December 21, 2022

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Anthony S. Fauci, M.D. Director National Institute of Allergy and Infectious Diseases

Wanda K. Jones, Dr.P.H., M.T.(ASCP) Acting Director The Office of Research Integrity U.S. Department of Health and Human Services

Via e-mail: <u>brownp@nih.gov; olaw@mail.nih.gov; afauci@niaid.nih.gov;</u> <u>wanda.jones@hhs.gov</u>

> Re: Colombian grant awardees Caucaseco Scientific Research Center, PHS Assurance F20-00459, and Malaria Vaccine and Development Center, PHS Assurance F16-00043

Dear Drs. Brown, Fauci, and Jones:

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals U.S.—PETA entities have more than 9 million members and supporters globally. PETA is in receipt of public records and eyewitness reports that document animal neglect and abuse and possible misconduct pertaining to projects funded by the National Institutes of Health (NIH) at the referenced facilities. PETA requests that:

- the Office of Laboratory Animal Welfare (OLAW) investigate serious findings and allegations of animal neglect and abuse and, if verified, withdraw its approval for the Public Health Service (PHS) Animal Welfare Assurances granted to the Centro de Investigación Científica Caucaseco [Caucaseco Scientific Research Center] (Caucaseco; PHS Assurance F20-00459) and the Malaria Vaccine and Development Center (MVDC; PHS Assurance F16-00043 [A5048-01];
- 2. the National Institute of Allergy and Infectious Diseases (NIAID) investigate alleged mishandling of funds and, if verified, immediately stop funding Caucaseco and demand that

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funds be reimbursed, and refrain from funding Caucaseco and the MVDC in the future; and,

3. The Office of Research Integrity (ORI) investigate possible grant application fraud and serious allegations of scientific misconduct by the heads of both organizations, Sócrates Herrera Valencia (Herrera) and his wife, Myriam Arévalo Ramírez (Arévalo) and, if verified, take all appropriate action.

Caucaseco and the MVDC are located in Cali, Valle del Cauca, Colombia. Both organizations have received more than \$17 million from the National Institutes of Health (NIH) since 2003. Caucaseco has two current grants funded by NIAID: "Discovery and Preclinical Development of Efficacious *P. vivax* Pre-Erythrocytic Stage Malaria Vaccines" (5U01AI155363) and "Discovery and Preclinical Evaluation of *Plasmodium falciparum* and *P. vivax* Coiled Coil Antigens for Malaria Vaccine Development" (5R01AI148843).

The grant applications show that Herrera and Arévalo have collaboration agreements with NIAID Laboratory of Malaria and Vector Research, Florida Atlantic University, Fred Hutchinson Cancer Center, Johns Hopkins Bloomberg School of Public Health, University of Washington, University of Montpellier, in France, and University of Basel and University of Lausanne, in Switzerland. They have also published with staff affiliated with the Centers for Disease Control and Prevention, Emory University, Georgia Institute of Technology, Harvard T.H. Chan School of Public Health, and University of Alabama at Birmingham, among many others. None of these institutions seems to be aware of alleged irregularities at Caucaseco and MVDC.

According to documents obtained by PETA through public record requests to Colombian agencies as well as interviews conducted with 11 individuals who worked for Herrera and Arévalo during different periods between 2012 and 2022, the way Caucaseco and MVDC are structured and allegedly managed calls into question the organizations' abilities to operate in good faith. Further, as documented, the associated organization that holds monkeys on behalf of Caucaseco and MVDC is under investigation for multiple serious violations of Colombian animal welfare laws. The public records and witness statements document:

1. *Violations of Colombian animal welfare laws and other regulations*. Herrera and Arévalo manage a facility in which they confine monkeys who are used in NIAID-funded experiments. An inspection to that facility—performed by the Corporación Autónoma Regional del Valle del Cauca (CVC) in November 2021—found that Herrera and Arévalo kept no records on the monkeys, were operating without IACUC approval, had no veterinarian on staff, ignored humane endpoints, didn't have procedures in place to take care of the monkeys, fed the animals an inappropriate diet, and confined them in cages covered with feces, among other serious violations. The agency also found that Herrera and Arévalo haven't had a required permit to breed them. Pictures taken by the inspector are available <u>here</u>, and pictures and video provided to PETA by whistleblowers are available <u>here</u> and <u>here</u>, respectively.

- 2. Discrepancies between salaries reported to NIAID and salaries actually paid to staff involved in NIAID-funded activities. PETA obtained contracts signed by former Herrera and Arévalo's employees that show salaries that correspond to only a fraction of those reported by Herrera in current NIAID grant applications.
- 3. Apparent illegal capture of Aotus monkeys—species listed as vulnerable by the Colombian government and used by Herrera and Arévalo in NIAID-funded experiments. The last permit obtained by Herrera and Arévalo to capture these monkeys expired in December 2018. However, according to an employee present at the time of the inspection performed in November 2021, the last monkeys were received at their facility around November 2019.
- 4. Apparent lack of properly established Institutional Review Board. According to the Colombian Ministry of Health and Social Protection, there are no records of IRBs operating within the organizations controlled by Herrera and Arévalo.
- 5. Dubious incorporation and management practices. Since its incorporation and for several years, Caucaseco's only board members were Herrera, Arévalo, and their three children, who were minors at the time the organization was established. According to recent meeting minutes, the make-up of the Caucaseco board remains the same, and Herrera and Arévalo are the sole board members for MVDC. According to former employees, MVDC is a business on paper only. Caucaseco and MVDC have experienced multiple charter changes that are inconsistent with their apparent focus on malaria research, and suggest a possible fraudulent use of Colombian law in order to be eligible to apply for funding from various sources.
- 6. *Unsupported statements in Herrera's NIAID grant applications*. Herrera's description of the performance of the organizations he and Arévalo control is not consistent with documents obtained by PETA related to these organizations.
- 7. Alleged failures to comply with biosafety standards that resulted in an employee being infected multiple times with the malaria parasite.
- 8. *Alleged lack of scientific integrity*. Allegedly, Herrera and Arévalo included false or manipulated data in progress reports submitted to funding agencies. Other allegations are related to mishandling of human samples and lack of proper IRB approval to ship human samples from Colombia to the US.

Appendix A is a detailed account of PETA's findings that includes supporting documentation.

As you know, foreign institutions receiving funding from NIH aren't required to report violations of animal welfare regulations, even when they have a PHS Policy Assurance, as Caucaseco and MVDC do. This is in stark contrast to U.S. laboratories, which are required to report violations of the PHS *Guide for the Care and Use of Laboratory Animals*. Caucaseco is not regularly visited by animal welfare inspectors from any country, but research facilities in the U.S. that confine monkeys and other species protected by the federal Animal Welfare Act are inspected at least annually by the U.S. Department of Agriculture. It took two years of pressure from a concerned citizen to get a Colombian state environmental agency to perform an inspection of Herrera and Arévalo's monkey facility. If Caucaseco and MVDC were located in the U.S., the negligence documented by the local inspector and described in whistleblowers' allegations would not have gone unnoticed for long. Facilities that commit to following animal welfare

regulations but are apparently openly ignoring them should not receive funds from American taxpayers.

It must also not be overlooked that the alleged conditions under which these monkeys are captured and transported (See Appendix B), as well as their documented mistreatment and deplorable confinement conditions would render any experiments-particularly those involving the immune system—useless. Continued funding only perpetuates an illegitimate enterprise.

PETA has also contacted Colombian Office of Attorney General—which has opened an investigation-and funding agencies.

You can contact me at MagnoliaM@peta.org. I look forward to your reply regarding this important matter.

Sincerely yours,

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Magnolia Martínez, Ph.D. Lead Projects Manager and Congressional Liaison Laboratory Investigations Department

cc with appendices: Lawrence A. Tabak, D.D.S, Ph.D., Acting Director, National Institutes of Health (tabakl@mail.nih.gov; lawrence.tabak@nih.gov)

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# **APPENDIX A: Detailed PETA's Findings**

Most of the information included in this appendix comes from documents obtained by PETA through Freedom of Information Act requests submitted to the National Institute of Allergy and Infectious Diseases (NIAID) and public records requests submitted to Colombian government agencies and local oversight entities. These documents are linked to in the footnotes. Other information comes from testimonies obtained by PETA from 11 former employees at organizations apparently under the control of Sócrates Herrera and Myriam Arévalo, which were previously or are currently funded by NIAID. These testimonies are not included at the request of the whistleblowers in order to protect their identities due to fear of retribution expressed by the whistleblowers.

Herrera's current grants funded by NIAID are:

- "Discovery and Preclinical Development of Efficacious *P. vivax* Pre-Erythrocytic Stage Malaria Vaccines" (5U01AI155363); and
- "Discovery and Preclinical Evaluation of *Plasmodium falciparum* and *P. vivax* Coiled Coil Antigens for Malaria Vaccine Development" (5R01AI148843).<sup>1</sup>

# Herrera and Arévalo's Caucaseco Consortium for Scientific Research

The Consorcio para la Investigación Científica Caucaseco [Caucaseco Consortium for Scientific Research] appears to be an unregistered consortium that is composed of five entities one of which also appears to be unregistered with Colombian authorities. (*See* Appendix B).The organizations formerly and currently funded by NIAID, and created and controlled by Herrera and Arévalo and, in one instance, also their adult children—Malaria Vaccine and Development Center/Centro Internacional de Vacunas (MVDC/CIV) and Centro de Investigación Científica Caucaseco (Caucaseco)—are portrayed by Herrera as being independent organizations that are part of the consortium.

However, information obtained by PETA show what appears to be a single enterprise operating under several different names with Herrera and Arévalo serving on all boards, in two instances serving as the sole board members, and in a third instance serving with their children as additional board members. The two organizations that have been the recipients of NIH funds have undergone unexplained name and charter changes over the years. Further allegations include the claims that all of the organizations are, in practice, overseen by Herrera, and share at least some interchangeable employees. The corporate structure, outlined above, raises the specter of impropriety and calls into question how and where monies granted by NIH are expended by Caucaseco and MVDC/CIV.

Adding to the apparent overlap in organizations, Caucaseco and FUCEP, the facility that confines the monkeys, operate at the same facility located in a rural suburb of Cali, the capital of Valle del Cauca, and the MVDC's registered address is the same as that of Asoclinic, which corresponds to an office in a five-story building in a residential area of Cali.

According to grant applications, the Consortium:

<sup>&</sup>lt;sup>1</sup>National Institutes of Health. <u>NIH RePORTER</u>. Accessed November17, 2022.

"hosts the Malaria Vaccine and Drug Development Center/Centro Internacional de Vacunas (MVDC/CIV), the Fundación Centro de Primates [Primate Center Foundation] (FUCEP), the Centro de Biotecnología Aplicada [Applied Biotechnology Center] (CBA), and the Instituto de Salud del Pacífico [Pacific Health Institute] (INSALPA)."<sup>2,3</sup>

According to the corsortium's website, Caucaseco and the clinical laboratory Asoclinic Inmunología [Asoclinic Inmunology] (Asoclinic) are also part of the consortium.<sup>4</sup> The CBA unlike the other organizations and as required by local law—was not registered with the Cámara de Comercio de Cali [Cali Chamber of Commerce] as of November 2, 2022, which means it doesn't legally exist under Colombian law.

Public records regarding the structure and purpose of the currently NIAID-funded Caucaseco document the following:

- Caucaseco was created in May 2004—initially under the name "Investigaciones Científicas S&M" [S&M Scientific Investigations]—by a board whose only members were Herrera, Arévalo, and their three minor children, Sonia Marcela Herrera Arévalo, Juan Sebastián Herrera Arévalo, and Adriana Lucía Herrera Arévalo, who at the time were 17, 15, and 12 years old, respectively. According to Caucaseco's incorporation documents, Herrera and Arévalo would represent their children until they legally became adults at the age of 18.
- The purpose listed for the organization was to perform medical and scientific research, to apply biomedical knowledge, and to have a positive impact on animals and the environment.<sup>5</sup>
- In February 2008, the organization's name was changed to "Centro de Investigación Científica Caucaseco" [Caucaseco Scientific Research Center], the current name.<sup>6</sup>
- In June 2011, the Caucaseco charter was changed to specify clean farming, food security, environmental toxicology, and the use of wildlife to develop drugs and cosmetics, among other products, as new objectives. The new charter also allowed the organization to perform commercial activities in order to develop and fulfill its scientific activities. These changes were registered with the Cámara de Comercio de Cali in August 2011.<sup>7</sup>
- In April 2012, Investigaciones Científicas S&M—the initial name of Caucaseco—and Productos para Investigación Molecular were listed as branches of Caucaseco.<sup>8</sup>
- Minutes from the in-person board meetings held between 2008 and 2014 listed the children as attendees, although at least two of them might have been living and attending college in a different city—280 miles away—when some of those meetings took place.<sup>9-10</sup>

<sup>&</sup>lt;sup>2</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>12</u>. July 2020.

<sup>&</sup>lt;sup>3</sup>Herrera S. Discovery and preclinical development of efficacious P. vivax pre-erythrocytic stage malaria vaccines, <u>14</u>. November 2020.

<sup>&</sup>lt;sup>4</sup>Consorcio para la Investigación Científica Caucaseco. Accessed September 9, 2022.

<sup>&</sup>lt;sup>5</sup>Herrera S, Arévalo M, Ossa C. <u>Caucaseco deed</u>. May 13, 2004.

<sup>&</sup>lt;sup>6</sup>Herrera S, Jordán J. <u>Caucaseco deed</u>. February 26, 2008.

<sup>&</sup>lt;sup>7</sup>Bernal F, Arévalo M. <u>Caucaseco meeting minutes</u>. June 7, 2011.

<sup>&</sup>lt;sup>8</sup>Herrera S. <u>Caucaseco registry renewal form</u>. April 10, 2012.

<sup>&</sup>lt;sup>9</sup>Herrera S, Arévalo M. <u>Caucaseco meeting minutes</u>. April 26, 2008.

<sup>&</sup>lt;sup>10</sup>Arévalo W, Torres G. <u>Caucaseco meeting minutes</u>. January 15, 2014.

Public records regarding the structure and purpose of the formerly NIAID-funded MVDC document the following:

- The MVDC was created in May 2000—under the name "Centro Internacional de Vacunas" [International Vaccine Center] (CIV)—by a board whose members consisted of Herrera, Arévalo, and three more people, one of whom was residing in France at the time and whom Herrera represented.<sup>11</sup>
- In October 2009, the organization's name was changed to "Fundación Centro Internacional de Vacunas/Malaria Vaccine and Drug Development Center."<sup>12</sup>
- In September 2010, during a meeting attended only by Herrera, Arévalo, and one more board member, the name of the organization was changed to "Fundación Centro Internacional de Vacunas and/or Malaria Vaccine and Development Center" (CIV/MVDC), the current name, and its objectives were modified to include research on education and work skills development training—none of which was related to biomedical research. These changes were registered with Cámara de Comercio de Cali in November 2010.<sup>13</sup>
- In January 2011, the CIV/MVDC obtained legal status from the Valle del Cauca government, which became its oversight entity. Herrera was executive director and president *pro tem* and Arévalo was secretary.<sup>14</sup>
- In July 2013, an administrative board appointed indefinitely by the Valle del Cauca government included Herrera as executive director and legal representative, Arévalo as executive director and legal representative *pro tem*, and William Arévalo Ramírez—Arévalo's brother—as secretary.<sup>15</sup>
- In December 2014, the CIV/MVDC charter was changed, removing from its mission the provision of health services and including the scientific character of its activities. The Cámara de Comercio de Cali became its oversight entity again.<sup>16</sup>
- In August 2016, the CIV/MVDC charter was changed to include its capacity to establish new organizations and to submit projects to those organizations—created by the MVDC—and carry out those projects on their behalf or on behalf of third parties.<sup>17</sup>

Since September 2010, the MVDC's registered name has been "Fundación Centro Internacional de Vacunas and/or Malaria Vaccine and Development Center."<sup>18,19</sup> The "Malaria Vaccine and Drug Development Center," the affiliation that Arévalo continues to include in her publications as recently as this year,<sup>20</sup> doesn't appear to legally exist under Colombian law.

<sup>&</sup>lt;sup>11</sup>Bernal F, Ramírez A. MVDC <u>Registry request, minutes, and charter</u>. June 20, 2000.

<sup>&</sup>lt;sup>12</sup>Bernal F, Arévalo M. <u>MVDC meeting minutes</u>. October 20, 2009.

<sup>&</sup>lt;sup>13</sup>Bernal F, Arévalo M. <u>MVDC meeting minutes</u>. September 25, 2010.

<sup>&</sup>lt;sup>14</sup>Lourido F, Villegas D. <u>Valle del Cauca Government Ruling 0017</u>. January 19, 2011.

<sup>&</sup>lt;sup>15</sup>Escobar J. <u>Valle del Cauca Government Ruling 337</u>. July 11, 2013.

<sup>&</sup>lt;sup>16</sup>Escobar J. <u>Valle del Cauca government letter</u>. December 16, 2014.

<sup>&</sup>lt;sup>17</sup>Herrera S, Arévalo M. <u>MVDC meeting minutes</u>. August 6, 2016.

<sup>&</sup>lt;sup>18</sup>Bernal F, Arévalo M. <u>MVDC meeting minutes</u>. September 25, 2010.

<sup>&</sup>lt;sup>19</sup>Herrera S. <u>MVDC RUES renewal form</u>. March 24, 2022.

<sup>&</sup>lt;sup>20</sup>Arévalo-Herrera M, Gaitán X, Larmat-Delgado M, et al. Randomized clinical trial to assess the protective efficacy of a Plasmodium vivax CS synthetic vaccine. *Nat Commun.* 2022;13(1):1603. doi:10.1038/s41467-022-29226-3

According to statements to PETA from former employees, Herrera acted as the direct supervisor of all the employees within the entire consortium, regardless of the organization for which each person was hired.

Former employees' contracts obtained by PETA show that individuals hired by FUCEP could be requested to work for other organizations at any time—with a different set of responsibilities— while maintaining their current position, salary, and contracts.<sup>21</sup> Two former FUCEP employees allegedly carried out tasks for Caucaseco and MVDC projects. Another person hired by FUCEP was allegedly never authorized to enter FUCEP's area.

Former employees referred to some the of consortium organizations as "business[es] on paper only" [*translated from Spanish*]. Specifically referring to the MVDC, a former employee stated that "it's 100% an only-on-paper organization" [*translated from Spanish*]. According to two almost identical sets of minutes obtained by PETA, at least on one occasion, Herrera and Arévalo have combined the meetings of two different organizations.<sup>22,23</sup>

In his NIAID grant applications, Herrera included sub-awards for and "cooperation agreements" between Caucaseco and FUCEP and the MVDC.<sup>24</sup> Regardless of which organization is receiving NIAID funds on paper, Herrera and Arévalo both presumably benefit from those funds.

Although the actions described above may adhere to local regulations for these types of organizations, they raise questions about the way Herrera and Arévalo are managing such organizations as well as the taxpayer money they have received.

# Violations of Colombian Animal Welfare Laws and Other Regulations Regarding the Breeding of Monkeys and Their Use in Experimentation

According to Caucaseco's current NIAID grant applications 5U01AI155363 and 5R01AI148843, experiments on monkeys *Aotus l. griseimembra*—a species listed as vulnerable<sup>25</sup> by the Colombian government—would be carried out at FUCEP, one of Herrera and Arévalo's consortium organizations. Documents obtained by PETA show FUCEP's appalling disregard for the welfare of the animals confined at its facilities.

Following a complaint submitted in August 2020 by a concerned citizen,<sup>26</sup> the Corporación Autónoma Regional del Valle del Cauca [Regional Autonomous Corporation of Valle del Cauca] (CVC)—the state environmental agency—requested information from FUCEP. In the CVC's February 2021 response to the concerned citizen, the agency confirmed that FUCEP failed to provide it with the permits required to confine Saimiri monkeys, the historical records

<sup>&</sup>lt;sup>21</sup>In order to protect the whistleblowers' identities, links to contracts are not provided. Redacted files could be made available on request.

<sup>&</sup>lt;sup>22</sup>Bernal F, Arévalo M. <u>MVDC Meeting minutes</u>. August 24, 2009.

<sup>&</sup>lt;sup>23</sup>Bernal F, Arévalo M. <u>FUCEP Meeting minutes</u>. August 24, 2009. Note the agenda. It appears that both sets of minutes were drafted on the same document and then split.

<sup>&</sup>lt;sup>24</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>6–7</u>. July 2020.

<sup>&</sup>lt;sup>25</sup>Murillo L. <u>Ministry of Environment and Sustainable Development Ruling 1912</u>. September 15, 2017.

<sup>&</sup>lt;sup>26</sup>Concerned Citizen. <u>Complaint submitted to Valle del Cauca police department</u>. August 1, 2020.

of all the monkeys who have been confined there, and required monkey-transport permits.<sup>27</sup> In the same letter, the CVC refers to a previous action against FUCEP due to its illegal dumping of waste on wetlands—locally known as "humedales" and considered vulnerable ecosystems.

On November 24, 2021, a CVC employee and a third-party organization's veterinarian performed an inspection at <u>FUCEP facilities</u>, which are made of chain-link fence with construction mesh for "walls" and a "roof." The inspection documented the following:<sup>28</sup>

- There were 127 Aotus monkeys and six Saimiri monkeys. According to the only person in charge of these animals, the last Aotus monkeys—approximately 60 animals—arrived at FUCEP about two years before the inspection (i.e., around November 2019).
- There were no windows in the enclosure where the monkeys are caged that allow airflow. Monkeys were either caged alone or kept in severely crowded cages.
- At the time of the inspection, no food was observed in the cages. The caretaker confirmed that the monkeys were normally fed at around 2 p.m. They were fed dog kibble soaked in sugary water. There were no records of the food given to the monkeys or whether it was based on individual nutritional needs. Two milliliters of Dayamineral—a mineral supplement made for humans—was administered to each monkey once a week.
- <u>Shelters inside the cages were covered with feces</u>. Surfaces were covered with fungus. Some Aotus monkeys were clearly in poor condition, <u>suffering from hair loss</u>, or exhibiting abnormal body posture.
- Procedures such as suturing and wound cleaning were carried out in the same room where necropsies were performed.
- There were no medical records, and humane endpoints were not established.
- No veterinarian was on staff.
- Three necropsy reports—none of them signed by a veterinarian—were available. Although the reports stated that organs and tissues had been sent for pathological analyses, according to the employee on site that wasn't actually done, because "there are no resources to do this type of analysis" [*translated from Spanish*].
- Employees reported that the Universidad del Valle had an ethics committee that authorized the procedures performed on these monkeys. The only documentation available to the inspector was an approval form issued by the Universidad del Valle's Comité de Ética con Animales de Experimentación Biomédica [Ethics Committee for Biomedical Experimentation With Animals] (CEAS), dated July 2015<sup>29</sup> and signed by Hernán Pimienta—one of FUCEP's previous board members.<sup>30</sup> The protocol approved was "*Plasmodium vivax* 48/45 gametocyte protein: functional characterization and vaccine potential assessment in preclinical studies."<sup>31</sup>

<sup>30</sup>Londoño M. <u>FUCEP certification</u>. September 5, 1997.

<sup>&</sup>lt;sup>27</sup>Hurtado D. <u>CVC response to a concerned citizen</u>. February 24, 2021. Saimiri monkeys were used in experiments funded by NIAID and described in a 2005 paper: Jordan-Villegas A, Zapata JC, Perdomo AB, et al. Aotus lemurinus griseimembra monkeys: a suitable model for Plasmodium vivas sporozoite infection. *Am J Trop Med Hyg*. 2005;73(5 Suppl):10-15. Accessed September 9, 2022. doi:10.4269/ajtmh.2005.73.10

<sup>&</sup>lt;sup>28</sup>Rodriguez G. <u>CVC report of inspection to FUCEP</u>. November 24, 2021.

<sup>&</sup>lt;sup>29</sup>Pimienta, H. <u>CEAS approval</u> of Arévalo's protocol "Plasmodium vivax 48/45 gametocyte protein: functional characterization and vaccine potential assessment in preclinical studies." July 16, 2015.

<sup>&</sup>lt;sup>31</sup>This protocol was funded by NIAID. See <u>NIH RePORTER</u>. Accessed September 9, 2022.

Photographs taken by officials during the inspection are available here.

Further investigation by the CVC revealed that FUCEP hasn't had any required permits to use monkeys in experimentation since 2012, which it would need to fulfill its obligations under current NIH contracts, and doesn't have the required permits to breed these animals; although it is unclear if the facility is intentionally engaged in breeding activities. These violations and the animal cruelty documented in November 2021 prompted CVC to pursue legal action against FUCEP and to ask the attorney's office to investigate and prosecute violations to animal welfare regulations.<sup>32,33</sup>

According to documents obtained by PETA, in September 2015, CEAS requested that the city of Cali's Departamento Administrativo de Gestión del Medio Ambiente [Administrative Department of Environmental Management] (DAGMA) evaluate Arévalo's protocol "Immunogenicity and Transmission-Blocking Capacity of *P. vivax* PVS48/45 Antigen in an Immunization/Boost/Challenge Protocol in Aotus monkeys." On October 5, 2015, DAGMA responded to CEAS that an opinion on the protocol couldn't be issued since the protocol didn't include descriptions of any procedures to be performed on the monkeys or of the equipment used to immobilize them. DAGMA also noted that the protocol included inconsistent information about the number of monkeys to be used.<sup>34</sup>

In correspondence with PETA, Universidad del Valle stated that no clinical or pre-clinical protocols by Herrera or Arévalo have been approved by the university's IRB or CEAS after they retired from their teaching positions in 2012 and 2018, respectively, and that Herrera and Arévalo "are not authorized to use old approval forms to support other projects" [*translated from Spanish*].<sup>35</sup> Referring to the 2015 CEAS approval form shown by FUCEP employees to the inspector in November 2021, Universidad del Valle stated that it was an expired,<sup>36</sup> provisional form and that CEAS never received a request from Herrera or Arévalo to obtain a final approval for that protocol.<sup>37</sup>

PETA requested necropsy reports for the period January 1, 2004, to May 31, 2022, and was provided four *Aotus lemurinus* necropsy reports dated June, July, August, and September 2020.<sup>38</sup> Three female monkeys and one male monkey were found dead in their cages. All the reports included an approximate age—1, 2, or around 3 years old. No dates of birth were listed. Three of the monkeys didn't have an ID number. Stress, cardiac arrest, and pneumonia were listed as presumptive causes of death, and thromboembolism, bleeding disorder, and sepsis of gynecological origin were listed as possible causes.

In interviews with PETA, 11 people employed by Herrera and Arévalo at various times between March 2012 and December 2021 alleged the following:

<sup>&</sup>lt;sup>32</sup>Hurtado D. <u>CVC response to PETA</u>. October 14, 2022.

<sup>&</sup>lt;sup>33</sup>Rodríguez G. <u>CVC response to PETA</u>. October 18, 2022.

<sup>&</sup>lt;sup>34</sup>Mozo M. Letter to CEAS. October 5, 2015.

 <sup>&</sup>lt;sup>35</sup>Valencia C. <u>Response to PETA</u>. October 12, 2022.
<sup>36</sup>Ibid

<sup>&</sup>lt;sup>37</sup>Matta L. <u>Response to PETA</u>. Octubre 27, 2022.

<sup>&</sup>lt;sup>38</sup>FUCEP. <u>Necropsy reports sent to CVC</u>. September 17, 2020.

- There were no records for any of the monkeys. Some of the monkeys had a microchip that only indicated the animal's sex, and there was no way of knowing whether a monkey had been used in an experiment.
- The construction mesh covering the area where the monkeys were was not secure and had shifted due to rain and wind, exposing the animals to the elements.
- The monkeys weren't properly isolated. Cats were in the area where the monkey cages were, putting the monkeys at risk of toxoplasmosis.
- The monkey enclosures and nests were rarely cleaned, if ever. The caregiver rinsed only the trays with water in order to remove feces. As a result, the area smelled strongly of urine and feces. In the area where the monkeys were, there were rats, cockroaches, and other insects. Tall weeds inhabited by snakes surrounded the enclosure. The facilities lacked a program to control those animals.
- The monkeys' food was very restricted, and it was changed or reduced due to budget cuts. At one time, the monkeys were fed only dog kibble and bananas. Employees' attempts to improve the animals' diet were not accepted by Herrera.
- Between fall 2018 and spring 2019, no experiments were conducted with monkeys, two monkeys died, and an abortion occurred.
- Four or five Aotus monkeys died suddenly between fall 2020 and spring 2021. Necropsies were performed, and the lungs revealed petechiae resembling those seen in lung infections.
- The monkey cages were rusty and did not provide any environmental enrichment. When the monkeys inserted their hands or feet between the bars, they sustained wounds that became infected.
- Herrera extracted a dead monkey's blood on at least one occasion when no veterinarian was available.
- It was difficult to obtain approval to receive specialized veterinary services, such as imaging or pathology, from outside the facility.
- On one occasion, a recently captured Aotus monkey bit their own hand, prompting an employee to recommend surgery to treat the wound. The surgery wasn't approved by Herrera, and the monkey died soon afterward, presumably from infection.
- Fights between monkeys resulted in finger wounds.
- Narcotics weren't consistently kept in a controlled area.
- Herrera repeatedly asked for more blood to be extracted from the monkeys than was safe, putting the animals in danger, especially given their average weight of 600 to 800 grams.
- The only caregiver for all the monkeys was also the only caregiver for all the mice, in addition to being the custodian and gardener. This person was an older adult who had worked for Herrera and Arévalo for many years, and he was unable to provide adequate care.
- The area where monkey splenectomy surgeries were to take place was so filthy that cleaning it took two people more than an hour.

Photographs and video provided to PETA by whistleblowers are available <u>here</u> and <u>here</u>, respectively.

Caucaseco/MVDC's mice colony reportedly doesn't meet animal welfare standards either, according to former employees:

- There were over 700 mice in the vivarium between summer and fall 2021 because someone failed to separate the males from the females. This resulted in overcrowded conditions with up to 30 mice in boxes designed for a maximum of five mice. Further, the mice weren't provided with adequate water Cannibalism occurred. Herrera and Arévalo ordered that more than half the mice be killed, but there were no appropriate euthanasia protocols. Instead, a cotton ball was soaked with chloroform and placed in a fish tank, next to a mouse. The fish tank remained closed until the mouse was sleepy, at which point a worker removed the animal from the fish tank and pulled their head and tail at the same time in order to cause cervical dislocation.<sup>39</sup>
- On one occasion, Herrera and Arévalo asked that 1 milliliter of blood be extracted from a mouse to make sera, which would have put the animal's life at risk.
- The mice were fed rabbit kibble. Staff arranged to get free samples of food specially formulated for mice, but Herrera never approved the purchase of a further supply.
- When it rained, water entered the area where the mice were confined, forming puddles on the floor—against basic sanitation standards for any facility that confines animals for biomedical research.

The pictures taken during the CVC inspection of FUCEP were taken on November 24, 2021, and those obtained by PETA from whistleblowers were taken about six months to three years apart, and as recently as in the summer of 2021. The similarities between them are clear evidence that for Herrera and Arévalo, the monkeys are merely disposable tools, kept only in order to perpetuate the couple's sham "scientific" activities. Meanwhile, in the NIAID-funded grant 5R01AI148843, Herrera requested \$213,000 for monkey and mice "maintenance" from September 1, 2019, to August 31, 2022.<sup>40-41</sup>

# Possible Discrepancies Between Salaries Reported to NIH and Other Funding Organizations and Salaries Actually Paid

Contracts obtained by PETA show that some professionals employed by Herrera and Arévalo in 2015, 2017, and 2018—who allegedly performed activities related to NIAID grants—received monthly salaries of \$582, \$695, and \$456, respectively.<sup>42</sup> According to Herrera's grant application 5U01AI155363, employees in similar positions would have received a monthly salary of \$2,166 to \$2,541 during the budget period of September 2019 to August 2020.<sup>43</sup> A former employee who was hired by Arévalo in 2017 allegedly saw progress reports addressed to another international funding source in which their monthly salary appeared to be \$2,737, when they were actually being paid \$684. Two other former employees alleged that they saw reports—one of them addressed to the Departamento Administrativo de Ciencia, Tecnología e Innovación

<sup>&</sup>lt;sup>39</sup>The use of chloroform as anesthetics for rodents is not listed as approved in the PHS *Guide*.

<sup>&</sup>lt;sup>40</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>60</u>. July 2020.

<sup>&</sup>lt;sup>41</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>66</u>. July 2020.

<sup>&</sup>lt;sup>42</sup>PETA obtained the contracts signed by these former employees. In order to protect the whistleblowers' identities, links to contracts are not provided. Dollar amounts were converted from Colombian pesos according to the exchange rate on the dates the contracts were signed.

<sup>&</sup>lt;sup>43</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>43</u>. July 2020.

[Administrative Department of Science, Technology, and Innovation, a Colombian government funding agency] (Colciencias)—in which Herrera reported salaries higher than those actually paid to their employees. On at least one occasion, Herrera allegedly decided to end an agreement with an international funding agency when that agency asked him for proof that his employees were being appropriately paid with the resources provided by the agency to this end.

#### **Apparent Failure to Accurately Report Revenue**

According to financial documents obtained by PETA, both Caucaseco and the MVDC apparently failed to report all the funds they received from NIH to Cali Chamber of Commerce, as required by Colombian law. In 2011 and 2012, Caucaseco received \$3,435,585 from NIAID but reported zero operating revenue on forms submitted to the Cámara de Comercio de Cali.<sup>44,45</sup> Between August 1, 2013, and January 1, 2021, Caucaseco and the MVDC received \$10,211,346 from NIAID<sup>46</sup> but only reported \$8.703.578 as operating revenue,<sup>47,48</sup> despite the fact that during these years, they had also received funding from the Colombian government<sup>49</sup> and the German government,<sup>50</sup> among other sources.<sup>51</sup>

#### **Unsupported Statements in NIAID Grant Applications**

Some of Herrera's statements in his current NIAID grant applications 5R01AI148843 and 5U01AI155363-02 aren't supported by documents obtained by PETA. On grant applications to NIAID, Herrera stated that at FUCEP and Caucaseco the monkeys and mice are kept under "conditions for immunogenicity studies" or that their "care and welfare" "are under the responsibility of a veterinarian and trained technicians and are regulated according to … international guidelines."<sup>52,53</sup> As previously described, based on its inspection in November 2021, the CVC determined that FUCEP's violations of Colombian animal welfare laws and other regulations warranted consideration of legal action. Failing to have a veterinarian on staff and lack of IACUC oversight were two of FUCEP's violations.<sup>54</sup>

<sup>&</sup>lt;sup>44</sup>Herrera S. <u>Caucaseco registry renewal form</u>. April 10, 2012. Includes 2011 financial information.

<sup>&</sup>lt;sup>45</sup>Bernal F. <u>Caucaseco RUES renewal form</u>. May 16, 2013. Includes 2012 financial information.

<sup>&</sup>lt;sup>46</sup>National Institutes of Health. <u>NIH RePORTER</u>. Accessed September 9, 2022.

<sup>&</sup>lt;sup>47</sup>This dollar amount was converted from the corresponding total reported in Colombian pesos using the exchange rate on the date of NIH fund distribution.

<sup>&</sup>lt;sup>48</sup>Herrera S. <u>MVDC RUES renewal form</u>. March 24, 2022. Includes 2021 financial information.

<sup>&</sup>lt;sup>49</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>23–24</u>. July 2020. Ongoing research support listed on the application includes grants from Colombian government entities Sistema Nacional de Regalías and Colciencias.

 <sup>&</sup>lt;sup>50</sup>See "Funding Statement" in Vallejo AF, Martínez NL, González IJ, Arévalo-Herrera M, Herrera S. Evaluation of the loop mediated isothermal DNA amplification (LAMP) kit for malaria diagnosis in P. vivax endemic settings of Colombia. *PLoS Negl Trop Dis*. 2015;9(1):e3453. Accessed September 9, 2022. doi:<u>10.1371/journal.pntd.0003453</u>
<sup>51</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>23–24</u>. July 2020. Ongoing research support listed on the application includes grant PATH GAT.0888-11-06147-COL 2013-2015.

<sup>&</sup>lt;sup>52</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>13</u>. July 2020.

<sup>&</sup>lt;sup>53</sup>Herrera S. Discovery and preclinical development of efficacious P. vivax pre-erythrocytic stage malaria vaccines, <u>15</u>. November 2020.

<sup>&</sup>lt;sup>54</sup>Rodriguez G. <u>CVC report of inspection to FUCEP</u>. November 24, 2021.

According to Herrera, mice and monkey colonies at the MVDC and FUCEP "have 20 years of noncontamination, because the Center avoids working simultaneously with different genetic lines. The genetic purity is periodically evaluated analyzing qualitative or quantitative characteristics (enzymes, immunological markers, DNA markers) and comparing them with internationally established reference values for the inbred line. ... For monkeys, ancestors and littermates will be used to compare genotypes. Records of animal genotyping are maintained in the center."<sup>55,56</sup> As the CVC inspection report notes and the whistleblowers pointed out, no records were kept of any animals at FUCEP.<sup>57</sup>

Herrera states that a "consortium for biomedical research was established in Cali, Colombia in 2000." But in 2000, the only registered business was Arévalo's laboratory<sup>58</sup> and the only registered nonprofit was FUCEP.<sup>59</sup> The MVDC submitted a registry request to the Cámara de Comercio de Cali in June 2000.<sup>60</sup> The nonprofit Insalpa was founded in 2013,<sup>61</sup> not "more than 30 years" ago, as stated in Herrera's current NIAID grant applications. The CBA is one of the organizations listed as a member of the consortium, but as of November 2 the Cámara de Comercio de Cali had no records associated with the CBA, which means the organization doesn't officially exist according to Colombian law.

Herrera's NIAID grant applications refer to Caucaseco's "solid administrative structure." Documents obtained by PETA show something different. On May 20, 2021, Herrera fired all Caucaseco's employees,<sup>62</sup> including those hired by the MVDC.<sup>63</sup> On February 7, 2022, Herrera requested that the Secretaría Departmental de Salud del Valle [Valle State Secretary of Health] approve the assignment of four recent medical school graduates to "research positions" at the MVDC.<sup>64</sup> Approval was granted on February 21, but the next day Herrera wrote back to the Secretaría Departamental de Salud, saying that the MVDC didn't have the funds to pay those four physicians.<sup>65</sup> The Secretaría Departamental de Salud canceled the MVDC assignments because the organization had failed to meet the terms of the agreement.<sup>66</sup>

<sup>&</sup>lt;sup>55</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>133</u>. July 2020.

<sup>&</sup>lt;sup>56</sup>Herrera S. Discovery and preclinical development of efficacious P. vivax pre-erythrocytic stage malaria vaccines, <u>189</u>. November 2020.

<sup>&</sup>lt;sup>57</sup>Rodriguez G. <u>CVC report of inspection to FUCEP</u>. November 24, 2021.

<sup>&</sup>lt;sup>58</sup>Arévalo M. <u>1991 financial statement</u>. January 7, 1992.

<sup>&</sup>lt;sup>59</sup>Arévalo M. <u>FUCEP registry request</u>. June 18, 1997. According to this request, FUCEP was initially incorporated in March 1991 and was affiliated with the Valle University School of Health.

<sup>&</sup>lt;sup>60</sup>Bernal F, Ramírez A. <u>MVDC registry request, minutes, and charter</u>. June 20, 2000.

<sup>&</sup>lt;sup>61</sup>Herrera S. <u>Insalpa incorporation request</u>. February 21, 2013. In the grants, this institute is listed as "Colombian Pacific Health Institute (INSALPA)."

<sup>&</sup>lt;sup>62</sup>Herrera S. <u>Memo to consortium staff</u>. May 20, 2021.

<sup>&</sup>lt;sup>63</sup>Herrera S. <u>Letter to state secretary of health</u>. June 23, 2021.

<sup>&</sup>lt;sup>64</sup>Herrera S. <u>Request to state secretary of health</u>. February 7, 2022.

<sup>&</sup>lt;sup>65</sup>Herrera S. <u>E-mail to state secretary of health</u>. February 22, 2022.

<sup>&</sup>lt;sup>66</sup>Lesmes, M. <u>Valle del Cauca government response to PETA</u>. June 10, 2022.

According to forms signed on March 2022 by Herrera and submitted to the Cámara de Comercio de Cali, Caucaseco had 15 employees<sup>67</sup> and the MVDC had six.<sup>68</sup> Between August 9 and August 14, the MVDC advertised 12 job openings for administrative and maintenance staff, including three positions posted as "urgent."<sup>69</sup> In May, the MVDC had eight job openings,<sup>70</sup> including two for research staff that required only two years of experience.<sup>71,72</sup> The apparent inconsistency between the number of employees reported in March and those sought in May—and then again only three months later—could be attributed to possible high staff turnover due to Herrera's purportedly hostile work environment, in which new employees were allegedly assigned responsibilities based on pending tasks—previously assigned to people who had resigned—regardless of the position for which they had been hired. According to former employees, during one job interview, a candidate to a professional position that would be responsible for the animals allegedly stated that they lacked the required experience, to which Herrera allegedly responded that lack of experience wasn't an issue and that by accepting the position, the applicant would have the opportunity to publish—an appealing proposition for a young scientist.

## **Apparently Illegal Capture of Vulnerable Species**

In 2017, the Colombian government listed *Aotus lemurinus* and *Aotus griseimembra* as vulnerable species.73 Herrera's current NIAID-funded grants include experiments on Aotus lemurinus griseimembra monkeys. PETA submitted public records requests to all the state environmental agencies with jurisdictions in which Aotus monkeys are likely to be found. Corporación de Desarrollo Sostenible para el San Jorge y La Mojana [Sustainable Development Corporation for San Jorge and La Mojana] (Corpomojana) appears to be the only entity that has received permit requests from FUCEP, Herrera and Arévalo's monkey facility. Documents obtained by PETA show that only three permits have been granted to FUCEP by Corpomojana: one in May 1999, which allowed for the capture of an unknown number of monkeys within two years; one in July 2002, which allowed for the capture of 50 monkeys within a year;<sup>74</sup> and one in December 2017, which allowed for the capture of 60 monkeys, but only up to 20 per trimester, in 2018.75 However, during the CVC inspection of FUCEP, an employee told the inspector that approximately 60 Aotus monkeys had arrived at FUCEP around two years before the inspection—around November 2019, which was 11 months after the capture permit had expired.<sup>76</sup> Furthermore, the Ministerio de Ambiente y Desarrollo Sostenible [Ministry of Environment and Sustainable Development] confirmed to PETA that no capture permits have been issued to Herrera and Arévalo that allow them to use genetic resources or any products obtained from monkeys.77

<sup>&</sup>lt;sup>67</sup>Herrera S. <u>Caucaseco RUES renewal form</u>. March 24, 2022. See p. 3 for the number of employees.

<sup>&</sup>lt;sup>68</sup>Herrera S. <u>MVDC RUES renewal form</u>. March 24, 2022. See p. 3 for the number of employees.

<sup>&</sup>lt;sup>69</sup>MVDC. <u>Job postings on Computrabajo</u>. August 16, 2022.

<sup>&</sup>lt;sup>70</sup>MVDC. Job postings on Computrabajo. May 24, 2022.

<sup>&</sup>lt;sup>71</sup>MVDC. <u>Chemist job posting on Computrabajo</u>. May 24, 2022.

<sup>&</sup>lt;sup>72</sup>MVDC. <u>Biologist job posting on Computrabajo</u>. May 24, 2022.

<sup>&</sup>lt;sup>73</sup>Murillo L. <u>Ministry of Environment and Sustainable Development Ruling 1912</u>. September 15, 2017.

<sup>&</sup>lt;sup>74</sup>Verbel L. <u>Corpomojana ruling 0126</u>. July, 9, 2002. See p. 1 for reference to the permit issued in May 1999. See p. 2 for the permit issued in July 2002.

<sup>&</sup>lt;sup>75</sup>Quiroz L. <u>Corpomojana ruling 452</u>. December 28, 2017.

<sup>&</sup>lt;sup>76</sup>Rodriguez G. <u>CVC report of inspection to FUCEP</u>. November 24, 2021.

<sup>&</sup>lt;sup>77</sup>Camargo L. <u>Response to PETA</u>. November 15, 2022.

According to whistleblowers' accounts, four trips to capture Aotus monkeys in forests under Corpomojana's jurisdiction were allegedly made between summer 2018 and spring 2019. In the summer of 2018, around 50 monkeys were reportedly captured. During each of the other trips, between 20 and 40 monkeys were captured. Based on these allegations and the information obtained during the CVC inspection, around 100 monkeys might have been illegally captured by FUCEP in 2018 and 2019. According to a former employee, the local people hired by Herrera and Arévalo to capture the monkeys apparently used a crude technique: When a monkey was alone, they would be forced into a tree and trapped in a cloth or sisal bag. Monkeys were also abducted from their nests. Allegedly, on one occasion, a monkey died of cardiopulmonary arrest during their capture and another died en route—a 20-hour, 590-mile journey by land from Colombian northern forests to Cali.

Former employees allegedly never saw newborn monkeys at FUCEP, although they were told that births had occurred. According to one of these employees, "When they said that there had been a birth in captivity, it was a lie. It wasn't that a baby had been born—it was that a baby had been captured" [*translated from Spanish*].

The cruelty involved in the capture of these monkeys—whether sanctioned by authorities or carried out illegally—is only one part of the problem. According to a 2017 FUCEP report, only 523 Aotus monkeys lived in the area where FUCEP would capture them.<sup>78</sup> This low number would explain the inclusion of Aotus as a vulnerable species by the Colombian government and the Corpomojana's permit restriction to FUCEP to capture only 60 monkeys—20 at a time—in nine months. As previously shown, FUCEP allegedly ignored the limit imposed by Corpomojana and continued abducting monkeys. This is an example of why the International Primatological Society recently recommended that biomedical research facilities end their use of wild-caught primates, which supports a practice that's decimating primate populations.<sup>79</sup>

# Apparent Lack of Properly Established IACUC and IRB

At least 24 papers by Herrera and/or Arévalo published between March 2015 and March 2022 state that the protocols were approved by the "Institutional Review Board" (IRB) of the "Malaria Vaccine and Drug Development Center" ("CECIV," "MVDC," or "MVDC-CECIV"),"<sup>80–81</sup> by the "Ethical Committee" of "Centro Internacional de Vacunas (CECIV),"<sup>82–83</sup> by the IRB of

<sup>79</sup>International Primatological Society. <u>Harvesting of wild primates for use in biomedical research</u>. March 31, 2022.
<sup>80</sup>Arévalo-Herrera M, Gaitán X, Larmat-Delgado M, et al. Randomized clinical trial to assess the protective efficacy of a Plasmodium vivax CS synthetic vaccine. *Nat Commun*. 2022;13(1):1603. Accessed September 9, 2022.

<sup>&</sup>lt;sup>78</sup>Arévalo M. <u>Individual collection permit report</u>. July 8, 2017. See p. 7.

doi:<u>10.1038/s41467-022-29226-3</u>

<sup>&</sup>lt;sup>81</sup>Arévalo-Herrera M, Vallejo AF, Rubiano K, et al. Recombinant Pvs48/45 antigen expressed in E. coli generates antibodies that block malaria transmission in Anopheles albimanus mosquitoes. *PLoS One*. 2015;10(3):e0119335. Accessed September 9, 2022. doi:<u>10.1371/journal.pone.0119335</u>

<sup>&</sup>lt;sup>82</sup>Arévalo-Herrera M, Miura K, Solano E, et al. Immunogenicity of full-length P. vivax rPvs48/45 protein formulations in BALB/c mice. *Vaccine*. 2022;40(1):133–140. Accessed September 9, 2022. doi:10.1016/j.vaccine.2021.11.036

<sup>&</sup>lt;sup>83</sup>Vallejo AF, Rubiano K, Amado A, Krystosik AR, Herrera S, Arévalo-Herrera M. Optimization of a membrane feeding assay for Plasmodium vivax infection in anopheles albimanus. *PLoS Negl Trop Dis.* 2016;10(6):e0004807. Accessed September 9, 2022. doi:<u>10.1371/journal.pntd.0004807</u>

"Caucaseco Scientific Research Center (CECIV),"<sup>84</sup> by the "IRB at the CIV,"<sup>85</sup> or simply by "CECIV"<sup>86</sup> or "MVDC."<sup>87</sup> A 2022 paper also mentions the "Animal Ethics Committee of MVDC."<sup>88</sup> As previously mentioned, the Malaria Vaccine and Drug Development Center has not formally existed since November 2010, when the name change—approved three months earlier—was registered with the Cámara de Comercio de Cali,<sup>89</sup> so there can't be a formally established IRB registered with the Ministerio de Salud y Protección Social [Ministry of Health and Social Protection], as local regulations require when communities are involved.<sup>90</sup> Furthermore, the MVDC allegedly doesn't have a functional, independent IRB or an institutional animal care and use committee (IACUC), nor does Caucaseco. Requests to Colombian government agencies and Arévalo made by PETA and the state health department, respectively, to produce documents that prove the existence of an IACUC and an IRB within Herrera and Arévalo controlled organizations haven't been answered.<sup>91,92</sup> Furthermore, in a November 2022 letter to Valle del Cauca Health Secretary, the Ministerio de Salud y Protección Social [Ministry of Health and Social Protection] confirmed that they have no records of any IRBs associated with the organizations controlled by Herrera and Arévalo.<sup>93</sup>

Two papers, published in 2020<sup>94</sup> and 2022<sup>95</sup> and respectively describing experiments on monkeys and mice, state that protocols were approved by the Universidad del Valle's Animal Ethical Committee. These papers don't include the dates when the experiments on animals were performed. However, according to the CVC, Universidad del Valle's Animal Ethical Committee had not met to review protocols involving animals used by Herrera and Arévalo.<sup>96</sup> The Universidad del Valle confirmed to PETA that no clinical or pre-clinical protocols by Herrera

Accessed September 9, 2022. doi: 10.1073/pnas.1920596117

<sup>&</sup>lt;sup>84</sup>Molina Gómez K, Caicedo MA, Gaitán A, et al. Characterizing the malaria rural-to-urban transmission interface: The importance of reactive case detection. *PLoS Negl Trop Dis*. 2017;11(7):e0005780. Accessed September 9, 2022. doi:<u>10.1371/journal.pntd.0005780</u>

<sup>&</sup>lt;sup>85</sup>Gardinassi LG, Arévalo-Herrera M, Herrera S, et al. Integrative metabolomics and transcriptomics signatures of clinical tolerance to Plasmodium vivax reveal activation of innate cell immunity and T cell signaling. *Redox Biol*. 2018;17:158–170. Accessed September 9, 2022. doi:<u>10.1016/j.redox.2018.04.011</u>

<sup>&</sup>lt;sup>86</sup>Pratesi F, Errante F, Pacini L, et al. A SARS-CoV-2 Spike receptor binding motif peptide induces anti-spike antibodies in mice and is recognized by COVID-19 Patients. *Front Immunol.* 2022;13:879946. Accessed September 9, 2022. doi:10.3389/fimmu.2022.879946

<sup>&</sup>lt;sup>87</sup>Arévalo-Herrera M, Lopez-Perez M, Dotsey E, et al. Antibody profiling in naïve and semi-immune individuals experimentally challenged with Plasmodium vivax sporozoites. *PLoS Negl Trop Dis.* 2016;10(3):e0004563. Accessed September 9, 2022. doi:<u>10.1371/journal.pntd.0004563</u>

<sup>&</sup>lt;sup>88</sup>Pratesi F, Errante F, Pacini L, et al. A SARS-CoV-2 Spike receptor binding motif peptide induces anti-spike antibodies in mice and is recognized by COVID-19 patients. *Front Immunol.* 2022;13:879946. Accessed September 9, 2022. doi:<u>10.3389/fimmu.2022.879946</u>

<sup>&</sup>lt;sup>89</sup>MVDC. <u>Minutes with change of name and purpose</u>. September 25, 2010.

<sup>&</sup>lt;sup>90</sup>MVDC. <u>Ministry of Health Ruling 8430</u>. April 10, 1993.

<sup>&</sup>lt;sup>91</sup>Mojica M. <u>Transfer of PETA request from Ministry of Health to State Health Department</u>. September 20, 2022.

 <sup>&</sup>lt;sup>92</sup>Lesmes M. <u>Request from State Health Department to Myriam Arévalo</u>. October 4, 2022.
<sup>93</sup>Pulgarín S. <u>Answer from Ministry of Health and Social Protection</u>. November 1, 2022.

 <sup>&</sup>lt;sup>94</sup>Fernandez-Becerra C, Bernabeu M, Castellanos A, et al. Plasmodium vivax spleen-dependent genes encode antigens associated with cytoadhesion and clinical protection. *Proc Natl Acad Sci USA*. 2020;117(23):13056–13065.

<sup>&</sup>lt;sup>95</sup>Arévalo-Herrera M, Miura K, Solano E, et al. Immunogenicity of full-length P. vivax rPvs48/45 protein formulations in BALB/c mice. *Vaccine*. 2022;40(1):133–140. Accessed September 9, 2022. doi:10.1016/j.vaccine.2021.11.036

<sup>&</sup>lt;sup>96</sup>Ramírez A. <u>CVC response to a concerned citizen</u>. July 15, 2022.

and Arévalo have been approved by its committees since 2012 and 2018, years when Herrera and Arévalo retired from the school, respectively.<sup>97</sup>

## Alleged Racist Practices and Alleged Lack of Scientific Integrity

Based on the testimonies of former employees, there have been integrity lapses in the way research data have been obtained, handled, reported, and published by Herrera and Arévalo. According to Herrera's current NIAID-funded grants, Insalpa "has established a very solid and stable interaction and collaboration with endemic communities of Colombia."98,99 However, it appears that these communities aren't "collaborating"-they appear to be manipulated in order to obtain samples from them that will later be used to obtain funding and establish professional connections. Insalpa's alleged main employees are female community health workers from African-Colombian communities where malaria is endemic, known as "promotoras" in Spanish. These employees, who reportedly don't have professional degrees, are in charge of taking blood samples and performing malaria thick smears and are, in most cases, the only ones responsible for obtaining informed consent. According to allegations by former employees, miscommunication between these employees and research staff was not unusual, and on several occasions, protocols for packing and shipping human blood samples weren't followed, resulting in samples being mishandled. Allegedly, Insalpa is actually the room or space where these employees draw blood, and it only has a desk, a chair, a microscope, and Styrofoam coolers for blood samples.

A former employee who allegedly had access to human blood samples taken by "promotoras" saw blood samples labeled as taken from minors. The same former employee was unaware of any informed consent obtained from their parents or responsible adults. This person also alleged that people from African-Colombian communities where malaria is endemic were paid \$119—half the current monthly minimum wage in Colombia—for allowing *Plaxmodium falciparum*—infected mosquitos to bite them. Speaking of the African-Colombian people participating in this project, Herrera allegedly said, "[T]hose people are black and stupid; who cares what we do to them?" [*translated from Spanish*].

Allegedly, human serum and plasma samples ordered by and shipped to Emory University in Atlanta from Colombia in 2017 by Arévalo's brother William Arévalo Ramírez were logged as vegetable samples due to a lack of IRB approval to ship human samples. Those samples may have been used in experiments described in a 2018 publication<sup>100</sup> by Herrera and affiliates of Emory University and the University of Alabama–Birmingham.

Former Herrera and Arévalo's employees alleged the following:

<sup>&</sup>lt;sup>97</sup>Valencia C. <u>Response to PETA</u>. October 12, 2022.

<sup>&</sup>lt;sup>98</sup>Herrera S. Discovery and preclinical evaluation of Plasmodium falciparum and P. vivax coiled coil antigens for malaria vaccine development, <u>12</u>. July 2020.

<sup>&</sup>lt;sup>99</sup>Herrera S. Discovery and preclinical development of efficacious P. vivax pre-erythrocytic stage malaria vaccines, 14. November 2020.

<sup>&</sup>lt;sup>100</sup>Gardinassi LG, Arévalo-Herrera M, Herrera S, et al. Integrative metabolomics and transcriptomics signatures of clinical tolerance to Plasmodium vivax reveal activation of innate cell immunity and T cell signaling. *Redox Biol.* 2018;17:158–170. Accessed September 9, 2022. doi:<u>10.1016/j.redox.2018.04.011</u>

- In a report addressed to Colciencias, Herrera included results from a population other than that which had been screened.
- Many of the dates specified in project reports were false and had been changed to accommodate funding agencies' budget timelines.
- A former employee once told Herrera that the antibody titers obtained could be false because the reagents used had expired. Herrera ignored this information. The budget for grant applications included the purchase of new reagents, but old reagents were used instead.
- A former employee once informed Arévalo that a protein she was planning to use was contaminated. Instead of throwing it away, Arévalo modified and used it.
- No protocols were in place to ensure that the results of experiments on rodents were reproducible.

According to documents obtained by PETA, Herrera graduated from medical school in 1979<sup>101</sup> and took a four-week course on immunology in 1982.<sup>102</sup> He characterizes this course as "postdoctoral" studies.<sup>103</sup> He doesn't hold a Ph.D. degree.

Caucaseco's internet domain (inmuno.co) is still that associated with the Instituto de Inmunología [Institute of Immunology] that was once affiliated with the Universidad del Valle but is no longer part of the school.<sup>104</sup> That Herrera and Arévalo continue using the name "Malaria Vaccine and Drug Development Center" and refer to a "Department of Immunology" established at the "Malaria Vaccine and Drug Development Center" and at "Caucaseco Scientific Research Center"<sup>105</sup> appear to be deliberate attempts to mislead the public, the scientific community, and funding agencies into believing that their organization is a serious academic institution, perhaps affiliated with an entity that was once part of the Universidad del Valle.

# Alleged Failure to Meet Biosafety Standards

There is also a mosquito colony in Caucaseco. The person who was in charge of the mosquito colony for many years allegedly became ill with malaria several times due to biosafety failures. Mosquitos were apparently fed blood drawn from malaria patients, but when this blood was unavailable, Caucaseco staff allegedly drew their own blood to feed the mosquitos.

# Alleged Sexual Harassment and Hostile Work Environment

PETA obtained documents and firsthand accounts by former employees that describe a hostile work environment. Herrera is reported to be rude and disrespectful and has used words such as "stupid," "thief," "useless," "fat," and "crazy" [*translated from Spanish*] to refer to his employees—even while speaking directly to them. A former employee allegedly witnessed that Herrera sexually harassed female coworkers by making inappropriate comments to them. Another former employee allegedly resigned because of workplace hostility and sexual

<sup>&</sup>lt;sup>101</sup>Universidad de Caldas. <u>Sócrates Herrera's undergraduate degree in medicine and surgery</u>. July 27, 1979. <sup>102</sup>Torrugiani G, Lambert P, Louis J. Attestation. June 25, 1984.

<sup>&</sup>lt;sup>103</sup>Asoclinic. Quiénes somos. Accessed August 30, 2022.

<sup>&</sup>lt;sup>104</sup>Universidad del Valle. Institutos, Centros y Grupos de Investigación. Escuela de Medicina.

<sup>&</sup>lt;sup>105</sup>Traoré A, Guindo MA, Konaté D, et al. Seroreactivity of the severe acute respiratory syndrome coronavirus 2 recombinant s protein, receptor-binding domain, and its receptor-binding motif in COVID-19 patients and their cross-reactivity with pre-COVID-19 samples from malaria-endemic areas. *Front Immunol.* 2022;13:856033. Accessed September 9, 2022. doi:10.3389/fimmu.2022.856033

harassment from Herrera, and yet another reportedly quit after dodging punches thrown at them by Herrera.

PETA obtained an audio recording in which a person that the whistleblower alleges is Herrera says the following to a then current employee:

[Y]ou're exposing yourself to my kicking you out at any moment and sending you to hell because you're pretending to be an idiot. ... You're not as stupid as you look ... of course, you're not very intelligent, but you're not that stupid. ... But you just pretend to be an idiot, so I'm going to kick you out. ... It's up to you if you let me kick you out ... you can't come here and take me as a cocksucker ... son of a bitch ... don't pretend to be an idiot [*translated from Spanish*].

Allegedly due to the hostile work environment created by Herrera, "there are always people quitting at Caucaseco; there were weeks in which three or four people quit; sometimes the director's [Herrera's] assistants worked for only 10 or 15 days" [*translated from Spanish*]. A former employee reportedly witnessed 15 resignations within a few months, and during a three-month period in 2021, four employees resigned as Herrera's assistant.

PETA obtained documents pertaining to a workplace harassment complaint filed with the Ministerio del Trabajo Dirección Territorial Valle del Cauca (the state office of the Ministry of Labor) by a former employee. Several other former employees reportedly also filed complaints with the same agency, but the allegations of a hostile work environment and sexual harassment were never investigated. Allegedly, on one occasion, Herrera forced his employees to express support for Dilian Francisca Toro Torres—who was governor of Valle del Cauca from 2016 to 2019—on an online poll and required them to send him a screenshot as proof that they had followed his instructions.<sup>106</sup>

<sup>&</sup>lt;sup>106</sup>The Colombian Supreme Court has launched two investigations into Toro's actions: In 2008 for her alleged involvement in parapolitics, and in 2012 for alleged money laundering. She was under preventive detention from July 25, 2012, to August 1, 2013. Both cases were closed. Toro Torres is the current national director of Colombian political party "Partido de la U."

# **APPENDIX B: Organizations Controlled by Sócrates Herrera and Myriam Arévalo**

The following organizations are part of the Consorcio para la Investigación Científica Caucaseco [Caucaseco Consortium for Scientific Research]. The consortium itself is not a registered entity. The Centro de Biotecnología Aplicada [Applied Biotechnology Center] (CBA) is not a registered organization as of November 2, 2022.

#### 1991

Fundación Centro de Primates [Primate Center Foundation] (FUCEP)

Board, according to meeting minutes #23, August 12, 2022, 2:00 pm:

- Sócrates Herrera Valencia, President
- Myriam Arévalo Ramírez
- José Edgar Vargas Trujillo
- Antonio Ramírez Rodríguez
- Anilza Bonelo Perdomo, representing deceased board member Francisco Bernal Campuzano

#### 2000

#### Centro Internacional de Vacunas/Malaria Vaccine and Development Center/(CIV/MVDC)

Formerly "Malaria Vaccine and Drug Development Center"

Board, according to meeting minutes #36, August 12, 2022, 9:00 am:

- Sócrates Herrera Valencia
- Myriam Arévalo Ramírez

#### 2004

**Centro de Investigación Científica Caucaseco** [Caucaseco Center for Scientific Research] (Caucaseco) Formerly "Investigaciones Científicas S&M" [S&M Scientific Investigations] Board, according to meeting minutes #2022-01, August 12, 2022, 11:00 am:

- Sócrates Herrera Valencia
- Myriam Arévalo Ramírez
- Sonia Marcela Herrera Arévalo (daughter)
- Adriana Lucía Herrera Arévalo (daughter)
- Juan Sebastián Herrera Arévalo (son)

#### 2006

#### Asoclinic

Board, according to March 2017 Charter:

- Sócrates Herrera Valencia
- Myriam Arévalo Ramírez

#### 2013

**Fundación Instituto de Salud del Litoral Pacífico** [Pacific Health Institute] (INSALPA)

Board, according to meeting minutes #2022-02, August 30, 2022, 4:00 pm:

- Sócrates Herrera Valencia
- Myriam Arévalo Ramírez
- Beatriz María del Pilar García Neuman
- Laureano Castellano Coca

In this INSALPA meeting, the members voted to appoint Juan Sebastián Herrera Arévalo (son) as president of the board.

# **APPENDIX C: Links to Photographs and Video**

Photos taken at FUCEP and obtained by PETA through a public records request to Corporación Autónoma Regional del Valle del Cauca (CVC) are available <u>here</u>.



Photos taken at FUCEP and MVDC/Caucaseco and obtained by PETA from whistleblowers are available <u>here</u>.



Photos taking during Insalpa's activities and obtained by PETA from a whistleblower are available <u>here</u>.



Video taken at FUCEP and obtained by PETA from a whistleblower is available <u>here</u>.

