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CITY BAR

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PERTAINING TO ANIMALS**

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Dr. Aronson,

Our Committee, Legal Issues Pertaining to Animals, of the Association of the Bar of the City of New York, has become aware of the NASA-funded research protocol, Ground-Based Studies in Neurobehavioral Biology, dated December 22, 2009 and submitted by Dr. Jack Bergman (hereinafter the "Bergman Protocol" or "the Protocol"). The Bergman Protocol calls for the exposure of 30 live squirrel monkeys to high doses of space radiation on a daily basis for up to four years, during which time these highly social animals shall be restrained in primate chairs or irradiation chambers and housed individually in stainless steel cages.

Based on our review, which was made in reliance upon the documents referenced in this letter, the Bergman Protocol appears to violate NASA research protocol compliance standards codified at 14 C.F.R. § 1232.104 and various sections of the Animal Welfare Act. For the reasons that follow, we urge you to deny approval of this study.

I. The Bergman Protocol Lacks IACUC Certification in Violation of 14 C.F.R. § 1232.104(b)

The Bergman Proposal was submitted and subsequently approved in connection with NASA Research Announcement NNJ09ZSA001N ("NRA NNJ09ZSA001N") which expressly requires compliance with various NASA protocol submission standards: "Proposals that do not conform to the standards outlined in this solicitation will be declared noncompliant and declined without review." (NRA NNJ09ZSA001N at p. 3) Among the standards outlined in the solicitation, and required pursuant to 14 C.F.R. § 1232.104(b), is the requirement of approval by the Animal Care and Use Committee ("IACUC") "certifying approval of the proposed animal research protocols and procedures" no later than 90 days after the proposal due date. (NRA NNJ09ZSA001N at p.

23; See also 14 C.F.R. § 1232.104(b), providing that “Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with the PHS Policy (IV.C.) and approved by the appropriate ACUC at the participating institution.”)

The due date for proposals submitted pursuant to NASA Research Announcement was June 25, 2009, and consequently the due date for IACUC approval in connection with any such proposal was September 25, 2009. Notwithstanding that the Bergman Protocol has failed to obtain IACUC approval, the Bergman Protocol was reviewed and approved by NASA on October 27, 2009, ostensibly in violation of 14 C.F.R. § 1232.104(b) and the express terms of NASA Research Announcement NNJ09ZSA001N.

II. The Bergman Protocol Violates the Animal Welfare Act

The Bergman Protocol appears to contain several violations of Section 2143 of the Animal Welfare Act (7 U.S.C. § 2143) and the implementing regulations set forth in 9 C.F.R. § 2.31.

First, the Animal Welfare Act provides that the principal investigator of a research protocol must “consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals” and “provide[] a written narrative description of the methods and sources . . . used to determine that alternatives were not available.” 9 C.F.R. § 2.31(d)(1)(ii). By merely providing conclusory statements that “the research also cannot be conducted using tissue samples or other biological material or computer modeling” and “No suitable alternative methods exist” (Bergman Protocol at 6-8) the Bergman Protocol appears to violate § 2.31(d)(1)(ii) by failing to include a narrative considering alternatives to the use of squirrel monkeys in long-term irradiation experiments and setting forth the methods and sources used to support the conclusion that no such alternatives exist.¹

Next, the Bergman Protocol appears to violate § 2.31(e)(3)-(4), which provides that “A proposal to conduct an activity involving animals . . . must contain . . . (3) A complete description of the proposed use of the animals; (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable . . . including provision for the use of analgesic, anesthetic, and tranquilizing drugs”. Although the Bergman Protocol provides for the exposure of monkeys to daily doses of irradiation on a long-term basis, a procedure which will ostensibly cause these animals “more than momentary or slight pain or distress” (See


¹ The February 18, 2010 “Petition to the NASA Office of the Inspector General for Investigation into Waste and Mismanagement in the Conduct of Research” submitted by Physicians Committee for Responsible Medicine (“the PCRM Petition”) cited several examples of validated non-animal research methods providing human-specific radiation exposure data. These methods include the Dose Estimation by Simulation of the ISS Radiation Environment (“DESIRE”), which accurately simulates the physics of radiation particles passing through spacecraft surfaces and human bodies and which has been utilized previously by NASA in the Columbus space module. (PCRM Petition at 14) Additionally, human phantom studies such as “Fred” and “Matroshka” have been used successfully in both NASA and German Aerospace Center studies to obtain radiation data. (PCRM Petition at 14-15) The viability and accuracy of DESIRE and the “Fred” and “Matroshka” phantom studies have been recognized by NASA as “accurate within 10% of the measured dose. That means it’s ‘all systems go’ for using these models to plan NASA’s return to the Moon or even a trip to Mars.” (Phillips T., “The Phantom Torso Returns”, *Science@NASA*, Available at http://science.nasa.gov/headlines/y2009/27may_phantomtorso.htm. Accessed March 9, 2010. Furthermore, there is apparently abundant data regarding space radiation obtained from studies of human astronaut exposures during actual and simulated space missions which occurred between 1965 to the present. (PCRM Petition at 15-18). Despite the existence of these recognized alternatives to the use of non-human primates in radiation experiments the Bergman Protocol fails to consider any such alternatives, ostensibly in violation of 9 C.F.R. § 2.31(d)(1)(ii).

Bergman Protocol at Section A, C), the Protocol fails to identify any provision for the use of analgesic or anesthetic drugs to relieve pain or discomfort at any point in the procedure. Notably, the "Procedure Specifics" section of the Bergman Protocol, which requires a list of "all chemical agents (sedatives, analgesics, anesthetics, paralytics, euthanasia, study drugs, radiotracers) administered to the animals", provides no such information with regard to either anesthetics or the irradiation elements themselves. (Bergman Protocol at 9, indicating "N/A" for all fields in section G) This omission is both inconsistent with previous submissions in Bergman Protocol Sections A and C (detailing the use of ionizing radiation) in apparent violation of § 2.31(e)(3), and ostensibly violative of § 2.31(e)(4) and § 2.31(d)(1)(iv)(A) for failure to make provisions for the administration of analgesic or anesthetic drugs to relieve pain or discomfort or to provide an adequate justification for withholding such drugs.

Further, the Bergman Protocol appears to violate § 2.31(d)(1)(iii) as it fails to provide adequate "written assurance that the activities do not unnecessarily duplicate previous experiments". In fact, to the contrary, in Section D.7 of the Proposal Dr. Bergman expressly states that squirrel monkeys "have been studied previously under experimental conditions similar to those detailed in this application." (Bergman Proposal at Section D.7) Despite this admission that the experimental conditions set forth in the Bergman Protocol have been conducted and studied previously, the Protocol fails to provide any assurance that the experiments proposed in the Bergman Protocol are not "unnecessarily duplicative" of such previous experiments ostensibly in violation of § 2.31(d)(1)(iii).

Based on our conclusion that the Bergman Protocol appears to violate the foregoing NASA research protocol compliance standards and various sections of the Animal Welfare Act, we urge you to deny approval to this study. The proposed use of these animals in painful long-term radiation experiments which lack approval from the IACUC, fail to provide for the administration of analgesic or anesthetic drugs to relieve pain or discomfort, inadequately consider the availability of non-animal alternatives, and are admittedly duplicative of previous experiments, the results of which may ultimately demonstrate that the "health risks of space radiation . . . may be trivial" (Bergman Protocol at A.1), is unsupportable by both legal and ethical standards.

Sincerely,



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