

**Vaccine Research Center
Animal Care and Use Committee Meeting
February 19th, 2020**

1. The VRC Animal Care and Use Committee convened at 1:00PM in the VRC, [Redacted by agreement]
[Redacted by agreement] One protocol and eleven amendments were reviewed with action taken.

2. Voting Members Present

Dr. Mario Roederer

Chair

Dr. Diana Scorpio

Attending Veterinarian

[Redacted by agreement]

Nonvoting Members and Guests Present

[Redacted by agreement]

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Members Absent

[Redacted by agreement]

3. Dr. Roederer called the meeting to order and the minutes from the January 22nd meeting were reviewed and approved as written.

4. Old Business

The following old business was discussed at the February 19th meeting:

- The VRC ACUC members were reminded to expect SOP review packets in the coming weeks.
- The VRC ACUC was reminded that the Spring Semi-annual program review and facility inspections would be occurring in the upcoming weeks. Inspection dates will be announced once confirmed.

5. New Business

The following new business was discussed at the February 19th meeting:

- The VRC ACUC was informed that a routine OLAW site visit and inspection would be taking place across all NIH institutes where animal work is conducted.

- Dr. Scorpio, the VRC Attending Veterinarian, described a workshop she had recently attended titled, “FOSTERING RIGOROUS RESEARCH: Lessons Learned from Non-human Primate Models and Charting the Path Forward.” She encouraged all ACUC members to access the archived sessions of this training session. The ACUC coordinator will provide links to specific sessions that would be beneficial for the VRC ACUC members.

6. New Protocol (s)

- [Redacted by agreement] “*Treatment of Chronic SHIV-infected Animals with Broadly Neutralizing Antibodies*,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 3, Section F: Experimental design, Injections, Inoculations, or Instillations, please correct the text from Table 1.3 to Table 1.2, 2) On page 3, Section F: Experimental design, Injections, Inoculations, or Instillations, please clarify that rabbit immunizations will be 1ml total, split as 500ul into each leg, 3) On page 7, Section K: Hazardous Agents, please list isoflurane under Hazardous Chemicals and add the associated language for safe handling and 4) Please submit a LSV recombinant registration amendment (RD-17-X-04) and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>). [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

7. Protocol Renewal (s)

None

8. Amendments

- [Redacted by agreement] “*In-Vivo Studies of Pre/Post-Fusion Nipah F Proteins in Mice*,” by [Redacted by agreement] 6th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Understanding the mechanism of protection after intravenous BCG vaccination against TB challenge*,” by [Redacted by agreement] 1th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) a. On page 1, Section 1, Please uncheck box F2. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Immunization of Influenza Virus Hemagglutinin displayed on various nanoparticle platforms and challenge by lethal dose of influenza viruses in mice*,” by [Redacted by agreement] 12th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Table 36, please remove the word challenge from the table title, 2) On page 1, Section B; Animal Requirements, please move these animals to Year 3, and 3) On page 7, Section H: Pain or Distress, please move these animals to Year 3. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*A study of pharmacokinetics of human monoclonal antibodies in human FcRn transgenic mice*,” by [Redacted by agreement] 7th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section 1, please uncheck Box F1 and 3) Please submit a recombinant registration amendment (RD-16-II-06) and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>). [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Evaluation of immunogenicity of Influenza hemagglutinin displayed on various nanoparticles in non-human primates," by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 5, Section K: Hazardous Agents Requested, please change the RD from RD-15-VIII-31 to RD-16-I-03 and 2) Please submit a plasmid DNA immunization RD amendment (RD-16-I-03) and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>). [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Investigation into the use of immune modulators and mAbs to control SIV infection," by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 4, Section F, Experimental Design, Table 5, please change the text for the last highlighted row to read 4+1,2,3, OR 4 days and 3) On page 7, Section K: Hazardous Agents, please change the PRD from 4038 to 7716 and 4234 to 7712. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Development and Evaluation of HIV-1 Envelope based Vaccine Candidates in Guinea pig," by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Evaluation of Immunogenicity of HIV-1 Env immunogens with the fusion peptide as the target in Nonhuman Primates," by [Redacted by agreement] 4th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Study of the Pharmacokinetic Parameters and Mucosal levels of anti-HIV-1 Broadly Neutralizing Antibodies in Rhesus Macaques," by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section 1, check Box F2 – Procedures. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Evaluation of Enterovirus D68 antibodies and vaccines in a murine infection model," by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) Please submit a registration amendment (7636) for the production of B3 subclade EV and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>). **The motion passed unanimously.**

- [Redacted by agreement] “*Protection against tuberculosis in rhesus macaques following intravenous rBCG (VPM1002,*” by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] refused herself from the ACUC meeting and discussion. **The motion passed unanimously**

9. Veterinary Verified Consultation (VVC)

The following amendments were mentioned in the ACUC meeting that were Verified via VVC:

- [Redacted by agreement] “*Therapeutic effect of combination mAbs during SIV infection,*” by [Redacted by agreement] 2nd Amendment.

This amendment modified the experimental schema.

- [Redacted by agreement] “*Evaluation of Immunogenicity of HIV-1 Env immunogens with the fusion peptide as the target in Nonhuman Primates,*” by [Redacted by agreement] 5th Amendment.

This amendment removed one of the boost timepoints of the study.

- [Redacted by agreement] “*Quarantine, Holding, and Limited Pre-Study Characterization of Mice and Guinea Pigs for VRC,*” by [Redacted by agreement]

This amendment added two strains of mice to the protocol.

- [Redacted by agreement] “*Investigating the contribution of antigen depots in lymphoid and peripheral tissues to protective immunity,*” by [Redacted by agreement]

This amendment modified the experimental schema.

- [Redacted by agreement] “*Study of the Protective Efficacy of Anti-HIV-1 Antibodies against SHIV Challenges in Rhesus macaques,*” by [Redacted by agreement]

This amendment added two strains of mice to the protocol.

10. Minor Amendments

- None

11. Annual Review Reports

The following annual review reports were approved at the ACUC meeting:

- [Redacted by agreement] “*Study of the Pharmacokinetic Parameters and Tissue levels of Neutralizing Antibodies Against Infectious Agents in Rhesus macaques,*” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “*Enhancing neoantigen-specific anti-tumor immunity through heterologous prime boost vaccination,*” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “*Intravascular Staining for the Discrimination of Vascular and Tissue Leukocytes in Nonhuman Primates following BCG immunization,*” by [Redacted by agreement] This is the 1st annual review report.

12. Designated Member Review

The following protocols/amendments were mentioned in the ACUC meeting that were Approved via DMR:

- [Redacted by agreement] “*Evaluation of HIV Env Immunogens in Rabbit*,” by [Redacted by agreement] 11th Amendment.
- [Redacted by agreement] “*Immunization of Influenza Virus Hemagglutinin displayed on various nanoparticle platforms and challenge by lethal dose of influenza viruses in mice*,” by [Redacted by agreement] 12th Amendment.
- [Redacted by agreement] “*Development and Evaluation of Vaccine Candidates against Coronaviruses in Mice*,” by [Redacted by agreement] 2nd Amendment.

13. Final Approvals

- Committee members were informed of the Protocol/Amendment Final Approvals from November 20th ACUC meeting.

14. General Announcements, Information

- The meeting adjourned at 4:00pm. The next VRC ACUC meeting will be held March 18th, 2020 2:00pm at the Vaccine Research Center, [Redacted by agreement]

Mario Roederer, PhD
Chair, VRC ACUC Committee

[Redacted by agreement]

**Vaccine Research Center
Animal Care and Use Committee Meeting
March 18th, 2020**

1. The VRC Animal Care and Use Committee convened at 2:00PM in the VRC, [Redacted by agreement]
[Redacted by agreement] Four protocols and eight amendments were reviewed with action taken.

2. Voting Members Present

Dr. Mario Roederer

Chair

Dr. Diana Scorpio

Attending Veterinarian

[Redacted by agreement]

Nonvoting Members and Guests Present

[Redacted by agreement]

NIH/OACU

Guest

Guest

Guest

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Members Absent

[Redacted by agreement]

3. Dr. Roederer called the meeting to order and the minutes from the February 19th meeting were reviewed and approved as written.

4. Old Business

The following old business was discussed at the March 18th ACUC meeting:

- The VRC ACUC members were reminded to expect SOP review packets in the coming weeks.
- The VRC ACUC was informed that the Spring semi-annual facility inspections that were not completed would be rescheduled. Members were reminded that the Spring semi-annual report will still be due on April 30th, 2020.

- The VRC Attending Veterinarian informed the Committee members that the OLAW site visit occurred on Friday, March 6th, 2020. Specific final comments and findings would be provided once OLAW sends a formal follow-up letter to NIH OACU.

5. New Business

The following new business was discussed at the March 18th ACUC meeting:

- The ACUC Chair mentioned protocol [Redacted by agreement] listed on the agenda for the meeting. Dr. Roederer informed the Committee that an expedited DMR process for this protocol had been approved for review of this protocol and named Dr. Scorpio and [Redacted by agreement] as the designated member reviewers. The protocol would be sent out to the Committee members for DMR review before COB 3/18/2020.

6. New Protocol (s)

- [Redacted by agreement] “*Evaluation of vaccine candidates in Kirin transgenic mice carrying human immunoglobulin genes*,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 2, Section E: Rationale for Animal Use, Statistical Justification, please remove the text that states you will be testing this immunogens in NHPs and 2) On page 6, Section K: Hazardous Agents, please list the correct registration in the recombinant DNA section and upload this ASP to the registration. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Evaluation of NA antibody composition after influenza infection*,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On pages 3-4, Section F: Experimental Design, Table 1, and Table 2, please change the challenge dose for Group 2 from 5x to 3x, 2) On page 3, Section F: Experimental Design, Blood Withdrawals, please ensure the language in this section aligns with the proposed schedules in the tables within the protocol, and 3) On page 3, Section F: Experimental Design, please clarify that all challenges will be at [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

7. Protocol Renewal (s)

- [Redacted by agreement] “*Development of Methods of Genetic Immunization for Viral Hemorrhagic Fever Infection in Monkeys*,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 1, Section 1, Administrative Data, remove “XXX” from the collaborator section, 2) Please submit registrations for the use of agents (4520, 4789, 4102, RD-99-XII-05, RD-08-I-04, RD-09-VII-08, RD-09-II-25) and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. Instructions on how to create a registration can be found by clicking on the question mark in the top right corner and then selecting PI-Dashboard>PIDB: Biological>PID PI User Guide from the menu on the left side of the screen, and 3) Please note: 4520, 4789, 4102, RD-08-I-04, RD-99-XII-05, RD-09-VII-08, RD-09-II-25. These are all over ten years old and should be replaced with new PRDs and RDs. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Examining immune mechanisms of protection of Ad5 Ebola through immune cell depletion,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 1, Section 1, Administrative Data, remove “XXX” from the collaborator section, 2) On page 2, Section B, Animal Requirements, remove USAMRIID and GNL from the procedure locations, 3) On page 3, Section E: Rationale for Animal Use, Statistical Justification, please add additional justification for the group size calculation for these experiments, 4)

On page 8, Section F: Experimental Design, Experimental Endpoint Criteria, please also add [Redacted by agreement] as a potential location for transfer of the NHPs, 5) Please submit registrations for the use of agents (4520, 4789, 4102, RD-99-XII-05, RD-08-I-04, RD-09-VII-08, RD-09-II-25) and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. Instructions on how to create a registration can be found by clicking on the question mark in the top right corner and then selecting PI-Dashboard>PIDB: Biological>PID PI User Guide from the menu on the left side of the screen, and 6) Please note: 4520, 4789, 4102, RD-08-I-04, RD-99-XII-05, RD-09-VII-08, RD-09-II-25. These are all over ten years old and should be replaced with new PRDs and RDs. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

8. Amendments

- [Redacted by agreement] “Immunization of Influenza Virus Hemagglutinin displayed on various nanoparticle platforms and challenge by lethal dose of influenza viruses in mice,” by [Redacted by agreement] 13th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted] recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “A study of pharmacokinetics of human monoclonal antibodies in human FcRn transgenic mice,” by [Redacted by agreement] 8th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 6, Section F: Experimental Design, Proposed Experimental Schema, please clarify that you will start this experiment at 800ug/kg and 2) On page 6, Section F: Experimental Design, Proposed Experimental Schema, please clarify the sampling schedule is for Groups 10-12. [Redacted] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Intravascular Staining for the Discrimination of Vascular and Tissue Leukocytes in Nonhuman Primates,” by Dr. Mario Roederer. 12th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. Dr. Roederer and [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Study of the immunogenicity of immune complexes of HIV-1 envelope glycoprotein and anti-HIV-1 monoclonal antibodies in humanized FcγR mice,” by [Redacted by agreement] 11th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Proposed Experimental Schema, please correct the IC immunogen in either Group 5 or Group 7 as they are currently listed as being identical, 2) On page 4, Section F: Experimental Design, Proposed Experimental Schema, please check the box indicating you will be using NPGCs on this protocol. [Redacted] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Investigation into the use of immune modulators and mAbs to control SIV infection,” by [Redacted by agreement] 12th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Proposed Experimental Schema, please modify Table 1 to clarify there are only two study groups, and 2) On page 3, Section F: Experimental Design, Proposed Experimental Schema, Injections, Inoculations, or Instillations, please clarify that you will be injecting 15mg/kg IV of each antibody. [Redacted by agreement] and [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Evaluation of Enterovirus D68 antibodies and vaccines in a murine infection model,” by [Redacted by agreement] 3rd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Proposed Experimental Schema, Please consider modifying the timepoint of infection, 2) On page 6, Section K: Hazardous Agents, under Hazardous Agents Requested, Recombinant DNA, please check “Yes” and add RD-15-VIII-31 to cover the EV-VLP work proposed on this amendment, and 3) Please submit a registration amendment to include this amendment on RD-15-VIII-31 via PI-Dashboard (<https://oms.ors.nih.gov/>). [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Exploratory Toxicology Study in NHPs Using anti-HIV-1 based T cell engaging Trifunctional Antibodies,” by [Redacted by agreement] 3rd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 6, Section F: Experimental Design, Proposed Experimental Schema, please clarify that you will start this experiment at 800ug/kg and 2) On page 6, Section F: Experimental Design, Proposed Experimental Schema, please clarify the sampling schedule is for Groups 10-12. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Animal Study of HIV Immunogens Evaluation,” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Proposed Experimental Design, Table 10.2, please add an additional study group of 5 animals/group. Please correct the overall animal total numbers requested on page 1 and page 6 and 2) On pages 3-4, Section F: Experimental Design, Proposed Experimental Design, Table 10.3, please add the experimental endpoint to this table and ensure that it aligns with the endpoint indicated in the text under the Experimental Endpoint Criteria. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

9. Veterinary Verified Consultation (VVC)

The following amendments were mentioned in the ACUC meeting that were Verified via VVC:

- [Redacted by agreement] “Treatment of Chronic SHIV Infection in NHP Using anti-HIV-1 based T cell engaging Trifunctional Antibodies,” by [Redacted by agreement] 12th Amendment.

This amendment modified the blood sampling schedule.

- [Redacted by agreement] “*Passive Immunization of Rhesus Macaques using SIV-specific neutralizing antibodies,*” by [Redacted by agreement] 2nd Amendment.

This amendment removed one of the boost timepoints of the study.

- [Redacted by agreement] “*Study of the Pharmacokinetic Parameters and Mucosal levels of Neutralizing Antibodies Against Infectious Agents in Rhesus Macaques,*” by [Redacted by agreement] 3rd Amendment.

This amendment clarified the procedures proposed on the experiment.

- [Redacted by agreement] “*Optimization of boosting strategies to enhance fusion peptide-directed HIV neutralizing responses in NHP,*” by [Redacted by agreement]

This amendment clarified the blood sampling schedule for the pilot study.

10. Minor Amendments

- None

11. Annual Review Reports

The following annual review reports were approved at the ACUC meeting:

- [Redacted by agreement] “*Immunization of Ferritin Nanoparticles Displaying Influenza Virus Hemagglutinin in Mice,*” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “*Immunization of Influenza Virus Hemagglutinin displayed on various nanoparticle platforms and challenge by lethal dose of influenza viruses in mice,*” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “*Raising mouse antibodies against non-human primate antigens,*” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “*Establishment of humanized mice to model human naive B cell repertoire and their use for evaluation of candidate immunogens,*” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “*Evaluation of immunogenicity and protective efficacy of influenza hemagglutinin-based mRNA vaccines in mice,*” by [Redacted by agreement] This is the 1st annual review report
- [Redacted by agreement] “*Evaluation of Immunogenicity of Influenza-nanoparticles in Non-Human primates,*” by [Redacted by agreement] This is the 1st annual review report
- [Redacted by agreement] “*A Female Pigtail Macaque Model to Study the Vaginal Microbiome,*” by [Redacted by agreement] This is the 1st annual review report
- [Redacted by agreement] “*Development of rapid methods for isolation and analysis of anti-influenza antibodies in rapid response to pandemics,*” by [Redacted by agreement] This is the 1st annual review report.

12. Designated Member Review

The following protocols/amendments were mentioned in the ACUC meeting that were Approved via DMR:

- None

13. Final Approvals

- Committee members were informed of the Protocol/Amendment Final Approvals from February 19th ACUC meeting.

14. General Announcements, Information

- The meeting adjourned at 4:00pm. The next VRC ACUC meeting will be held April 15th, 2020 2:00pm at the Vaccine Research Center, Redacted by agreement or through a virtual online meeting platform.

Mario Roederer, PhD
Chair, VRC ACUC Committee

Redacted by agreement

**Vaccine Research Center
Animal Care and Use Committee Meeting
April 15th, 2020**

1. The VRC Animal Care and Use Committee convened at 2:00PM in the VRC, [Redacted by agreement]
[Redacted by agreement] Four protocols and six amendments were reviewed with action taken.

2. Voting Members Present

Dr. Mario Roederer

Chair

[Redacted by agreement]

Dr. Diana Scorpio

Attending Veterinarian

[Redacted by agreement]

Nonvoting Members and Guests Present

[Redacted by agreement]

NIH/OACU

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Members Absent

[Redacted by agreement]

3. Dr. Roederer called the meeting to order and the minutes from the March 18th meeting were reviewed and approved as written.

4. Old Business

The following old business was discussed at the April 15th ACUC meeting:

- The VRC ACUC members were reminded to expect SOP review packets in the coming weeks.
- The VRC Attending Veterinarian informed the Committee members that the OLAW site visit occurred on Friday, March 6th, 2020. Specific final comments and findings would be provided once OLAW sends a formal follow-up letter to NIH OACU.

5. New Business

The following new business was discussed at the April 15th ACUC meeting:

- **A motion was made and seconded to approve** the following ad-hoc ACUC site visit consultants:

[Redacted by agreement]

[Redacted by agreement]

The motion passed unanimously.

- The VRC animal facility manager, [Redacted by agreement] provided an update regarding the [Redacted by agreement] [Redacted by agreement] operating status since the COVID-quarantine measures were implemented.
- The VRC ACUC was informed that a finalized Spring Semi-annual report would be emailed out after the meeting and signatures would be obtained electronically.

6. New Protocol (s)

- (b)(5)

Discussion/Decision: A motion was made and seconded to Table the protocol for review pending the following modifications changes: (b)(5)

(b)(5)

- [Redacted by agreement] “Evaluating Coronavirus Infection in Nonhuman Primates,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 2, Section D: Scientific Objectives, please refer to ASP [Redacted by agreement] 2) On page 2, Section E: Rational for Animal Use, under statistical justification, please clarify [Redacted by agreement] that this is model development and not a pilot study, 3) On page 6, Section F: Experimental Design, please remove immunogen information from the NPGC table and check the box for “NO, I will not be using non-PGCs on this protocol,” 4) On page 9, Section K: please remove immunogen info about rRNA-1273, RD-13-IV-04 and RD-17-X-02, and 5) This may require a new NHPBBF (Not the 7635 PRD listed on the ASP). Please submit a COVID infected non-human primate blood and body fluid registration amendment and include this ASP via PI-Dashboard. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

7. Protocol Renewal (s)

- [Redacted by agreement] “Development of therapeutics for both passive and active protection against human malaria,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 11, Section K: Hazardous Agents, under recombinant DNA section, please list all mAbs and vaccines that are used in this ASP and their corresponding RDs, 2) Please submit Chimeric P.berghei sporozoites expressing P.falciparum CSP – HPRD 7109 registration amendment and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval, and 3) Please submit a recombinant registration amendment for the newly cloned antibodies, nanoparticle vaccines, and all other recombinant vaccine candidates produced for this ASP and include this ASP via PI-Dashboard. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*In-Vivo Studies of Pre/Post-Fusion Nipah F Proteins in Mice*,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 3, Section F: Experimental Design, Table 1-1, please correct the final group to be Group 101, 2) On page 4, Section F: Experimental Design, Methods of Restraint, please clarify that you may also use isoflurane for electroporation procedures, 3) On page 8, Section K: Please remove Nipah F, G, F/G chimeric proteins from “Biological agents” section and include in “recombinant DNA section”, 4) On page 8, Section K: Please add the following language for isoflurane use: “Isoflurane will be scavenged in a chemical fume hood, downdraft table, anesthesia machine Activated Charcoal Adsorption Filter Capture system, local active exhaust ventilation system, or possibly a combination of these methods as approved by the Division of Occupational Health and Safety (DOHS),” 5) Please submit a recombinant registration amendment [Redacted by agreement] and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- (b)(5)

Discussion/Decision: This protocol was not reviewed. No discussion or vote occurred.

8. Amendments

- [Redacted by agreement] “*A Female Pigtail Macaque Model to Study the Vaginal Microbiome*,” by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section K: Hazardous Agents, please remove “human” from the table. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Development and Evaluation of Vaccine Candidates against Coronaviruses in Mice*,” by [Redacted by agreement] 4th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 6, Section F: Experimental Design, Proposed Experimental Schema, Table 4.2, please modify the dose to 0.2ug in Groups 2 and 4, 2) On page 7, Section F: Experimental Design, Proposed Experimental Schema, Table 4.4, please modify the dose to 0.2ug in Group 2, 3) On page 10, Section F: Experimental Design, Proposed Experimental Schema, please add UV-inactivated SARS-CoV-2 to the NPGC table, and 4) Are any of these vaccine variants novel from parental protocol or earlier mods? If so, please submit a recombinant registration amendment [Redacted by agreement] and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Evaluating Coronavirus Vaccines in Nonhuman Primates*,” by [Redacted by agreement] 3rd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section 1, please check box F1, 2) On page 3, Section F: Experimental Design, Proposed Experimental Schema, please clarify that nasal swabs will not be conducted more than three days consecutively and consider which timepoints are essential for this experiment. Please modify the sampling schedules accordingly, 3) On page 3, Section F: Experimental Design, Proposed Experimental Schema, Table 2.1, please remove the first footnote and state the dose of inactivated virus that will be used in the table, 4) On page 4, Section F: Experimental Design,

Proposed Experimental Schema, Post -challenge readouts, please ensure this text matches the proposed timepoints in table 2.3, and 5) Please submit a recombinant registration amendment [Redacted by agreement] and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Evaluation of vaccine candidates in wild type and Kirin transgenic mice carrying human immunoglobulin genes,*” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Proposed Experimental Schema, Blood Withdrawals, please add LAM SOP 6311-5 and clarify that blood may be drawn using any of the methods on that SOP and 2) Please submit a recombinant registration amendment [Redacted by agreement] and include this ASP via PI-Dashboard. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- Multi-ASP amendments:

- [Redacted by agreement] and [Redacted by agreement] by [Redacted by agreement] (PI change to [Redacted by agreement])

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement]
[Redacted by agreement] by [Redacted by agreement] (PI change to [Redacted by agreement])

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

9. Veterinary Verified Consultation (VVC)

The following amendments were mentioned in the ACUC meeting that were Verified via VVC:

- [Redacted by agreement] “*Evaluation of HIV Env Immunogens in Rabbits,*” by [Redacted by agreement] 14th Amendment.

This amendment clarified a dose range for anesthesia.

- [Redacted by agreement] “*Evaluating Coronavirus Vaccines in Nonhuman Primates,*” by [Redacted by agreement] 1st Amendment.

This amendment modified the experimental schema.

10. Minor Amendments

- [Redacted by agreement] “*Evaluation of Immunogenicity of HIV-1 Env immunogens with the fusion peptide as the target in Nonhuman Primates,*” by [Redacted by agreement] 1st Amendment.

This amendment added a co-investigator to the protocol.

- [Redacted by agreement] “*Monitoring Mycobacterium tuberculosis infection in rhesus macaques using serial positron emission tomography and computed tomography (PET-CT),*” by [Redacted by agreement] 1st amendment.

This amendment added personnel, removed two co-investigators, and clarified necropsy for animals scheduled to be euthanized.

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 1st Amendment.

This amendment clarified challenge to be done at [Redacted] and that animals will remain VRC owned.

11. Annual Review Reports

The following annual review reports were approved at the ACUC meeting:

- [Redacted by agreement] “Intravascular Staining for the Discrimination of Vascular and Tissue Leukocytes in Nonhuman Primates,” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “Passive Immunization of Rhesus Macaques using SIV-specific neutralizing antibodies,” by [Redacted by agreement] This is the 2nd annual review report.
- [Redacted by agreement] “Pilot Reactogenicity Study of GLP-grade Trispecific Anti-HIV-1 Antibody in Swine,” by [Redacted by agreement] This is the 1st annual review report.
- [Redacted by agreement] “Evaluation of immunogenicity of nanoparticles (co)displaying influenza virus neuraminidase and hemagglutinin,” by [Redacted by agreement] This is the 1st annual review report.
- [Redacted by agreement] “Therapeutic effect of combination mAbs during SIV infection,” by [Redacted by agreement] This is the 1st annual review report.
- [Redacted by agreement] “Investigation into the use of immune modulators and mAbs to control SIV infection,” by [Redacted by agreement] This is the 1st annual review report.

12. Designated Member Review

The following protocols/amendments were mentioned in the ACUC meeting that were Approved via DMR:

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement]

13. Final Approvals

- Committee members were informed of the Protocol/Amendment Final Approvals from March 18th ACUC meeting.

14. General Announcements, Information

- The meeting adjourned at 4:00pm. The next VRC ACUC meeting will be held May 20th, 2020 2:30pm at the Vaccine Research Center, [Redacted by agreement] or through a virtual online meeting platform.

Mario Roederer, PhD
Chair, VRC ACUC Committee

Redacted by agreement

Vaccine Research Center
Animal Care and Use Committee Meeting
May 20th, 2020

1. The VRC Animal Care and Use Committee convened at 2:30PM in the VRC, [Redacted by agreement]
[Redacted by agreement] Six protocols and five amendments were reviewed with action taken.

2. Voting Members Present

Dr. Mario Roederer

[Redacted by agreement]

Dr. Diana Scorpio

[Redacted by agreement]

Chair

Vice Chair

Attending Veterinarian

Nonvoting Members and Guests Present

[Redacted by agreement]

NIH/OACU

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Members Absent

[Redacted by agreement]

3. Dr. Roederer called the meeting to order and the minutes from the April 15th meeting were reviewed and approved as written.

4. Old Business

The following old business was discussed at the May 20th ACUC meeting:

- The VRC ACUC members were reminded to expect SOP review packets in the coming weeks.
- The VRC ACUC was informed that the final Spring Semi-Annual Report packet was submitted to the NIH/OACU office.
- The VRC animal facility manager, [Redacted by agreement] provided an update regarding the [Redacted by agreement]
[Redacted by agreement] operating status since the COVID-quarantine measures were implemented.

5. New Business

The following new business was discussed at the May 20th ACUC meeting:

- The Committee was informed that Dr. Diana Scorpio would be stepping down as Attending Veterinarian at the end of May. Members were also informed that Dr. Ruth Woodward/NICHD would be appointed as the VRC Attending Veterinarian to ensure continuing coverage for the animal program. Dr. Woodward will also provide clinical services for research animals in [Redacted by agreement]
- The VRC ACUC was provided an incident report regarding unexpected mortality in the animal facility. During the AM checks of the animal rooms after the weekend, a cage of retired female breeders was found dead by the project manager. The Attending Veterinarian and investigator were immediately notified of the incident as well as the VRC ACUC Chair, and [Redacted by agreement] OACU.

After evaluation of the event, the project management team proposed the following steps to address the issue: 1) return to standard work shifts 2) retraining of caretaking staff to emphasize the importance of health check observations and verifying adequate feed and water levels. The Attending Veterinarian and project manager also proposed a modification to the cage change schedule.

The Committee members agreed with the proposed solutions and will follow-up with this report at the next convened ACUC meeting.

6. New Protocol (s)

- [Redacted by agreement] "Evaluation of universal beta-coronavirus immunogens in mice," by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) Please submit a recombinant registration amendment for the SARS CoV-2, the rTTHC variant of this vaccine and all other recombinant vaccine candidates produced for this ASP and include this ASP via PI-Dashboard. [Redacted] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Heterologous prime boost as a personalized vaccination strategy for cancer therapy," by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 2, Section D and E, Study Objectives and Rationale for Animal Use, please clarify which cell lines will be used for the proposed experiments and 2) Please submit a registration for MVA (PRD/RD) and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- (b)(5)

Discussion/Decision: This protocol was not reviewed. No discussion or vote occurred.

- (b)(5)

Discussion/Decision: A motion was made and seconded to Table the protocol for review at the next convened ACUC meeting pending the following modifications: (b)(5)

(b)(5)

(b)(5)

- (b)(5)

Discussion/Decision: A motion was made and seconded to Table the protocol for Designated Member Review by Redacted by and the Chair, VRC ACUC, pending the following modifications changes: (b)(5)

(b)(5)

7. Protocol Renewal (s)

- Redacted by agreement “Evaluating HIV-1 MPER Immunogens in Mice,” by Redacted by agreement

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On pages 4-6, Section F: Experimental Schema, Experiment 1, a week 15 immunization timepoint is listed in Table 1.2 but is missing from Table 1.3. Please correct the text and tables so they match with the proposed study timepoints. Redacted by accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- Redacted by agreement Redacted by agreement “Training of Vaccine Research Center Personnel Using Animals,” by Redacted by agreement

Discussion/Decision: A motion was made and seconded to approve the protocol as written. Redacted by Redacted by agreement recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

8. Amendments

- [Redacted by agreement] “Breeding of humanized mice for vaccine studies,” by [Redacted by agreement] 3rd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted] recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Animal Study of Immunogen Evaluation for Lassa and Other Arenaviruses,” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 4, Section F: Experimental Design, Proposed Experimental Schema, Table 3.2, please correct the animal number total under the table and update the total animals requested in the corresponding sections of the amendment. [Redacted] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Animal Study of HIV Immunogens Evaluation,” by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 4, Section F: Experimental Design, Proposed Experimental Schema Table 11.3, please clarify when mice from Group 2 are terminated, 2) On page 4, Section F: Experimental Design, Proposed Experimental Schema, Table 11.3, please ensure the total number of animals euthanized matches the proposed numbers in Table 11.2, and 3) On page 7, Section K: Hazardous Agents, please uncheck the box for Recombinant DNA under Hazardous Agents requested. [Redacted] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Animal Study of Immunogen Evaluation for Influenza,” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section K: Hazardous Agents, please correctly check the boxes in the table. [Redacted] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Evaluating Coronavirus Infection in Nonhuman Primates,” by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 2, Section F: Experimental Design, Proposed Experimental Schema, please correct the mAb to CR3022. **The motion passed unanimously.**

9. Veterinary Verified Consultation (VVC)

The following amendments were mentioned in the ACUC meeting that were Verified via VVC:

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 4th Amendment.

This amendment added additional biosampling timepoints.

- [Redacted by agreement] “Evaluating Coronavirus Infection in Nonhuman Primates,” by [Redacted by agreement] 1st Amendment. 1st Amendment.

This amendment added additional biosampling timepoints

10. Minor Amendments

- [Redacted by agreement] “Evaluation of Immunogenicity of HIV-1 Env immunogens with the fusion peptide as the target in Nonhuman Primates,” by [Redacted by agreement] 1st Amendment.

This amendment added a co-investigator to the protocol.

- [Redacted by agreement] “Monitoring Mycobacterium tuberculosis infection in rhesus macaques using serial positron emission tomography and computed tomography (PET-CT),” by [Redacted by agreement] 1st amendment.

This amendment added personnel, removed two co-investigators, and clarified necropsy for animals scheduled to be euthanized.

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 1st Amendment.
- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 5th Amendment.

This amendment added personnel to the protocol.

11. Annual Review Reports

The following annual review reports were approved at the ACUC meeting:

- None

12. Designated Member Review

The following protocols/amendments were mentioned in the ACUC meeting that were Approved via DMR:

- [Redacted by agreement] “A study of pharmacokinetics of human monoclonal antibodies in human FcRn transgenic mice,” by [Redacted by agreement] 9th Amendment.

13. Final Approvals

- Committee members were informed of the Protocol/Amendment Final Approvals from April 15th ACUC meeting.

14. General Announcements, Information

- The meeting adjourned at 4:00pm. The next VRC ACUC meeting will be held June 17th, 2020 at 2:30pm at the Vaccine Research Center, [Redacted by agreement] or through a virtual online meeting platform.

Mario Roederer, PhD
Chair, VRC ACUC Committee

Redacted by agreement

**Vaccine Research Center
Animal Care and Use Committee Meeting
June 17th, 2020**

1. The VRC Animal Care and Use Committee convened at 2:30PM via an online virtual Zoom.gov meeting. Two protocols and five amendments were reviewed with action taken.

2. Voting Members Present

Dr. Mario Roederer

Chair

Dr. Ruth Woodward

Attending Veterinarian

Redacted by agreement

Nonvoting Members and Guests Present

Redacted by agreement

Guest

Guest

Guest

Guest

Guest

Guest

Members Absent

Redacted by agreement

3. Dr. Roederer called the meeting to order and the minutes from the May 20th meeting were reviewed and approved as written.

4. Old Business

The following old business was discussed at the June 17th ACUC meeting:

- The Committee was informed that Dr. Ruth Woodward had been appointed to the VRC ACUC as the new Attending Veterinarian.
- The VRC animal facility manager, [Redacted by agreement] provided an update regarding the [Redacted by agreement] [Redacted by agreement] operating status since the COVID-quarantine measures were implemented.
- The ACUC reviewed the final summary report regarding an incident presented at the May meeting. The proposed solutions and revised facility SOP for animal husbandry were also provided to the members prior to the meeting. The members agreed that the actions for resolution were enough and the final report could be provided to the NIH Office of Animal Care and Use.

5. New Business

The following new business was discussed at the June 17th ACUC meeting:

- No new business was discussed.

6. New Protocol (s)

- [Redacted by agreement] “*Human norovirus infection model in non-human primates*,” by [Redacted by agreement]

Discussion/Decision A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 3, Section F: Experimental Design, please clarify the benchmark for confirming a “successful” infection in these animals, 2) On page 4, Section F: Experimental Design, Table 3, please move the pre-jejunal biopsy timepoint to Week -3, 3) On page 9, Section M: Special Considerations, please clarify that animals will be pair housed 2 weeks after the end of the study or after they have demonstrated a negative result for norovirus infection. [Redacted by agreement] accepted the Committee recommendations and recused themselves from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Elicitation of HA stem targeted anti-flu antibody lineages in human Vh6-1 knock in mice*,” by [Redacted by agreement]

Discussion/Decision: A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 1, Section B: Animal Requirements, please add [Redacted by agreement] to the procedure and holding locations, 2) On page 5, Section F: Experimental Schema, Injections, Inoculations, or Instillations, please site that blood withdrawal limits will be in compliance with ARAC guidelines, and 3) [Redacted by agreement] Please submit a registration amendment for all recombinant immunogens listed in this ASP [Redacted by agreement] as well as any other recombinant vaccines listed in this ASP (Germline Abs), and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

7. Protocol Renewal (s)

None

8. Amendments

- [Redacted by agreement] “*Understanding the mechanism of protection after intravenous BCG vaccination against TB challenge*,” by [Redacted by agreement] 16th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 3, Section F: Experimental Design, Proposed Experimental Schema, please add rationale for using a CD8 α depleting antibody. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Evaluation of Immunogenicity of HIV-1 Env immunogens with CD4bs deglycosylation in Nonhuman Primates*,” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted by agreement] recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Breeding of Knock-In Mice and Wild Type Mouse Strains,” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section B: Animal Requirements, please clarify the total animal number. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Evaluation of universal beta-coronavirus immunogens in mice,” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 4, Section F: Experimental Design, Proposed Experimental Schema Table 11.3, please clarify when mice from Group 2 are terminated, 2) On page 4, Section F: Experimental Design, Proposed Experimental Schema, Table 11.3, please ensure the total number of animals euthanized matches the proposed numbers in Table 11.2, and 3) On page 7, Section K: Hazardous Agents, please uncheck the box for Recombinant DNA under Hazardous Agents requested. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “Evaluating Coronavirus GrAd-based Vaccines in Nonhuman Primates,” by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section 1, please check box F2 – Procedures, 2) On page 2, Section F: Experimental Design, Previous Schema and Data, please modify the title of Table 1.1 to be “Assess protection with GrAd32 (Spike) vaccine in NHP at various doses, following one or two immunizations.”, 3) On page 2, Section F: Experimental Design, Proposed Experimental Schema, Table 2, please move the nasal wash from Week 6 to Week 5, 4) On page 3, Section F: Experimental Design, Proposed Experimental Schema, please clarify that that the challenge dose may go up to 1×10^6 pfu, and 5) On page 5, Section K: Hazardous Agents, Hazardous Agents Previously Approved, please clarify that the PRD listed is for COVID-infected NHP BBF samples. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

9. Veterinary Verified Consultation (VVC)

The following amendments were mentioned in the ACUC meeting that were Verified via VVC:

- [Redacted by agreement] “Intravascular Staining for the Discrimination of Vascular and Tissue Leukocytes in Nonhuman Primates,” by [Redacted by agreement] 9th Amendment.

This amendment added additional biosampling timepoints to a previously approved experiment.

- [Redacted by agreement] “Development and Evaluation of HIV-1 Envelope based Vaccine Candidates in Guinea pig,” by [Redacted by agreement] 1st Amendment.

This amendment added additional boosts to the schedule.

- [Redacted by agreement] “Treatment of Chronic SHIV-infected Animals with Broadly Neutralizing Antibodies,” by [Redacted by agreement] 1st Amendment.

This amendment modified the immunogens to be used in the experimental group.

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 8th Amendment.

This amendment modified the immunization schedule for one group.

- [Redacted by agreement] “Evaluating Coronavirus GrAd-based Vaccines in Nonhuman Primates,” by [Redacted by agreement] 1st amendment.

This amendment modified the control group immunizations and biosampling schedule.

10. Minor Amendments

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 7th Amendment.

This amendment clarified the replacement of an animal on the protocol due to veterinary reasons.

11. Annual Review Reports

The following annual review reports were approved at the ACUC meeting:

- None

12. Designated Member Review

The following protocols/amendments were mentioned in the ACUC meeting that were Approved via DMR:

- [Redacted by agreement] “Evaluating Coronavirus GrAd-based Vaccines in Nonhuman Primates,” by [Redacted by agreement]
- [Redacted by agreement] “Comparison of SARS-CoV-2 Spike Protein and Adjuvant Formulations,” by [Redacted by agreement]

13. Final Approvals

- Committee members were informed of the Protocol/Amendment Final Approvals from May 20th ACUC meeting.

14. General Announcements, Information

- The meeting adjourned at 4:00pm. The next VRC ACUC meeting will be held July 15th, 2020 at 2:30pm at the Vaccine Research Center, [Redacted by agreement] or through a virtual online meeting platform.

Mario Roederer, PhD
Chair, VRC ACUC Committee

[Redacted by agreement]

**Vaccine Research Center
Animal Care and Use Committee Meeting
July 15th, 2020**

1. The VRC Animal Care and Use Committee convened at 2:30PM via an online virtual Zoom.gov meeting. Five protocols and six amendments were reviewed with action taken.

2. Voting Members Present

Dr. Mario Roederer

Chair

Dr. Ruth Woodward

Attending Veterinarian

Redacted by agreement

Nonvoting Members and Guests Present

Redacted by agreement

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Guest

Members Absent

Redacted by agreement

3. Dr. Roederer called the meeting to order and the minutes from the June 17th meeting were reviewed and approved as written.

4. Old Business

The following old business was discussed at the July 15th ACUC meeting:

- The VRC animal facility manager, [Redacted by agreement] provided an update regarding the [Redacted by agreement] operating status since the COVID-quarantine measures were implemented.

5. New Business

The following new business was discussed at the July 15th ACUC meeting:

- The ACUC was informed that OLAW had reviewed the incident report and concluded no further action was needed.

6. New Protocol (s)

- [Redacted by agreement] "Evaluation of PCSK9 immunogens in nonhuman primates to reduce blood cholesterol," by [Redacted by agreement]

Discussion/Decision A motion was made and seconded to approve the protocol with the following administrative changes: 1) a. On page 1, Section A: Administrative Data, please add [Redacted by agreement] as a co-principal investigator and 2) Please submit a non-human primate blood and body fluid registration amendment and include this ASP via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- (b)(5)

Discussion/Decision A motion was made and seconded to Table the protocol for the next convened ACUC meeting pending the following modifications: (b)(5)

(b)(5)

7. Protocol Renewal (s)

- [Redacted by agreement] "Mechanisms of Antibody and T-cell Responses to Vector-Based subunits and platform-based subunits Vaccines," by [Redacted by agreement]

Discussion/Decision A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 9, Section K: please replace correct the text to "ABSL.", 2) On page 9, Section K: please replace the old RSV PRD number with PRD 7847, and 3) On page 9, Section K: if not performing any immunizations, please remove PRD 5472 since immunizations are performed elsewhere. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Treatment of Chronic SHIV Infection in NHP Using anti-HIV-1 based T cell engaging Trifunctional Antibodies," by [Redacted by agreement]

Discussion/Decision A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 1, please correct the ASP number to 20-0874, 2) On page 1, Section B: Animal Requirements, please correct the total number of animals to 22, 3) On page 13, Section K: Hazardous Agents, please remove the RD listed, and 4) Please submit a non-human primate blood and body fluid registration amendment and include this ASP renewal via PI-Dashboard. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] "Investigation of Correlates and Mechanisms of Protection after IV BCG immunization in nonhuman primates," by [Redacted by agreement]

Discussion/Decision A motion was made and seconded to approve the protocol with the following administrative changes: 1) On page 11, Section K: Hazardous Agents, please add ABSL-2 to the table and the appropriate safety language for animal work, 2) Please submit a non-human primate blood and body fluid registration amendment and include this ASP renewal via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval, and 3) Please submit a BCG registration amendment and include this ASP renewal via PI-Dashboard (<https://oms.ors.nih.gov/>) for IBC review/approval. [Redacted by agreement]

[Redacted] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

8. Amendments

- [Redacted by agreement] “*A study of pharmacokinetics of human monoclonal antibodies in human FcRn transgenic mice,*” by [Redacted by agreement] 10th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted] recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Evaluation of immunogenicity and protective efficacy of influenza hemagglutinin-based mRNA vaccines in mice,*” by [Redacted by agreement] 3rd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment as written. [Redacted] recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Evaluation of Immunogenicity of Influenza-nanoparticles in Non-Human primates*” by [Redacted by agreement] 1st Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) a. On page 5, Section K: Hazardous Agents, Hazardous Agents Previously Approved, please correct the NHP PRD listed to PRD 7365. [Redacted by agreement] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- (b)(5)

Discussion/Decision: A motion was made and seconded to Table the amendment for Designated Member Review pending the following modifications: (b)(5)

(b)(5)

- [Redacted by agreement] “*Evaluating Coronavirus Infection in Nonhuman Primates,*” by [Redacted by agreement] 7th Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section A: Administrative Data, please add [Redacted] as a collaborator on this protocol. [Redacted] accepted the Committee recommendations and recused herself from the ACUC meeting and discussion. **The motion passed unanimously.**

- [Redacted by agreement] “*Comparison of SARS-CoV-2 Spike Protein and Adjuvant Formulations,*” by [Redacted by agreement] 2nd Amendment.

Discussion/Decision: A motion was made and seconded to approve the amendment with the following administrative changes: 1) On page 1, Section B: Animal Requirements, please correct the

total number of animals previously approved and 2) On page 3, Section F: Experimental Design, Proposed Experimental Schema, Table II, please correct the boost timepoint to Week 3. [Redacted by agreement] accepted the Committee recommendations and recused himself from the ACUC meeting and discussion. **The motion passed unanimously.**

9. Veterinary Verified Consultation (VVC)

The following amendments were mentioned in the ACUC meeting that were Verified via VVC:

- [Redacted by agreement] “Evaluating Coronavirus Infection in Nonhuman Primates,” by [Redacted by agreement] 5th Amendment.

This amendment added a -24 hour infusion timepoint to a previously approved experiment and increased the dose.

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 11th Amendment.

This amendment clarified the biosampling schedule.

- [Redacted by agreement] “Comparison of SARS-CoV-2 Spike Protein and Adjuvant Formulations,” by [Redacted by agreement] 1st Amendment.

This amendment reduced the dose used in the previously approved experiment.

10. Minor Amendments

None

11. Annual Review Reports

The following annual review reports were approved at the ACUC meeting:

- [Redacted by agreement] “Generation Breeding and Analysis of Transgenic Mice and Other Mutant Mouse Strains,” by [Redacted by agreement] This is the 1st annual review report.
- [Redacted by agreement] “Investigating the contribution of antigen depots in lymphoid and peripheral tissues to protective immunity,” by [Redacted by agreement] This is the 1st annual review report.
- [Redacted by agreement] “In situ vaccination of polymer-drug conjugates for enhanced cancer immunotherapy in mice,” by [Redacted by agreement] This is the 1st annual review report.

12. Designated Member Review

The following protocols/amendments were mentioned in the ACUC meeting that were Approved via DMR:

- [Redacted by agreement] “Evaluating Coronavirus Vaccines in Nonhuman Primates,” by [Redacted by agreement] 10th Amendment.

13. Final Approvals

- Committee members were informed of the Protocol/Amendment Final Approvals from June 17th ACUC meeting.

14. General Announcements, Information

- The meeting adjourned at 4:00pm. The next VRC ACUC meeting will be held August 19th, 2020 at 2:30pm at the Vaccine Research Center, [Redacted by agreement] or through a virtual online meeting platform.

Mario Roederer, PhD
Chair, VRC ACUC Committee

[Redacted by agreement]