INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, December 10, 2025**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Inova Health Care Services, Fairfax, VA
Principal Investigator:	**Jafar Al-Mondhiry, MD**
Protocol:	TuHURA Biosciences, Inc., **MCC 2021-01**
NCT Number:	NCT06947928
Meeting Type:	Initial Review of Protocol and Site
Title:	A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of IFx-hu2.0 as an Adjunctive Therapy to Pembrolizumab in Checkpoint-inhibitor Naïve Participants with Advanced or Metastatic Merkel Cell Carcinoma

1. Call to order:

The Meeting was called to order at 10:01 am Eastern 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 two Institutional Representatives 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 Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for IFx-Hu2.0 since it consists of a DNA plasmid administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of IFx-Hu2.0 locally**, provided that all biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

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 Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to reflect that absorbent material will be added to the Ziploc-style bag prior to transporting the study agent.
2. The Committee recommended that Biosafety SOP Section 3.5 be revised to reflect that the sterile gauze pad is disposed of as biohazardous waste after priming the needle.
3. The Committee recommended that Biosafety SOP Sections 5.1.4a.ii and 5.1.4b.ii be revised to reflect that the wet contact time for Peridox RTU is 3 minutes.
4. The Committee recommended that Biosafety SOP Sections 5.2.2, 5.2.3, 5.2.4 and 5.2.6 be revised to reflect either the specific institutional policy referenced or brief details as to what the institutional policy entails.
5. The Committee discussed that two of the seven biological safety cabinets (BSCs) are noted on the certification reports as being in the [redacted] room and the Site Map indicates that there are BSCs in [redacted]. An Institutional Representative confirmed that study agent preparation only occurs inside [redacted]. The Committee recommended that site documents be revised to correctly reflect which BSCs are used for study agent preparation.
6. The Committee recommended that all biohazardous waste containers be labeled with a biohazard symbol.
7. The Committee recommended that an updated photo clearly showing the labeled biohazardous waste container in the [redacted] dosing room be provided to IBC Services.
8. The Committee recommended that site documents be revised to reflect that aerosol-generating activities, such as vortexing, are performed inside of a BSC.
9. An Institutional Representative confirmed that the alternate phone number on the Biohazard Sign is monitored 24/7. The Committee recommended that the sign be revised to reflect this.
10. The Committee recommended that the PPE listed on the Biohazard Sign be in a larger font and bold text.
11. An Institutional Representative confirmed that the internal transport container is hard-sided and that absorbent material is placed inside the container during study agent transport.
12. An Institutional Representative confirmed that the placard next to the door to the [redacted] biohazardous waste storage area is labeled with a small biohazard symbol and that per institutional policy, they are unable to place a larger biohazard sign on the door itself.
13. An Institutional Representative confirmed that plumbed eyewash stations are checked daily and that a log of this action is maintained.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

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

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:17 am Eastern Time.