



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 5, 2023

Dr. Sócrates Herrera Valencia
Director and Principal Investigator
Caucaseco Scientific Research Center
Carrera 37 2 BIS # 5E - 08 OF 201
Cali, Colombia 760042

Dear Dr. Herrera Valencia:

The NIH National Institute of Allergy and Infectious Diseases (NIAID) is writing to Caucaseco Scientific Research Center (CSRC) to follow up on our meeting held on June 8, 2023 as a result of an insufficient response to our letter dated April 25, 2023 and our concerns regarding noncompliance with awards 5R01AI148843-04 and 5U01AI155363-03.

Given the remaining noncompliance concerns, NIAID will immediately suspend awards 5R01AI148843-04 and 5U01AI155363-03 based on CSRCs insufficient response to demonstrate compliance with NIH Grants Policy Statement (NIHGPS); specifically, Chapter 4.1.1.4 Foreign Recipients and Foreign Performance Sites which requires compliance with policies of the recipients local jurisdiction, as it relates to compliance with animal license requirements in Colombia. The suspension will be implemented on both awards by a specific award condition (SAC), per 8.5.1 Specific Award Conditions: Modification of the Terms of Award. In addition, NIAID will disallow costs if it is determined that CSRC was noncompliant with the award terms and conditions. Disallowed costs would include all funding support associated with animal research, including data analysis associated with animal research, that occurred without the proper animal licenses.

Based on the assertions CSRC stated on the June 8, 2023 call with NIAID, CSRC must confirm that the supporting documentation provided to NIAID on June 16, 2023 fully addresses the following questions regarding compliance with the animal license requirements of Columbia, or provide additional documentation to address the following:

- Demonstrate the “legitimate confidence” law, as described to NIAID by CSRC on June 8, 2023 was in effect and applicable for this license at the time the relicensing request was submitted
- Clarify what documentation CSRC needed to submit for the license
- Demonstrate that all requirements and supporting documentation for the license were provided by CSRC to the issuing organization
- Identify long the Columbian government had to respond to the license request under the “legitimate confidence” law

CSRC will need to sufficiently demonstrate compliance with the animal license requirement for NIAID to accept the responsive documentation and lift the suspension. If CSRC cannot demonstrate compliance, it will be required to provide documentation of total animal costs at its site and all costs associated with animal work that occurred in noncompliance.

Alternately, and as previously discussed on June 8, 2023 CSRC can agree to bilateral termination. If the awards are bilaterally terminated, CSRC may reapply for NIH/NIAID funding after its internal issues are resolved, and after it has an active SAM registration. Please be advised that NIH's acceptance of a bilateral termination should not be construed as a settlement, or any positive determinations regarding your institution's compliance status, nor is it an indication of government approval of or acquiescence regarding your financial or administrative management of NIH grant awards.

CSRC has 14 calendar days to respond to this letter with the confirmation, or additional supporting documentation to address the requested information. If CSRC does not provide a sufficient response, NIAID will disallow costs and can take additional enforcement actions including termination, per NIHGPS [8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support](#).

This enforcement action is being instituted in accordance with 2 C.F.R. § 200.339, Remedies for Noncompliance, and the NIH Grants Policy Statement (GPS), Section 8.5.2, Enforcement Actions: Suspension, Termination, and Withholding of Support.

This letter represents the final decision of NIH. It shall be the final decision of the Department of Health and Human Services unless, in accordance with 2 C.F.R 200.342, within 30 days after receiving this decision, you send, via email with a read receipt, a written notice of appeal to:

Michelle G. Bulls
NIH Grant Appeals Officer
National Institutes of Health

Email: grantsappeal@od.nih.gov

If there are any questions, please contact me at emily.linde@niaid.nih.gov.

Sincerely,

**Emily B.
Linde -S**  Digitally signed by
Emily B. Linde -S
Date: 2023.07.05
10:04:49 -04'00'

Emily Linde
Chief, Grants Management Program
NIAID, NIH

cc: Dr. Annie Mo, Program Officer