

HENRY FORD HEALTH INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING



Friday, November 21, 2025

Board Meetings: Quarterly
Quorum = 5

MEMBER ATTENDANCE:

| PRESENT | ABSENT | MEMBER NAME | DEGREE EARNED | AREA OF SPECIALTY | DEPARTMENT | AFFILIATE OF HFH? |
|---------|--------|-----------------------------|---------------|----------------------------|---------------------------------------|-------------------|
| I | | Wilson, George (C) | PhD | Biomedical/Radiobiology | Research Administration | Yes |
| I | | Palanisamy, Nallasivam (VC) | PhD | Genomics Technology | Urology | Yes |
| I | | Baker, Kevin C. | PhD | Animals | Bone and Joint | Yes |
| I | | Bobbitt, Kevin | PhD | Viral Immunology | Public Health Services | Yes |
| V | | Hay, Nancy | MHSA | Community Interest | Non-Affiliated | Yes |
| I | | Liu, Xianshuang | PhD | Gene Therapy | Neurology | Yes |
| I | | Notebaert, Andrea | BS | Animals | Bioresources | Yes |
| V | | Nyati, Shyam | PhD | Gene Therapy | Radiation Oncology | Yes |
| V | | Ramesh, Mayur | MD | Human Clinical Trials | Infectious Disease | Yes |
| I | | Swiecki, Mark | BS | Community Interest | Non-Affiliated | No |
| V | | Woodcroft, Kimberly | PhD | Biostatistics/Epidemiology | Biostatistics & Research Epidemiology | Yes |

IBC Quorum Rules: *The National Institutes of Health (NIH) Guidelines, which govern recombinant and synthetic nucleic acid research, do not explicitly define a quorum for an IBC; however, HFH IBC considers a quorum to be a majority of the total voting membership (50% of the membership for the year plus one).*

CONSULTANTS/INVITED GUESTS:

| PRESENT | NAME | DEGREE/S EARNED | ROLE | AFFILIATED W/ HFH? |
|---------|------------------|-----------------|-------------------------|--------------------|
| I | Combs, Lena | BS, MJ | Research Administration | Yes |
| | Eliya, Sonia | PharmD | Research Pharmacy | Yes |
| | Pabla, Pardeep | PharmD | Research Pharmacy | Yes |
| I | Raju, Vivek | MS | Research Administration | Yes |
| | Trancik, Emily | PhD | Ethics | Yes |
| | White, Mary Jo | MBA | Compliance | Yes |
| I | Hughes, Jennifer | | Research Administration | Yes |

Others Present may include regularly attending consultants, IBC administrative staff and representatives of the HFH Office of General Counsel. Consultants/Staff are not members of the IBC and shall not vote. However, they must disclose any conflicts of interest. During this meeting, staff or consultants may be called upon to provide advice or counsel to the IBC concerning study activities.

Presiding: George Wilson, Ph.D., Chair

Recording: Minutes for this meeting were recorded by Vivek Raju, Senior Research Compliance Coordinator.

1.0 GENERAL INFORMATION

1.1 QUORUM AND CALL TO ORDER

The Chair of the meeting verified that quorum requirements were met. The meeting was called to order at 11: 56 AM with 11 of 11 members present. The meeting was conducted in person at Henry Ford One Ford Place Research Administration Conference room as well as via video conferencing, and it was confirmed that all present members were able to participate in the discussion. All IBC members and consultants received access to all pertinent materials for review prior to the meeting.

1.2 REVIEW OF PREVIOUS MEETING MINUTES


The meeting minutes from the previous IBC meeting on July 18, 2025 were provided to all the attendees prior to the meeting for review. The minutes were voted on and approved by the committee with minor edits to be made to the reviewer names listed.

| APPROVED: Minutes were approved with minor edits to reviewer names listed to be made administratively. | | | | |
|---|-------|-----------|-------------|--------------|
| TOTAL MEMBERS VOTING | # FOR | # AGAINST | # ABSTAINED | # RECUSAL(S) |
| 11 | 11 | 0 | 0 | 0 |

1.3 DISCUSSION REGARDING HFH IBC OVERSIGHT OF PDX STUDIES

The committee went over a presentation from Dr. G. Wilson regarding the HFH IBC's oversight of studies involving chemotherapeutic agents and patient derived xenografts.

2.0 REVIEW OF APPLICATIONS

| Event Type | Agenda # | Reviewers | PI | Protocol # | Protocol Title: |
|--------------------------|----------|---|--|------------|---|
| New Protocol Application | 2.1 | Baker, Kevin, PhD <i>Primary</i> Woodcroft, Kim, PhD <i>Secondary</i> Swiecki, Mark, BS <i>Non-Affiliated Reviewer</i> |  | IBC2025.16 | Regulation of MAIT Cell Development and Function by microRNAs and Histone Modifications |

PURPOSE: The study is to investigate how MAIT cells respond to various infections in the context of miRNA and histone demethylase enzymes. By utilizing models of infection in which bacteria is given through oral gavage or through intranasal exposure will uncover the role MAIT cells play in mediating the responses to infections.

Training: Complete for all study members listed.

RG2, BSL-2 NIH Section III-F

REVIEWER PRESENTATION AND DISCUSSION:

-K. Baker provided an overview of the submission. Dr. M. Ramesh recommends that they provide an SOP on the intranasal delivery of substances as well as details on the amount of potential aerosolization. Dr. M. Ramesh also recommended that the provided SOP include oral Personal Protective Equipment requirements for those dealing with aerosolized substances. A. Notebaert also noted that the euthanasia mentioned in the protocol is not standard procedure in the ABSL2 room, and the study team will need to provide specified arrangements with Bioresources for the anesthesia. K. Baker motioned to withhold pending response to the requested changes.

ACTION TAKEN BY IBC: Approved with Conditions. The IBC action was taken pursuant to a motion made by the reviewer of this study which was seconded by another IBC committee member:

| <u>Approved with Conditions:</u> The protocol will need to be resubmitted with the following requested changes to be reviewed via expedited procedures by a Committee member: -Provide an SOP for the intranasal delivery of substances, as well as provide more details regarding the amount of aerosolization. This SOP should include Oral PPE requirements for anyone dealing with aerosolized substances. -Arrangements will need to be made with Bioresources regarding the use of euthanasia in the ABSL2 Room. | | | | |
|---|--------------|------------------|--------------------|---------------------|
| TOTAL MEMBERS VOTING | # FOR | # AGAINST | # ABSTAINED | # RECUSAL(S) |
| 11 | 11 | 0 | 0 | 0 |

4.0 MEETING ADJOURNMENT

The meeting was adjourned at 1:15 pm.

Meeting minutes respectfully submitted by Vivek Raju, MS.