Institutional Biosafety Committee Meeting Minutes

Element	Descriptions
Institution	PATH Seattle, WA USA
Meeting Date	Monday, February 2, 2026
Meeting Time	3:00 PM – 4:30 PM PDT
Meeting Type	In person and virtual meeting
IBC Members Present	Sampa Pal, IBC Chair Nerie Roa, IBC Biosafety Officer (BSO) Jessica White, IBC Member Gonzalo Domingo, IBC Member Marcus Estrada, IBC Member Stephen Libby, IBC Member (external)
Quorum	The IBC has 8 voting members, and 6 members (including the IBC Chair, BSO, and one local non-affiliated member are required to conduct business) were present for the duration of the meeting. Quorum was met.
Other Individuals in Attendance	Shawn Sandlin, Office of Research Affairs Coordinator
Call to Order	The IBC Chair called the meeting to order at 3:04 PM
Conflicts of Interest (COIs)	The IBC Chair reminded all members present to identify any conflicts of interest as each registration (application) is reviewed. No one declared any COIs.

Review and approval of previous meeting minutes	IBC minutes from meeting held on October 7, 2025. Marcus asked Shawn to correct the last meeting minutes, the quorum information and the end time. Motion: Jessica made a motion to approve minutes with the above changes. Votes: 6 for, 0 against, 0 abstain.
Review of Prior Business	Announcement from the NIH regarding the launch of a new biosafety modernization initiative. Acknowledgement of application IBC0021 reviewed and approved via exemption. Renewal of application IBC0019 (approved). Update of PATH.org page to create a space where meeting minutes are to be posted publicly to meet the new NIH requirement.

New IBC Registrations and Amendments for Review (repeat for each registration)	
PI Name(s)	David Boyle
Registration Number/Title	New Registration IBC0024, HCV Standard
Project Overview	We want to make a standard for aiding in assessing in the analytical performance of an isothermal molecular diagnostic method to detect hepatitis C virus (HCV) RNA. We will extract HCV RNA from a clinical sample, amplify it by reverse transcription PCR, and clone the near full-length HCV genome into a plasmid. The plasmid will then be used to produce multiple copies of the viral RNA. This will be used as a uniform standard to reliably inform on the R&D of an isothermal molecular assay for the sensitive detection of HCV.
NIH Guidelines Section	The activity best fits under Section III-D of the NIH exemption guidelines.
Risk Assessment and Discussion	All activities will be done at the BSL2 level containment. Human serum containing HCV. Risk is minimal but not zero. IBC members asked if there is already published work about this activity's objective? Biggest risk is from handling HCV. All proper PPE will be used. Remove "ethanol" references. Ethanol wipes are not acceptable nor recommended by the EPA as a sterilization method. NPD is stable for nearly 30 days. Steve to give examples of BSL level information for team to put on application (to keep them current).

Training	• Basic Laboratory Biosafety • Protocol/Agent specific biosafety training • High containment laboratory proficiency training • Blood borne pathogen training 1. All training required for all lab staff listed in the registration is complete. IBC approval is granted pending verification by the BSO that all staff listed in the registration have completed the required training.
Occupational Health Representative review (if applicable):	Not applicable.
Biosafety Level Assignment	BSL2 for all activities.
IBC Vote	Stephen made a motion to approve the registration as III-D. Votes: • For/Against/Abstain: 6 for, 0 against, 0 abstain • Conflict(s) of Interest: None.

New IBC Registrations and Amendments for Review (repeat for each registration)	
PI Name(s)	David Boyle
Registration Number/Title	New Registration IBC0025, Tools for screening sequence variation to support assay development
Project Overview	We aim to develop a tool to test the performance of an isothermal amplification assay specific to hepatitis C virus (HCV). To achieve this, we will clone a segment of the 5' untranslated region (UTR region), the target of the HCV assay into a plasmid. After creating this clone, we will generate multiple iterations of this region by introducing mutations to see if they then affect amplification. These mutations reflect the natural genetic variability observed in HCV genomes and so will be used to assess the analytical sensitivity and specificity of this method with respect to observing how the assay performs with known mutations in the primer and/or probe sequences.
NIH Guidelines Section	The activity best fits under Section III-F of the NIH exemption guidelines.
Risk Assessment and Discussion	All activities will be done at the BSL2 level. No concerns from any IBC members given the exempt status.

Training	• Basic Laboratory Biosafety • Protocol/Agent specific biosafety training • High containment laboratory proficiency training • Blood borne pathogen training 1. All training required for all lab staff listed in the registration is complete. IBC approval is granted pending verification by the BSO that all staff listed in the registration have completed the required training.
Occupational Health Representative review (if applicable):	Not applicable.
Biosafety Level Assignment	BSL2 for all activities.
IBC Vote	Stephen made a motion to approve the registration as is. Votes: • For/Against/Abstain: 6 for, 0 against, 0 abstain • Conflict(s) of Interest: None.

New IBC Registrations and Amendments for Review (repeat for each registration)	
PI Name(s)	David Boyle
Registration Number/Title	New Registration IBC0026, Developing an Internal Process Control to support assay development activities
Project Overview	We aim to generate an E. coli strain with a synthetic DNA fragment that will be integrated onto the genome via a shuttle plasmid. It will be used to generate viral like particles (VLPs) or armored RNA with a target sequence that includes the 5'UTR of the HCV genome, an MS2 phage genome fragment, and a unique random sequence that will all be packaged together into the VLP. VLPs are incapable of replication and so represent a biosafe mimic of pathogens RNA. The goal is to develop a method to generate VLPs that bypasses the need for generation from plasmid clones as we have found that the plasmid DNA contributes to carry-over of the target DNAs in the detection of the RNA from packaged in these VLPs. The plasmid DNA co-purifies with the VLPs and is very resistant to digestion by DNases. This makes it more challenging to assess the reverse transcription (RT) component of the HCV/MS2 assays as the plasmid DNA co-amplifies and so masks the reverse transcription activity that produces complementary DNA from amplification.
NIH Guidelines Section	The activity best fits under Section III-F of the NIH exemption guidelines.
Risk Assessment and Discussion	All activities will be done at the BSL2 level. IBC members impressed with novel approach.

Training	• Basic Laboratory Biosafety • Protocol/Agent specific biosafety training • High containment laboratory proficiency training • Blood borne pathogen training 1. All training required for all lab staff listed in the registration is complete. IBC approval is granted pending verification by the BSO that all staff listed in the registration have completed the required training.
Occupational Health Representative review (if applicable):	Not applicable.
Biosafety Level Assignment	BSL2 for all activities.
IBC Vote	Stephen made a motion to approve the registration as is. Votes: • For/Against/Abstain: 6 for, 0 against, 0 abstain • Conflict(s) of Interest: None.

New Business/ Additional Topics	• New CVs needed from all members for annual IBC registration with the NIH Office of Science Policy (OSP) • Coming 2026 changes to biosafety course from CITI
Review of Incidents	Nothing to report.
Inspections/ Ongoing Oversight	NIH does not specify frequency of periodic inspections.
IBC Training	No training conducted during this meeting. All IBC members have completed Biosafety/Biosecurity training requirement.
Public Comments	There were no public comments. Shawn to review PATH IBC Guidelines to confirm public comments must be reserved for the end of the meeting.
Adjournment	The IBC Chair moved to adjourn the meeting at 3:54pm. The next meeting is scheduled for April 7, 2026.