



IN DEFENSE OF ANIMALS

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January 20, 2004  
VIA certified mail

Ms. Joyce McDonald  
FOIA Coordinator  
National Center for Research Resources  
NIH  
Room 978  
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Bethesda, MD 20892  
301-435-0888 (phone)  
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Freedom of Information Act Request

Dear Ms. McDonald:

Please consider this letter a formal request by In Defense of Animals ("IDA") to obtain National Institutes of Health ("NIH") records under the Freedom of Information Act.

IDA requests copies of the following records related to the Alamogordo Primate Facility ("APF"), a government-owned, contractor-operated facility located on Holloman Air Force Base in New Mexico. Before it was known as the APF, the facility was operated by The Coulston Foundation. In June 2001, Charles River Laboratories ("CRL") took over operation of what is now known as the APF under a contract with the NIH.

REQUEST FOR APF OPERATIONAL RECORDS

Except where otherwise indicated (i.e., numbers 1 through 4 below), this first section, "APF Operational Records," is date-limited to CRL's operation of the APF since June 2001. For this request, the term "APF employee" refers to those persons in the employ of CRL to operate the APF. Similarly, other references to the APF (i.e., the APF Advisory Board, APF IACUC, etc.) refer to CRL's operation of the APF.

1. The NIH's Requests for Proposals ("RFP") and all amendments that led to the award of the current contract to CRL to operate the APF. The RFP was originally issued in the summer of 2000.
2. The proposals and all amendments submitted by CRL in response to the RFP for the APF contract.
3. The current APF contract and all amendments between the NIH and CRL, as well as all progress reports, and any other reports, submitted by CRL that are required by the contract. The contract was signed in approximately 2000-2001.
4. All records relating to the NIH's decision to award the APF contract to CRL.
5. All internal APF records sent or received by any current or former APF employees regarding any aspect of the clinical care, treatment, well-being, husbandry, enrichment and/or psychological well-being, diagnosis, monitoring, observation, cause(s) of death, surveillance and/or adequacy of any of the chimpanzee-specific records described later in this request.
6. All APF records relating to the availability of controlled substances such as euthanasia drugs, including but not limited to consequences of lack of such controlled substances, necessity for such controlled substances, when and if such controlled substances had to be borrowed, etc.
7. All APF records relating to availability of ultrasound machine(s) and any other equipment or resources necessary for the care of chimpanzees, including but not limited to consequences of lack of such equipment, necessity of such equipment, etc.
8. All records related to the APF Institutional Animal Care and Use Committee ("IACUC"), including but not limited to semi-annual inspections, investigations of any complaints, minutes of meetings, discussions related to care, treatment, diagnosis, enrichment, etc. of chimpanzees, compliance with conditions of the contract between the NIH and CRL, etc.
9. All records related to the APF Advisory Board, including but not limited to site visits, recommendations, criticisms, findings, minutes of meetings, etc.
10. All records related to any internal investigations conducted by CRL related to any aspect of chimpanzee care, diagnosis, treatment, enrichment, etc., and/or compliance with conditions of the contract between CRL and the NIH to operate the APF.
11. All records related to any internal complaints, concerns, etc. made by any current or former APF employees regarding any aspect of the clinical care, treatment, well-being, observation, monitoring, diagnosis, enrichment and/or psychological well-being,

husbandry, cause(s) of death, surveillance and/or adequacy of any of the chimpanzee-specific records described later in this request.

12. All records related to any meetings of current or former APF staff that in any way addressed any aspect of the clinical care, treatment, well-being, observation, monitoring, diagnosis, enrichment and/or psychological well-being, husbandry, cause(s) of death, surveillance and/or adequacy of any of the chimpanzee-specific records described later in this request, including but not limited to minutes, notes, memos, etc. of such meetings.

13. All records relating to internal complaints, comments, questions, concerns, etc. regarding the clinical competence, training and/or experience of any veterinarians ever employed by CRL at the APF.

14. All records relating to veterinary turnover at the APF, including but not limited to the resumes/C.V.'s of any and all veterinarians ever employed by CRL at the APF, amount of clinical chimpanzee experience at the time of hire, etc.

#### REQUEST FOR CHIMPANZEE-SPECIFIC RECORDS

We also request all records related to the chimpanzees at the APF as identified below, including but not limited to those records transferred from The Coulston Foundation to the APF as well as all records generated by the APF since CRL took over operations in 2001.

15. All chimpanzees who have died since CRL took over operation of the APF, including those who have been euthanized.

16. All chimpanzees who have received intensive care and/or emergency care since CRL took over operation of the APF.

17. The 14 chimpanzees whom The Coulston Foundation transferred to the NIH on April 9, 2002 and placed under the care of the APF. According to USDA records, these are the 14 chimpanzees (names followed by identification numbers):

Ricky, 1495

Sakari, 1587

Nicki, CA0218

Donovan, 1588

Owen, CB0087

Jimmy, CB0671

Fun Face, CB0339

Sterling, 1441

Angel, 1436

Muna, CB0376

Peter, CB0159

Opal, 1435

Ranso, CB0323

Rudy, CA0047.

This request for records specified above includes, but is not limited to, clinical diagnostic summaries; observation records; gross necropsy reports; histopathology reports; diagnosis records; clinical histories; clinical records; all lab results (i.e., urine results, clinical chemistry, laboratory exam reports, etc.); physical examination records; medication records; surveillance records; intensive care records; emergency care records; specimen reports; behavioral histories and preferences; housing records; socialization records; behavioral observations; descriptions of individual chimpanzees' personality, behavior and demeanor; psychological enrichment records; clinical observations; clinical notes; monitoring records; clinical diagnosis, notes, memos, worksheets, checklists, etc. of veterinarians and any other current or former APF employee involved in any aspect of animal care, monitoring, diagnosis, observation, etc.; case histories; treatment records; surgical records; anesthesia records; sedation records; blood pressure records; EKG records; radiology records; staff meeting records; euthanasia records; TB testing records; incident reports; accident reports.

We also request videos, CDs, DVDs, photographs or any other visual or audio representation of these chimpanzees, including but not limited to observations, procedures, care, husbandry, identification, etc. We request that any copies of said visual representations be provided to us in color; we are prepared to pay extra, if necessary, for color copies. If said visual representations are digital (i.e., digital photographs), we request that the computer files comprising the digital representations be provided to us.

Request for News Media Fee Waiver

In Defense of Animals requests a waiver of search and review fees on the grounds that IDA is eligible for waiver of these fees as a qualified news media entity pursuant to 5 U.S.C. § 552(a)(4)(A)(ii)(II) and 45 C.F.R. § 5.41.

IDA is a news media entity that provides information on animal welfare issues to a wide cross-section of the public. IDA is an international, non-profit animal advocacy organization dedicated to protecting the rights, welfare and habitats of animals. As part of its mission, IDA regularly gathers information and disseminates important news through a network of media outlets, including a printed newsletter, multiple Internet web sites, e-mail alerts, and fact sheets.

Currently, IDA's printed, quarterly newsletter reaches over 65,000 people in all 50 states and abroad. This circulation compares favorably to publications such as the *Weekly Standard* (65,000), *The American Prospect* (47,000) and *The New Republic* (85,000). IDA's newsletter routinely publishes analysis of FOIA information relating to various issues of great public concern, including the welfare of animals in laboratories, government oversight of animal research, proper stewardship of taxpayer money, data integrity, protection of human health, and workplace safety. See Exhibit A, Copy of IDA Newsletter.

IDA also maintains an active web site on the Internet.<sup>1</sup> This site and its associated sites average over 55,000 hits per day and over 1.6 million hits per month. The Internet is a highly accessible source of current information, and IDA's web site provides significant opportunities for IDA to disseminate breaking news regarding animal welfare and various FOIA-related information of interest to the general public.

In addition, IDA has over 5,000 subscribers to its e-mail alerts. These alerts typically present current information on animal welfare issues that require immediate attention. See Exhibit B, Copy of E-Mail Alert.

Finally, IDA produces brochures and fact sheets that are often based on information we have obtained through FOIA and other sources. These materials are regularly disseminated to IDA's member base and beyond. See Exhibit C, Copy of IDA Fact Sheet on The Coulston Foundation lab.

IDA's efforts to gather and disseminate news to the public are longstanding and extensive. These efforts qualify IDA as a news media entity and entitle IDA to a waiver of the NIH's search and review fees.

#### Request for Public Interest Fee Waiver

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<sup>1</sup> The web site can be viewed at <http://www.idausa.org>.

In addition to the news media waiver, In Defense of Animals seeks a waiver of all fees connected with this request based on the public interest waiver in 5 U.S.C. § 552(a)(4)(A)(iii) and 45 C.F.R. § 5.45. This records request is not in the commercial interest of IDA or any of its members, and disclosure of the requested information is likely to significantly contribute to public understanding of the operations and activities of the NIH. In particular, these records will be analyzed and used by IDA to shed light on the NIH's oversight and management of the care of the chimpanzees at the APF. Disclosure of these records also will help the public understand the degree to which the NIH is fulfilling its duties under the Animal Welfare Act and the PHS Policy for the Humane Care and Use of Laboratory Animals, particularly when the NIH is confronted with chimpanzee deaths and injuries potentially resulting from violations of these federal animal welfare laws. IDA has a long history of obtaining, interpreting and disseminating such records – from various animal research facilities – in order to expose the operations of government agencies such as the NIH and the U.S. Department of Agriculture as well as to document deficiencies in animal care and compliance with federal animal welfare and patient and employee safety laws.

IDA has a longstanding commitment to protecting the well-being of the chimpanzees at the APF and has provided invaluable assistance to the government and the public in uncovering abuses at this facility when it was operated by The Coulston Foundation. Throughout IDA's involvement since 1994, IDA has shared its findings with appropriate government regulatory agencies, Congressional committees, other news media outlets, and the public at large. IDA remains committed to enhancing the public's understanding of the NIH's activities and operations at the APF. IDA intends to share the requested documents and the results of IDA's analysis of those documents with the general public through various methods, including our web sites, alerts, newsletter and our network of other national and international media contacts.

As you know, IDA has filed numerous credible complaints and reports with regulatory agencies, including the NIH, the U.S. Department of Agriculture ("USDA"), the Food and Drug Administration ("FDA"), and the Occupational Safety and Health Administration ("OSHA"). These agencies have taken regulatory enforcement actions against multiple facilities based on these complaints and evidence submitted by IDA. These complaints have not been limited to violations of federal animal welfare laws, but have also included evidence of violations of the FDA's Good Laboratory Practice ("GLP") regulations, which ensure data integrity and human safety, and federal workplace safety laws.

As an especially pertinent example, IDA filed a series of detailed formal complaints with the USDA against The Coulston Foundation, which previously operated the facility now known as the APF. IDA was directly involved in all four sets of formal USDA charges filed against The Coulston Foundation in July 1995, March 1998, February 1999 and July 2001. Many of these complaints were based heavily on documents that IDA

obtained under the Freedom of Information Act.<sup>2</sup> IDA provided the USDA with key information and analysis, especially in the latter three complaints. *See, e.g.*, Exhibit D, IDA's January 8, 1998 submission to the USDA, "Report on the Deaths of Echo and Jello" and a copy of the subsequent formal charges filed by the USDA against Coulston on March 19, 1998.

These complaints and the information they provided to the USDA played a central role in that agency's filing an unprecedented four sets of formal charges against The Coulston Foundation for violations of the Animal Welfare Act. *See, e.g.*, Exhibit E, *U.S. News & World Report* (August 14, 1995) ("[p]rodded in part by . . . In Defense of Animals, the U.S. Department of Agriculture cited Coulston last month for violations of the Animal Welfare Act that could carry fines of at least \$7,500 per day"); Exhibit F, *New York Times* (Sept. 14, 1999) ("The Agriculture Department, partly as a result of investigations by an animal protection advocacy group, In Defense of Animals, filed charges in 1997 and then again this year"); Exhibit G, *Nature* (April 22, 1999) (stating that IDA "has been vindicated at least in part by three formal complaints issued by the United States Department of Agriculture (USDA), charging that the lab has violated the Animal Welfare Act"); and Exhibit H, *Albuquerque Journal*, "Good Life Awaits Primates: Former Lab Animals were Saved by an Intense Campaign by In Defense of Animals" (November 12, 2002) ("In Defense of Animals had waged an aggressive eight-year campaign against Coulston, using whistle-blowing veterinarians to prompt tough regulatory action by the Food and Drug Administration and the U.S. Department of Agriculture. Coulston's revenues eventually shriveled up and the lab got out of chimp-based research").

The FDA also took serious action against Coulston after IDA filed its complaints. This action included two formal Warning Letters from the agency (dated December 22, 1999 and October 11, 2001) as well as the unprecedented proceedings initiated by the FDA on March 18, 2003 to disqualify Coulston as a GLP lab.<sup>3</sup> The FDA announced at the PhRMA Bioresearch Monitoring Committee Annual Meeting in April 2003 that Coulston had been officially disqualified as a GLP lab. This was the first time that the FDA had ever disqualified a nonclinical GLP lab.

IDA has a proven expertise in reviewing, interpreting, and disseminating to the public the types of records requested in this letter. In particular, IDA has performed detailed analyses and reviews of medical literature, medical records such as necropsy/histopathology reports, clinical notes, clinical histories, surgical/anesthesia

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<sup>2</sup> In many respects, those documents are similar to the ones IDA now seeks from the NIH concerning CRL's care of the chimpanzees at the APF.

<sup>3</sup> *See* Exhibit I. These documents are also currently available through the FDA's online FOIA at: [http://www.fda.gov/foi/warning\\_letters/m3295n.pdf](http://www.fda.gov/foi/warning_letters/m3295n.pdf); [http://www.fda.gov/foi/warning\\_letters/g1990d.pdf](http://www.fda.gov/foi/warning_letters/g1990d.pdf); and <http://www.fda.gov/foi/nooh/coulston.pdf>.

logs, radiology records, physical examination records, surgical records, etc. for specific animals, as well as numerous consultations with experts having decades of experience in the field of animal research. IDA has consistently provided the results of these analyses to regulatory agencies, the public and Congress.

For example, IDA testified before the House Appropriations Subcommittee on Labor/HHS/Education on March 21, 2000 regarding the NIH's actions relating to The Coulston Foundation. See Exhibit J, "Prepared Testimony Regarding the National Institutes of Health and The Coulston Foundation." This testimony provides ample evidence of IDA's ability to interpret and disseminate information obtained under the Freedom of Information Act that would not have otherwise been made known to the public. Furthermore, IDA's detailed analysis of federal statutes and regulations governing animal research demonstrates IDA's expertise and knowledge of those statutes.<sup>4</sup>

Notably, during the hearing, then-chair Rep. John Porter (R-IL) specifically asked if IDA had a solution to the crisis at Coulston. Within weeks, IDA, along with the Doris Day Animal League and the Society for Animal Protective Legislation, presented Rep. Porter with just such a plan. This indicates Congress's recognition of IDA's expertise and credibility on this issue, fueled in large part by our interpretation and dissemination of information that had been disclosed under the Freedom of Information Act.

Finally, disclosure of the requested records is likely to contribute significantly to public understanding of the operations and activities of the NIH. The APF is a federal facility under the direct control of the NIH. The APF houses dozens of the famous Air Force chimpanzees, and when operated by The Coulston Foundation, it had a history of multiple, repeated violations of federal laws and regulations – much of which was documented and brought to light by IDA. This history, and its status as one of the world's largest captive chimpanzee colonies, has garnered widespread public attention and concern.<sup>5</sup> As discussed above, IDA's previous efforts to disclose documents related to the APF (while it was operated by The Coulston Foundation) led to major discoveries of violations and significant agency involvement to curtail the abuses. IDA's current request for records is likely to uncover new, ongoing abuses with equally large ramifications.

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<sup>4</sup> Based on documents obtained under the Freedom of Information Act, IDA's testimony also raised concerns about the integrity and validity of all the NIH-funded studies conducted at Coulston. These public interest concerns were subsequently validated when the FDA took the unprecedented step of disqualifying Coulston as a GLP lab. IDA also used the findings of the USDA and the FDA to shed light on the NIH's operations, particularly that of the office responsible for ensuring compliance with federal animal welfare laws.

<sup>5</sup> See Exhibit L, *Washington Post* article dated May 15, 2000, and Exhibit F, *New York Times* article dated September 14, 1999 for more details on the national attention focused on these chimpanzees and this facility. See also <http://www.savethechimps.org>.

Moreover, on March 13, 2003, the House Committee on Energy and Commerce initiated a broad investigation into the NIH's management and oversight of billions of dollars in publicly funded grants that the agency administers. See Exhibit K, Congressional letter dated March 13, 2003. In its letter initiating the investigation, Reps. Greenwood and Tauzin specifically mention concern about the NIH's actions regarding Coulston. They note that the Committee had initiated an investigation of the NIH's actions regarding Coulston the previous year and required more documents.<sup>6</sup>

If for any reason this request for records cannot be sent free of charge, I request that I be notified immediately of the reasons behind the denial and the cost that will be involved prior to any copying. IDA does not give up its right to appeal any denial.

### Conclusion

In Defense of Animals respectfully requests copies of the records identified above. Moreover, IDA seeks a search and review fee waiver based on IDA's status as a news media entity and a complete fee waiver based on the public interest bases for the disclosure.

IDA expects a response within twenty days as required by law. Please provide copies of the requested records as they become available, rather than wait to deliver all records at the end of your search. Should you decide any of the requested material is not to be disclosed, please describe the material withheld and specify in detail the statutory or administrative basis for withholding it. All segregable, non-exempt parts of documents should be provided. If you have any questions, or require clarification of this request, please contact me at the phone number listed below and also FAX me the

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<sup>6</sup> See also Exhibit M, *Washington Times* article dated July 30, 2003 ("The subcommittee decided to launch the investigation [of NIH in March 2003] in part based on its finding last year that the NIH was providing grants to the Coulston Foundation, an animal research facility in Alamogordo, N. M., that recently declared bankruptcy and had been cited by the Food and Drug Administration and the U.S. Department of Agriculture for regulatory violations.")

See also Exhibit N, House Committee on Energy and Commerce's Oversight Plan for the 108<sup>th</sup> Congress, page 16, under the heading of "National Institutes of Health" ("In the 108<sup>th</sup> Congress, the Committee will conduct an examination of NIH's organizational structure, priority setting and research activities. In particular, the Committee will examine how NIH exercises oversight over grant-receiving institutions. During one of the Committee's investigations last year, the Committee learned that NIH was providing grants to the Coulston Foundation, a registered animal research facility in Alamogordo, New Mexico, which had recently declared bankruptcy and had been cited by two other Federal agencies for violations of various Federal regulations. This incident raises the question whether NIH oversight ensures that its grant funds are properly managed, and that grantee institutions are not in violation of Federal regulations").

questions and/or need for clarification at the FAX number listed below. Thank you for your prompt attention to this matter.

Sincerely,

Eric Kleiman  
In Defense of Animals  
717-939-3231 (phone)  
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Enclosures (Exhibits A through N)