



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Center for
Research Resources
Bethesda, Maryland 20892

May 18, 1999

Frederick Coulston, Ph.D.
Chairman and Chief Executive Officer
Coulston Foundation
1300 La Velle Road
Alamogordo, NM 88310

FXED
5/18/99

NCRR Grant Number: U42 RR 03582

Dear Dr. Coulston:

As you know from our contact with you, we at NCRR continue to be concerned about the Coulston Foundation's financial stability. The documentation provided by staff of the Foundation reflecting the very precarious financial status of the organization conflicts with the positive and optimistic reports that you continue to provide about the current and future financial status of the Foundation. While your correspondence and personal conversations have reported new projects and sources of income, you have provided no documentation to indicate that the financial situation has changed since our site visit in April. It is important that NIH have an accurate picture of the financial status of the organization in order to help us determine what steps we must take to assure the continued well-being of the animals under your responsibility.

With this goal in mind, we request that you provide the following information to us by close of business on Monday, May 24, 1999. Please send it to the attention of Dr. Strandberg via fax (301/480-3558).

1. An updated cash flow statement providing anticipated income and expenses by month for the next 12 months. If this cash flow statement reflects substantial changes from the one provided during our site visit, please explain the changes. If there is a major incongruity between the income and expenses of the organization, explain how the Foundation intends to maintain operations under those circumstances.
2. A budget and justification for essential expenses over next 30 days required for the care and upkeep of the animals that are not provided for through other income sources.
3. A stated commitment from you that you will begin development of a specific medium-term (next 12 months) and long-term plan for the financial stability of the Foundation, including animals supported under the Chimpanzee Biomedical Research Program and for the Coulston Foundation colony as a whole. We would like to meet with you, Dr. Couch, and Dr. Javadian in Bethesda in mid- to late June to discuss your plans. We will speak with you soon to determine the exact dates.

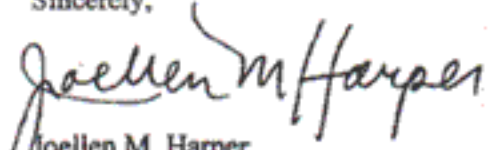
Page 2 -- Dr. Frederick Coulston, Ph.D.

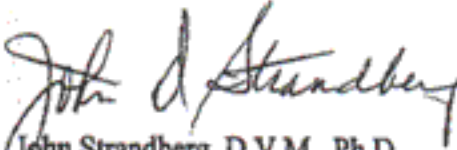
4. Due to our substantial concerns about the availability of Dr. E. Christopher Staley and his ability to devote necessary effort and bring required leadership to the NCRR award, we request that you nominate a new person to serve as Principal Investigator (PI) of the CBRP cooperative agreement. We request that the new PI be someone who is a full-time Foundation employee and a member of the professional staff. If this individual is not a veterinarian, the effort of the other veterinary staff on the CBRP should be adjusted to assure that the total effort is the equivalent of one-half (50 percent) FTE. Please provide an updated list of the personnel on the project, including their names, titles, levels of effort, and salary to be charged to the grant.

During the site visit, we were provided interim financial statements through December 31, 1998. We were informed that statements for January, February, and March were in progress. At your earliest convenience, no later than by COB June 1, please send to Ms. Harper the most recently completed financial statements (including a balance sheet, revenue and expense statements, and supporting statements). Accompanying this, please provide a detailed explanation and breakdown (including source and type of contribution) of the "contribution income" listed under Revenue on the Revenue and Expense Statement. Based on information provided during the site visit, we are unclear whether this represents an actual contribution to the organization or a loan. If this is a loan, please provide details regarding the outstanding balance. Finally, we would like a list of all Coulston Foundation employees' names and titles/positions. This information should be sent to Ms. Harper at 6705 Rockledge Drive, Room 6086, Bethesda, Maryland, 20892-7965 (or 20817 for express mail).

If you have any questions, please feel free to contact Ms. Harper on 301/435-0844 or Dr. Strandberg on 301/435-0744. We look forward to your response.

Sincerely,


Joellen M. Harper
Director, Office of Grants Management


John Strandberg, D.V.M., Ph.D.
Director, Comparative Medicine

cc:

Dr. L. Ramm, NCRR
Dr. L. Sibal, Office of Extramural Research
Dr. R. Couch
Dr. A. Javadian

SECTION IV - ADDITIONAL TERMS AND CONDITIONS - 3 U42 RR03582-12S1

This supplemental award reflects a change in Principal Investigator to Dr. Ronald Couch and provides additional funds in accordance with the grantee's letter of request dated May 24, 1999. In addition, this award imposes special terms and conditions in accordance with HHS regulations at 45 CFR 74.14 as delineated below. All correspondence and required reports should be sent to the attention of:

Ms. Joellen M. Harper
Director, Office of Grants Management
National Center for Research Resources
6705 Rockledge Drive, Room 6086
Bethesda, Maryland, 20892-7965
(20817 for courier/express mail)
301/435-0844
301/480-3777 (fax)

Special Terms and Conditions Imposed in Accordance with 45 CFR 74.14

Due to the serious financial problems being experienced by the Coulston Foundation and questions about the financial stability of the organization, NCRR is imposing the following special terms and conditions in accordance with HHS regulations on the administration of grants, 45 CFR 74.14.

The Coulston Foundation is directed to develop a concrete plan with short, medium, and long-term milestones for obtaining the necessary financial support for the animals owned by or under the responsibility of the Foundation. Additional details and a deadline for submission of this plan will be provided by NCRR in future correspondence.

The direct funds provided in this supplemental award and the parent award may not be used to repay any notes/loans or to pay installments on notes/loans of the Foundation, including loans or contributions provided by Dr. Frederick Coulston.

The direct funds provided in this supplemental award and the parent award may not be used to pay for the current or past due amounts for utilities at the Holloman Air Force Base facility.

The funds provided in the parent award for per diem support of the animals must be used for specific expenditures (e.g., food, medicine, salaries) related to care and maintenance of the animals. Funds may not be drawn from the Payment Management System and charged to the grant on a per diem rate basis.

In addition to the annual financial status report, additional financial reporting is required as follows. By the 30th of each month, the Foundation must submit to NCRR financial statements as of the last day of the previous month, including a balance sheet and revenue and expense statement. In addition, the Foundation must submit a summary of expenses charged to the grant, broken down by line item, accompanied by supporting documentation (invoices and cancelled checks) for all such expenses. Finally, the Foundation must prepare cashflow statements comparing by month expected income and expenses with actual income and expenses (following the same line-item format used in previous statements provided to NCRR).

In addition to the annual progress report, a quarterly programmatic progress report must be submitted to NCRR on September 1, December 1, March 1, and June 1. These reports must describe the status of the colony supported by NCRR, including a list of the animals supported by the cooperative agreement award; any changes in personnel of the Foundation; the status of projects ongoing at the Foundation; and any other activities or occurrences at the Foundation that may be relevant to the award.

Any changes in the cooperative agreement key personnel (Couch, Stauffer, Lausen, Albersmeyer, Correa-Serment, Bowsher, Rice, and Gonzales) or their levels of effort as outlined in the grantee's letter dated May 24, 1999, requires prior written approval from the National Center for Research Resources. Effective as of the issue date of this award, Marc Murray, Research Coordinator, may no longer be supported on this grant.

The salaries and fringe benefits of the following personnel may not be supported by the direct costs of the NCRR cooperative agreement award: Stacy Ames, Dana Blazer, Craig Coulston, Frederick Coulston, Caroline Ellis, Cary Fechner, Tracy Gonzales, Lovice Julian, John Marr, Donald McKinney, Marc Murray, Elizabeth O'Reilly, Esmeralda Pacheco, Joseph Savage, Lisa Simpson, Deborah Smith, E. Chris Staley, Mary Villegas, Roxanne Waskiewicz, Frances Wood, and Ding Yan. No funds may be used to pay the salary or fringe benefits of individuals in comparable positions to those listed here.

Program income means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (see 45 CFR 74.24 (e) and (h) for exclusions). Effective as of the issue date of this award, disposition of program income generated under this cooperative agreement award is subject to the deductive alternative. This means that program income earned during the project period shall be deducted from the total project or program allowable cost in determining the net allowable costs on which the Federal share of costs is based. Costs incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award. The Foundation must maintain a detailed accounting of the program income generated under the award.

These special terms and conditions of award will remain in effect until such time as the Coulston Foundation can demonstrate to NCRR that it has obtained sources of financial support to provide for the day to day operation of the organization, including the care and maintenance of the animals owned by or under the responsibility of the Foundation. NCRR program and grants management staff will work closely with staff of the Coulston Foundation during the remainder of the project period to provide technical assistance regarding the programmatic, financial and business management aspects of the organization as they relate to this cooperative agreement award. In addition, the Foundation is strongly encouraged to obtain the advice and assistance of an outside professional expert in the financial and business management of federal assistance awards.

Once the Foundation demonstrates that it has sources of financial support equal to its monthly expenses, it may request that NCRR reconsider the imposition of these special terms and conditions. If the Foundation is unable to achieve substantial progress towards this goal within 6 months, NCRR will consider the imposition of additional terms and conditions of award as necessary.

Harper, Joellen (NCRR)

From: Robinson, Jerry
Sent: Wednesday, November 18, 1998 5:20 PM
To: Vaitukaitis, Judy
Cc: Harper, Joellen; Whitehair, Leo; Strandberg, John; Ramm, Louise
Subject: RE: chimps, what else?

Importance: High

Dr. V.,

Wanted to give you a status report on our attempts to find out what's going out there. After John heard the rumor, he asked me to contact them which I tried to do. The P.I. did not return my phone calls. Late yesterday, I got together with Joellen to discuss options. We decided to try contacting the administrative official but learned that Travis Griffin retired 2 weeks ago. We were put in touch with Dr. Ron Couch who has assumed that authority and talked to us about the status of the grant and the animals.

He informed us that the 20 people were mainly administrative personnel and they were just "laid off". This all was the consequence of some "downsizing of the company", things that happen in the business world.

I was most concerned with the people being paid on the grant and the change of P.I. status. All the people except 2 listed on the grant are still employed, presumably doing the work designated on the grant. One is the P.I. who has been replaced by the co-P.I., Dr. Staley. They had not made a formal request for the change although Coulston had sent a letter just stating that there was a new P.I. Joellen and I (I just spoke with Couch again) have given them instructions on the proper procedure and it is being addressed. The other person who has left was a veterinarian and the co-P.I. designate. We have requested the identity and qualifications of a replacement. Dr. Staley is also only listed as on the grant and we are insisting that more effort is required.

Dr. Couch assured that everything was fine and the animals were NOT being neglected and that nothing else had changed to alter the scope of the grant.

Joellen queried him about the potentially outstanding obligations against the grant. He assured us that everything was being taken care of as far as the grant expenditures were concerned. Joellen tried to probe a bit more about the rumors of outstanding debts and was told that was company business and in essence, none of ours. Similar response we got during our June, 1996 site visit when we tried to learn about the disposition of endowment funds.

Dr. Couch asked where all this was coming from and I responded that we heard it from USDA via OPRR and that Dr. Varnus' office had made some inquiries as well. He understood and appeared willing to cooperate with getting things straight with the grant and us. We're awaiting on the paperwork.

Will let you know if we learn anything else.

Jerry

From: Vaitukaitis, Judy
Sent: Wednesday, November 18, 1998 8:00 AM
To: Baldwin, Wendy (OD)
Subject: RE: chimps, what else?

Wendy

I do not have all the facts, but it appears to be a simmering serious problem. My staff is trying to get facts which are not readily available. My personal opinion is that the AF chimps helped break the camel's back.

Judy

Judith L. Vaitukaitis, M.D.
 Director, National Center for Research Resources
 Building 31, Room 3B11
 9000 Rockville Pike
 Bethesda, MD 20892-2128
 Telephone: (301)496-5793
 Fax: (301)402-0006
 Email: vaitukaitis@nih.gov

Ramm, Louise (NCRR)

From: Strandberg, John
Sent: Wednesday, February 10, 1999 4:18 PM
To: Ramm, Louise; Harper, Joellen
Cc: Strandberg, John
Subject: FW: Coulston Chimpanzee Contract

FYI - This gets more byzantine all the time!

John

From: Sibal, Louis (OD)
Sent: Wednesday, February 10, 1999 3:31 PM
To: Strandberg, John
Subject: FW: Coulston Chimpanzee Contract

What advice should I give him. Let's talk soon.

-----Original Message-----

From: Randy Elkins [SMTP:RELKINS@atlas.niaid.nih.gov]
Sent: Wednesday, February 10, 1999 10:00 AM
To: Sibal, Louis <ls8t>
Cc: Doris Wong
Subject: Coulston Chimpanzee Contract

Good morning Lou,

Bob Purcell requested that I apprise you that the FDA Contract with the Coulston Foundation to breed chimpanzees for hepatitis research will expire on 14 September 1999. The FDA will not renew this contract. The NIAID and CDC access juvenile chimpanzees from this contract to support their respective hepatitis research and vaccine development programs via Interagency Agreements into which they pay endowment funds for chimpanzees acquired throughout a FY. The endowment fee is currently \$57,000. Paul Scarborough, FDA Contracting Officer, advised me that he would temporarily extend the contract to accommodate Dr. Purcell's continuing need for research chimpanzees while the NIAID contemplates recompetition. FDA would then procure their chimpanzees either by PO or an Interagency Agreement with NIAID. The other members of the Chimpanzee Breeders and Program Management Committee (Southwest Foundation for Biomedical Research, New Iberia Research Center, MD Anderson Cancer Center, and Yerkes Regional Primate Research Center) have not expressed an interest in this contract because they want the Government to both own and endow the chimpanzees. The Coulston Foundation is not AAALAC accredited and will not be. They hired a board-certified laboratory animal veterinarian 2 years ago to facilitate the accreditation process for them but he departed Coulston in the last year. My source at Coulston said that Dr. Coulston does not support the AAALAC process or have the funds available for facility modification necessary for AAALAC accreditation identified in a site visit last spring. I am certain you are aware of the negative publicity which adversely affects Coulston. Coulston does, however, supply us with excellent quality chimpanzees for Dr. Purcell's hepatitis research. I have apprise Dr. Jim Taylor, OACU, of the possibility that NIAID will need to recompetete this contract and that Coulston might be the only bidder. At this juncture Bob and I seek your advice and wise counsel. Very best regards,

Randy

Ramm, Louise (NCRR)

From: Ramm, Louise (NCRR)
Sent: Thursday, June 10, 1999 6:08 AM
To: Baldwin, Wendy (OD)
Subject: RE: coulston- conversation with USDA re: a meeting....

Back to back meetings would be fine. I will probably be in California on July 13 -15, stamping out another fire; however, Judy is working with some folks to work out the dates, so it's not a sure thing (a very long story....). John and Joellen will probably be here, but I haven't checked their schedules.

Also, I think it's important that Javadian be there; however, *E PERSONAL INFORMATION*

☐ John spoke with Javadian who expressed enthusiasm over a vet coming out to help them. I have a call into Axel and hope he'll agree to do this.

From: Baldwin, Wendy (OD)
Sent: Wednesday, June 09, 1999 10:21 AM
To: Ramm, Louise (NCRR)
Subject: RE: coulston- conversation with USDA re: a meeting....
Importance: High

I would like to have USDA are part of the process to make sure FC realizes that he has to come to grips with this. what about scheduling these as back to back meetings? that way FC and javadian could come east once, how's that sound?

-----Original Message-----

From: Ramm, Louise (NCRR)
Sent: Wednesday, June 09, 1999 12:19 PM
To: Baldwin, Wendy (OD)
Subject: RE: coulston- conversation with USDA re: a meeting....

If this meeting concerns the subpoena from USDA to CF, we should not be involved. If it has to do with meeting with Coulston for him to explain his future plans, etc., that should be NIH's meeting (which USDA could certainly attend) I don't think we should be involved with a situation with USDA in its regulatory role with animals that were not on NIH protocols. John also agrees with this.

From: Baldwin, Wendy (OD)
Sent: Wednesday, June 09, 1999 11:58 AM
To: Ramm, Louise (NCRR)
Cc: Sibal, Louis (OD)
Subject: coulston- conversation with USDA re: a meeting...
Importance: High

week of July 12, is that a possibility for a meeting with Coulston. USDA needs to know. Dunn's office will get in touch with ron dahaven re: their position they can initiate a meeting through their attorneys. best for Coulston to come here...needs to be face to face...I told him that Javadian had to be there too.

If you think that this is not good timing, or that we should meet separately, email me instantly... they are thinking about the type of proposal they will put before him

your thoughts? wendy