were four Institutional Representatives, the Principal Investigator, and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Principal Investigator provided an overview of the project.

Points of Discussion:

1. The Committee determined as a **Condition of Approval** that a concise project summary be provided for IBC review. The summary should include: a description of the research goals, experimental approaches involved, and a list of all biological materials used (cell lines, vectors, mice).
2. The Principal Investigator stated that the only vector being used in the research is an AAV2 vector encoding E1/E2 proteins from Hepatitis C virus. The Chair noted that use of other vectors would require evaluation by the IBC.
3. The Committee recommended that a vector schematic and that any published literature describing creation and past use of the vector be provided for IBC review.
4. The Principal Investigator stated that the vector has already been produced but if there is an insufficient supply more will be made.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for AAV2 vector creation in 293T cells and handling of samples collected from AAV2-exposed mice.

The Committee determined that **ABSL-2 containment facilities and practices** are required for AAV2 vector administration and sample collection from mice.

The Committee determined that **IBC oversight will continue as long as the research is active** at the institution.

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8. Vote on project:

The Committee voted for following determination on the Project:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following condition must be met before the proposed research can proceed:

- a. A concise project summary must be provided for IBC review. The summary should include: a description of the research goals, experimental approaches involved, and a list of all biological materials used (cell lines, vectors, mice).

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator Qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Principal Investigator provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. An Institutional Representative stated that all needles used in the research have safety mechanisms.
2. An Institutional Representative stated that staff who wear N95 respirators or PAPRs are fit tested on an annual basis as part of an established respiratory protection program.
3. The Principal Investigator stated that the research does not involve specific aerosol-generating activities. The Committee recommended that the Site Inspection Checklist (#13) be revised to indicate this.
4. The Committee recommended at least a 20-minute contact time for bleach and that the Site Inspection Checklist (#18) be revised to indicate this.
5. The Committee recommended that research materials be transported in hard-sided containers, labelled with biohazard symbols, with absorbent material inside and that photos of these containers be provided to IBC Services.
6. The Committee recommended that wooden boards not be used since they are very hard to decontaminate and that the SOP for AAV Vector Delivery into the Mouse SG be revised to reflect this.
7. The Committee noted that AAV vectors are difficult to inactivate and recommended that a list of available onsite disinfectants be provided to IBC Services for review.
8. An Institutional Representative stated that there are multiple types of biohazardous waste containers onsite provided by Stericycle. The Committee recommended that photos of these be provided to IBC Services.
9. The Chair noted that OSHA requires an Exposure Control Plan to be in place if employees may be exposed to blood or other potentially infectious materials at the institution.
10. The Committee recommended that BBP and SOP training logs be provided to IBC Services.
11. The Committee recommended that DOT/IATA training certifications be provided to IBC Services.

11. Site responsibilities:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the Principal Investigator.

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12. Vote on the site:

The Committee voted for following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:58 am Central Time.

15. Post-Meeting Notes: The Condition of Approval was met on the following date: **January 6, 2026**.

Resolution of condition for Conditional Approval:

Condition No.	Resolution	Date of Resolution	Approved by Chair
a.	A project summary, including a description of the research goals, experimental approaches involved, and list of all biological materials used, was provided to IBC Services	01-06-2026	01-06-2026