`

HENRY FORD HEALTH INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

Board Meetings: Quarterly
Quorum = 6

Thursday, June 6, 2025

MEMBER ATTENDANCE:

PRESENT	ABSENT	MEMBER NAME	DEGREE EARNED	AREA OF SPECIALTY	DEPARTMENT	AFFILIATE OF HFH?
X		Wilson, George (C)	PhD	Biomedical/Radiobiology	Research Administration	Yes
X		Palanisamy, Nallasivam (VC)	PhD	Genomics Technology	Urology	Yes
	X	Baker, Kevin C.	PhD	Animals	Bone and Joint	Yes
X		Bobbitt, Kevin	PhD	Viral Immunology	Public Health Sciences	Yes
	X	Hay, Nancy	MHSA	Community Interest	Non-Affiliated	Yes
X		Liu, Xianshuang	PhD	Gene Therapy	Neurology	Yes
X		Notebaert, Andrea	BS	Animals	Bioresources	Yes
X		Nyati, Shyam	PhD	Gene Therapy	Radiation Oncology	Yes
	X	Ramesh, Mayur	MD	Human Clinical Trials	Infectious Disease	Yes
	X	Swiecki, Mark	BS	Community Interest	Non-Affiliated	No
X		Woodcroft, Kimberly	PhD	Biostatistics/Epidemiology	Public Health Sciences	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?
X	Combs, Lena	BS, MJ	Research Administration	Yes
	Eliya, Sonia	PharmD	Research Pharmacy	Yes
	Pabla, Pardeep	PharmD	Research Pharmacy	Yes
X	Raju, Vivek	MS	Research Administration	Yes
	Trancik, Emily	PhD	Ethics	Yes
	White, Mary Jo	MBA	Compliance	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 3:30pm with 7 of 11 members present. The meeting was conducted 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.

2.0 REVIEW OF APPLICATIONS

Event Type	Agenda #	Reviewers	PI	Protocol #	Protocol Title:
Re-Submitted Application	2.1	Liu, Xianshuang, PhD *Primary* Baker, Kevin, PhD *Secondary* Swiecki, Mark, BS *Non-Affliate Reviewer*	[redacted]	IBC2025.10	Salt sensitive hypertension: Role of renal superoxide

PURPOSE: To study the roles of the primary cilium, glycocalyx and TMEM184a in mechanotransduction in thick ascending limbs by reducing the expression of specific proteins critical to each.

Training: Complete for all study team members listed.

NIH III-D-4-a, RG-1, BSL-1

REVIEWER PRESENTATION AND DISCUSSION: Dr. G. Wilson summarized the protocol review process thus far. Protocol seems to be a Risk Group 1 (RG1) because of the use of an Adeno associated virus, which does not have any other helper viruses or oncogene and does not replicate. This protocol was previously tabled because Dr. X. Liu, and Dr. K. Baker requested additional details within the application. As a result, the principal investigator, Dr[redacted] resubmitted revisions for review by IBC. Dr. X. Liu accepted the updated information in the study methodology section to include info regarding the delivery of the agent, details of the animal study, and measures to ensure safety. The application also included an added statement in the lay summary regarding the methodology/technology used with the AAV carrying siRNA's. Dr. Liu stated he was satisfied with the changes and had no additional concerns. Dr. G. Wilson informed the committee of the email approval submitted by the secondary reviewer, Dr. K. Baker. The committee's lay member, M. Swiecki, also conducted a review, requesting a small grammatical error, but approved via email correspondence. Dr. N. Palanisamy questioned whether the vectors will be developed in the HFH lab or from an outside source. Dr. G. Wilson confirmed that the vectors will be made to order and shipped in from the University of Iowa by the PI. Dr. S. Nyati had similar concerns, but Dr. G. Wilson confirms that no synthesization of the virus will occur at Henry Ford. A. Notebaert mentioned the Bio Safety Cabinet listed in the IBC application for this protocol is inaccurate as we do not have an AB2 Cabinet, but rather an A1 cabinet. The A1 cabinet is still sufficient for the study's methodology but is listed improperly. A. Notebaert also noted that the submitted SOP contains inaccurate disposal processes. Although many animal facilities can incinerate used bedding prior to disposal, HFH does not have that capability and will not be able to dispose bedding as normal waste. It would need to be autoclaved before disposal. A. Notebaert suggested editing

phrasing to specify that it is not "disposed of as normal animal waste" can be adjusted to say "disposed of following procedures by bioresources". Dr. K. Woodcroft mentioned the IBC SOP templates focus the dangers of the vectors or nucleic acids used and are not specific to actual procedures in Animal Care.

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

APPROVED: The IBC determined the study met the IBC criteria of approval pursuant to the National Institute of Health's Guidelines as described in the Federal Register.				
TOTAL MEMBERS VOTING	**# FOR**	**# AGAINST**	**# ABSTAINED**	**# RECUSAL(S)**
7	7	0	0	0

3.0 GENERAL INFORMATION

3.1 NIH REQUIREMENTS

The Chair discussed posting of the IBC roster/contact info to fulfill NIH new requirements. V. Raju is finalizing a dedicated space on the website to post the information.

3.2 MSU UPDATES

The Chair discussed an upcoming Meet and Greet with the Michigan State University IBC and invited committee members to join. Dr. G. Wilson will provide them with updates once the time/date of the meeting is set.

4.0 MEETING ADJOURNMENT

The meeting was adjourned at 3:50pm.

Meeting minutes respectfully submitted by Vivek Raju, MS.