`

HENRY FORD HEALTH INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

Board Meetings: Quarterly
Quorum = 6

Friday, July 18, 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 Services	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	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?
	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 2:00 pm with 9 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.

1.2 REVIEW OF JUNE 5, 2025 MEETING MINUTES

Committee members reviewed the provided June 5, 2025 meeting minutes prior to the meeting. No issues were found and minutes were voted on and approved by the committee.

2.0 REVIEW OF APPLICATIONS

Event Type	Agenda #	Reviewers	PI	Protocol #	Protocol Title:
New Protocol Application	2.1	Nyati, Shyam, PhD *Primary* Liu, Xian Shuang, PhD *Secondary* Swiecki, Mark, BS *Non-Affiliated Reviewer*	[redacted]	IBC2025.11	Generation of Knockout Cancer Cell Lines for Mechanistic Studies in Lung and Ovarian Cancer Metabolism, Immunometabolism, Therapy Resistance, and the Impact of Dietary Interventions on Antitumor Immune Responses

PURPOSE: To study a Lentiviral vector system to transduce different cell lines especially in lung and ovarian cancer models.

Training: Complete for all study members listed.

RG2, BSL-2 NIH Section III-F-7

REVIEWER PRESENTATION AND DISCUSSION: K. Woodcroft recommended for the study team to remove the line indicating HIV is the parent virus, as this may cause confusion.

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:

WITHHELD PENDING RESPONSE (APPROVED WITH CONDITIONS): The following modification is requested by the committee and will require re-submission for and expedited review:

-Request study team to remove line from protocol mentioning that HIV is the parent virus to prevent confusion.				
TOTAL MEMBERS VOTING	**# FOR**	**# AGAINST**	**# ABSTAINED**	**# RECUSAL(S)**
9	9	0	0	0

Event Type	Agenda #	Reviewers	PI	Protocol #	Protocol Title:
New Protocol Application	2.2	Woodcroft, Kim, PhD *Primary* Nyati, Shyam, PhD *Secondary* Swiecki, Mark, BS *Non-Affiliated Reviewer*	[redacted]	IBC2025.14	Epigenetic Circuit Between Tumor Cells and their Microenvironment

PURPOSE: Team aims to use commercially available tools to investigate how these proteins impact cancer development and progression as well as determine novel mechanisms influencing cancer progression and the tumor microenvironment.

Training: Complete for all study members listed.

RG1 (Non-Hazardous Recombinant DNA Work) and RG2 (Lentiviral and Mammalian cell work), BSL-1, NIH Section III-D-3

REVIEWER PRESENTATION AND DISCUSSION: K. Woodcroft recommended we ask the study team whether their COVID-19 patient PBMC preps possibly contain the COVID-19 virus. If it does, they're not allowed to work with live virus in our institution for COVID-19.

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:

WITHHELD PENDING RESPONSE (APPROVED WITH CONDITIONS): The following modification is requested by the committee and will require re-submission for and expedited review: -Confirm with study team whether the COVID-19 patient preps contain the live COVID-19 Virus.				
TOTAL MEMBERS VOTING	**# FOR**	**# AGAINST**	**# ABSTAINED**	**# RECUSAL(S)**
9	9	0	0	0

Event Type	Agenda #	Reviewers	PI	Protocol #	Protocol Title:
New Protocol Application	2.3	Baker, Kevin, PhD *Primary*	[redacted]	IBC2025.16	In Vitro Testing of Commercially Available Irrigation Solutions on Efficacy of Clearing Infection from Various Medical Devices

Bobbitt, Kevin, PhD
Secondary

Hay, Nancy, BS
Non-Affiliated Reviewera

Rat femoral implantation model as an in vivo mechanical and infection control testing model for joint implanted medical devices.

PURPOSE: The goal of this project is to test the efficacy of several irrigation solutions currently used by orthopedic surgeons for joints infections occurring after joint replacement surgeries with implants in place. The model we created mimics the clinical scenario of joint infection and revision. Testing various irrigations solutions in vitro on common pathogens seen in the operating room educates surgeons on which solutions are most effective against which organisms. Testing the efficacy of these solutions in vivo educated surgeons on efficacy and possible tissue damage caused by the solutions.

Training: Complete for all study members listed.

RG1 for Cutibactrium Asnes, RG2 for Staphylococcus Aureus, BSL-2, NIH Section III-D-4

REVIEWER PRESENTATION AND DISCUSSION: K. Baker described the study procedures and confirmed that the study team has addressed all of his requested changes prior to the meeting. K. Baker also noted that secondary reviewer K. Baker had also been satisfied with changes made by the study team. Chair G. Wilson questioned whether the Animal Facility at Providence where this will take place will fall under Henry Ford Health system leadership. A. Notebaert stated that as of October 1st the Providence facilities would fall under Henry Ford leadership. A. Notebaert also noted that with the pending IACUC protocol for this study it would not start until after the October 1st, at which point it would fall under HFH Bioresources SOP's and procedures. K. Baker motioned for approval and S. Nyati seconded that motion.

ACTION TAKEN BY IBC: Approved. 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)**
9	9	0	0	0

Event Type	Agenda #	Reviewers	PI	Protocol #	Protocol Title:
Protocol Modification	2.4	Pallanisamy, Nallasivam, PhD *Primary* Baker, Kevin, PhD *Secondary* Hay, Nancy, BS *Non-Affiliated Reviewer*	[redacted]	IBC2022.07	ROLES OF MIRNAS AND HISTONE MODIFICATION IN MAIT CELL DEVELOPMENT AND FUNCTION

PURPOSE: Modification of protocol to include bacterium Helicobacter Tyhphlonius.

Training: Complete for all study members listed.

RG2, BSL-1 NIH section III-D-4

REVIEWER PRESENTATION AND DISCUSSION: A. Notebaert noted that the bacterium they plan to study Helicobacter Tyhphlonius is already present in the HFH animal colonies. Committee is satisfied with the safety aspects of the modification but want to clarify with the study team that they still want to continue with the study despite the H. Typhlonius bacterium already being present in the animal colonies

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

TABLED; REQUIRES MODIFICATIONS TO SECURE APPROVAL*: The IBC determined that the following changes are required to secure approval pending review and approval at a subsequent IBC meeting: -Committee would like to confirm with the study team that they are aware of the bacterium being present in the animal colony and if this affects their decision to continue with the study. *Addendum on 11/18/2025: Although the committee voted to table this protocol, the study team subsequently decided to submit a new protocol (2025.17) incorporating the recommendations identified above. Protocol 2025.17 will be reviewed during the November 21st IBC meeting.

TOTAL MEMBERS VOTING	# FOR	# AGAINST	# ABSTAINED	# RECUSAL(S)
9	9	0	0	0

4.0 MEETING ADJOURNMENT

The meeting was adjourned at 3:07 pm.

Meeting minutes respectfully submitted by Vivek Raju, MS.