



JAN 23 2015

The Honorable Lucille Roybal-Allard
United States House of Representatives
Washington, D.C. 20515

Dear Representative Roybal-Allard:

Thank you for writing to the National Institutes of Health (NIH) to express your concerns about reports in the popular press about non-human primate research conducted at an NIH-funded facility in Poolesville, Maryland.

The NIH takes animal welfare allegations seriously and has numerous policies and protocols in place to assure the ethical treatment and use of these invaluable resources. Please note that prior to initiating any federally-funded research with animals, several reviews must occur to ensure the safety and welfare of the animals. The research at the Poolesville facility was no exception. However, given the specific nature of the allegations raised, the NIH implemented an additional level of investigation into the research being conducted (summarized below). These investigations have recently drawn to a close and I am confident that the process was thorough and systematic. The NIH believes that the findings from these investigations and the actions pursued, taken together with the existing NIH processes for reviewing and justifying animal research protocols, are sufficient in addressing the concerns raised. Your letter suggested that a review by the NIH Department of Bioethics should be conducted, but that Department focuses on and has expertise in issues related to human research subjects. Instead, the NIH Office of Laboratory Animal Welfare (OLAW) is most appropriate to investigate animal welfare issues in research.

Indeed, the recent NIH review included OLAW:

- OLAW opened an investigation on September 9, 2014, in response to the allegations raised. As required by federal regulation, OLAW requested that the responsible official at the National Institutes of Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Animal Care and Use Committee (ACUC) address the following issues:
 - How discomfort, distress and pain was avoided or minimized;
 - Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury and a description of the methods used to alleviate this;
 - Steps taken to ensure that use of stressors was minimum to obtain valid results;
 - Justification why alternatives to this animal model could not be used;
 - Steps taken to replace, reduce, or refine the use of animals;
 - Rationale for the age and choice of species used;

- The living conditions of the young non-human primates and the appropriateness for the species;
- Qualifications and training of individuals directly involved; and
- Measures taken to ensure the humane treatment of infant primates.
- ACUC members consulted extensively with the research investigator, the USDA, non-human primate center scientists, veterinarians, animal care staff, and other relevant experts. Members also visited the Poolesville facility multiple times to observe its conditions and the general behavior of the monkeys.
- Given that allegations had also been raised regarding the appropriateness of classification of the research under the U.S. Department of Agriculture's (USDA) pain/distress category C, the ACUC also undertook an assessment to respond to these concerns.

Through its deliberations, ACUC members reached the conclusion that the classification of the research protocol under the current pain/distress category C was, in fact, appropriate. However, the investigation did yield additional findings that have led to several important refinements that will further protect and improve animal welfare. These include amendments to the existing protocol to remove several procedures, which previously yielded important data, but are not currently needed to achieve the research goals (e.g. neonatal EEG analyses, spinal taps, and reduction of blood draws) and a new protocol amendment that will define distress behaviors more clearly.

The NICHD is also revising its peer review process to address research animal welfare issues at the time of scientific review, thus making better use of the knowledge and experience of the outside reviewers that are brought in to assess scientific merit of the NICHD intramural research program. Specifically, the NICHD will now ask these scientific reviewers also to comment directly on the appropriateness of chosen animal models, animal numbers, and species appropriateness. This was previously done separately and at different times.

In summary, the NIH has taken the allegations raised by external stakeholders very seriously and initiated a thorough investigation in response to these claims. As a result, we have taken important steps to improve the protocols that were of concern. I hope you are reassured by this letter that the NIH does, in fact, have very rigorous processes in place to investigate and address concerns about the welfare of animals. The NIH remains committed to protecting animals while, at the same time, advancing biomedical research. Thank you for your ongoing interest in the NIH's research efforts. A similar response has been sent to the other co-signers of your letter.

Sincerely yours,



Francis S. Collins, M.D., Ph.D.
Director



JAN 23 2015

The Honorable Dina Titus
United States House of Representatives
Washington, D.C. 20515

Dear Representative Titus:

Thank you for writing to the National Institutes of Health (NIH) to express your concerns about reports in the popular press about non-human primate research conducted at an NIH-funded facility in Poolesville, Maryland.

The NIH takes animal welfare allegations seriously and has numerous policies and protocols in place to assure the ethical treatment and use of these invaluable resources. Please note that prior to initiating any federally-funded research with animals, several reviews must occur to ensure the safety and welfare of the animals. The research at the Poolesville facility was no exception. However, given the specific nature of the allegations raised, the NIH implemented an additional level of investigation into the research being conducted (summarized below). These investigations have recently drawn to a close and I am confident that the process was thorough and systematic. The NIH believes that the findings from these investigations and the actions pursued, taken together with the existing NIH processes for reviewing and justifying animal research protocols, are sufficient in addressing the concerns raised. Your letter suggested that a review by the NIH Department of Bioethics should be conducted, but that Department focuses on and has expertise in issues related to human research subjects. Instead, the NIH Office of Laboratory Animal Welfare (OLAW) is most appropriate to investigate animal welfare issues in research.

Indeed, the recent NIH review included OLAW:

- OLAW opened an investigation on September 9, 2014, in response to the allegations raised. As required by federal regulation, OLAW requested that the responsible official at the National Institutes of Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Animal Care and Use Committee (ACUC) address the following issues:
 - How discomfort, distress and pain was avoided or minimized;
 - Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury and a description of the methods used to alleviate this;
 - Steps taken to ensure that use of stressors was minimum to obtain valid results;
 - Justification why alternatives to this animal model could not be used;
 - Steps taken to replace, reduce, or refine the use of animals;
 - Rationale for the age and choice of species used;

- The living conditions of the young non-human primates and the appropriateness for the species;
- Qualifications and training of individuals directly involved; and
- Measures taken to ensure the humane treatment of infant primates.
- ACUC members consulted extensively with the research investigator, the USDA, non-human primate center scientists, veterinarians, animal care staff, and other relevant experts. Members also visited the Poolesville facility multiple times to observe its conditions and the general behavior of the monkeys.
- Given that allegations had also been raised regarding the appropriateness of classification of the research under the U.S. Department of Agriculture's (USDA) pain/distress category C, the ACUC also undertook an assessment to respond to these concerns.

Through its deliberations, ACUC members reached the conclusion that the classification of the research protocol under the current pain/distress category C was, in fact, appropriate. However, the investigation did yield additional findings that have led to several important refinements that will further protect and improve animal welfare. These include amendments to the existing protocol to remove several procedures, which previously yielded important data, but are not currently needed to achieve the research goals (e.g. neonatal EEG analyses, spinal taps, and reduction of blood draws) and a new protocol amendment that will define distress behaviors more clearly.

The NICHD is also revising its peer review process to address research animal welfare issues at the time of scientific review, thus making better use of the knowledge and experience of the outside reviewers that are brought in to assess scientific merit of the NICHD intramural research program. Specifically, the NICHD will now ask these scientific reviewers also to comment directly on the appropriateness of chosen animal models, animal numbers, and species appropriateness. This was previously done separately and at different times.

In summary, the NIH has taken the allegations raised by external stakeholders very seriously and initiated a thorough investigation in response to these claims. As a result, we have taken important steps to improve the protocols that were of concern. I hope you are reassured by this letter that the NIH does, in fact, have very rigorous processes in place to investigate and address concerns about the welfare of animals. The NIH remains committed to protecting animals while, at the same time, advancing biomedical research. Thank you for your ongoing interest in the NIH's research efforts. A similar response has been sent to the other co-signers of your letter.

Sincerely yours,



Francis S. Collins, M.D., Ph.D.
Director



JAN 23 2015

The Honorable Eliot Engel
United States House of Representatives
Washington, D.C. 20515

Dear Representative Engel:

Thank you for writing to the National Institutes of Health (NIH) to express your concerns about reports in the popular press about non-human primate research conducted at an NIH-funded facility in Poolesville, Maryland.

The NIH takes animal welfare allegations seriously and has numerous policies and protocols in place to assure the ethical treatment and use of these invaluable resources. Please note that prior to initiating any federally-funded research with animals, several reviews must occur to ensure the safety and welfare of the animals. The research at the Poolesville facility was no exception. However, given the specific nature of the allegations raised, the NIH implemented an additional level of investigation into the research being conducted (summarized below). These investigations have recently drawn to a close and I am confident that the process was thorough and systematic. The NIH believes that the findings from these investigations and the actions pursued, taken together with the existing NIH processes for reviewing and justifying animal research protocols, are sufficient in addressing the concerns raised. Your letter suggested that a review by the NIH Department of Bioethics should be conducted, but that Department focuses on and has expertise in issues related to human research subjects. Instead, the NIH Office of Laboratory Animal Welfare (OLAW) is most appropriate to investigate animal welfare issues in research.

Indeed, the recent NIH review included OLAW:

- OLAW opened an investigation on September 9, 2014, in response to the allegations raised. As required by federal regulation, OLAW requested that the responsible official at the National Institutes of Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Animal Care and Use Committee (ACUC) address the following issues:
 - How discomfort, distress and pain was avoided or minimized;
 - Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury and a description of the methods used to alleviate this;
 - Steps taken to ensure that use of stressors was minimum to obtain valid results;
 - Justification why alternatives to this animal model could not be used;
 - Steps taken to replace, reduce, or refine the use of animals;
 - Rationale for the age and choice of species used;

- The living conditions of the young non-human primates and the appropriateness for the species;
- Qualifications and training of individuals directly involved; and
- Measures taken to ensure the humane treatment of infant primates.
- ACUC members consulted extensively with the research investigator, the USDA, non-human primate center scientists, veterinarians, animal care staff, and other relevant experts. Members also visited the Poolesville facility multiple times to observe its conditions and the general behavior of the monkeys.
- Given that allegations had also been raised regarding the appropriateness of classification of the research under the U.S. Department of Agriculture's (USDA) pain/distress category C, the ACUC also undertook an assessment to respond to these concerns.

Through its deliberations, ACUC members reached the conclusion that the classification of the research protocol under the current pain/distress category C was, in fact, appropriate. However, the investigation did yield additional findings that have led to several important refinements that will further protect and improve animal welfare. These include amendments to the existing protocol to remove several procedures, which previously yielded important data, but are not currently needed to achieve the research goals (e.g. neonatal EEG analyses, spinal taps, and reduction of blood draws) and a new protocol amendment that will define distress behaviors more clearly.

The NICHD is also revising its peer review process to address research animal welfare issues at the time of scientific review, thus making better use of the knowledge and experience of the outside reviewers that are brought in to assess scientific merit of the NICHD intramural research program. Specifically, the NICHD will now ask these scientific reviewers also to comment directly on the appropriateness of chosen animal models, animal numbers, and species appropriateness. This was previously done separately and at different times.

In summary, the NIH has taken the allegations raised by external stakeholders very seriously and initiated a thorough investigation in response to these claims. As a result, we have taken important steps to improve the protocols that were of concern. I hope you are reassured by this letter that the NIH does, in fact, have very rigorous processes in place to investigate and address concerns about the welfare of animals. The NIH remains committed to protecting animals while, at the same time, advancing biomedical research. Thank you for your ongoing interest in the NIH's research efforts. A similar response has been sent to the other co-signers of your letter.

Sincerely yours,



Francis S. Collins, M.D., Ph.D.
Director



JAN 23 2015

The Honorable Sam Farr
United States House of Representatives
Washington, D.C. 20515

Dear Representative Farr:

Thank you for writing to the National Institutes of Health (NIH) to express your concerns about reports in the popular press about non-human primate research conducted at an NIH-funded facility in Poolesville, Maryland.

The NIH takes animal welfare allegations seriously and has numerous policies and protocols in place to assure the ethical treatment and use of these invaluable resources. Please note that prior to initiating any federally-funded research with animals, several reviews must occur to ensure the safety and welfare of the animals. The research at the Poolesville facility was no exception. However, given the specific nature of the allegations raised, the NIH implemented an additional level of investigation into the research being conducted (summarized below). These investigations have recently drawn to a close and I am confident that the process was thorough and systematic. The NIH believes that the findings from these investigations and the actions pursued, taken together with the existing NIH processes for reviewing and justifying animal research protocols, are sufficient in addressing the concerns raised. Your letter suggested that a review by the NIH Department of Bioethics should be conducted, but that Department focuses on and has expertise in issues related to human research subjects. Instead, the NIH Office of Laboratory Animal Welfare (OLAW) is most appropriate to investigate animal welfare issues in research.

Indeed, the recent NIH review included OLAW:

- OLAW opened an investigation on September 9, 2014, in response to the allegations raised. As required by federal regulation, OLAW requested that the responsible official at the National Institutes of Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Animal Care and Use Committee (ACUC) address the following issues:
 - How discomfort, distress and pain was avoided or minimized;
 - Procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury and a description of the methods used to alleviate this;
 - Steps taken to ensure that use of stressors was minimum to obtain valid results;
 - Justification why alternatives to this animal model could not be used;
 - Steps taken to replace, reduce, or refine the use of animals;
 - Rationale for the age and choice of species used;

- The living conditions of the young non-human primates and the appropriateness for the species;
- Qualifications and training of individuals directly involved; and
- Measures taken to ensure the humane treatment of infant primates.
- ACUC members consulted extensively with the research investigator, the USDA, non-human primate center scientists, veterinarians, animal care staff, and other relevant experts. Members also visited the Poolesville facility multiple times to observe its conditions and the general behavior of the monkeys.
- Given that allegations had also been raised regarding the appropriateness of classification of the research under the U.S. Department of Agriculture's (USDA) pain/distress category C, the ACUC also undertook an assessment to respond to these concerns.

Through its deliberations, ACUC members reached the conclusion that the classification of the research protocol under the current pain/distress category C was, in fact, appropriate. However, the investigation did yield additional findings that have led to several important refinements that will further protect and improve animal welfare. These include amendments to the existing protocol to remove several procedures, which previously yielded important data, but are not currently needed to achieve the research goals (e.g. neonatal EEG analyses, spinal taps, and reduction of blood draws) and a new protocol amendment that will define distress behaviors more clearly.

The NICHD is also revising its peer review process to address research animal welfare issues at the time of scientific review, thus making better use of the knowledge and experience of the outside reviewers that are brought in to assess scientific merit of the NICHD intramural research program. Specifically, the NICHD will now ask these scientific reviewers also to comment directly on the appropriateness of chosen animal models, animal numbers, and species appropriateness. This was previously done separately and at different times.

In summary, the NIH has taken the allegations raised by external stakeholders very seriously and initiated a thorough investigation in response to these claims. As a result, we have taken important steps to improve the protocols that were of concern. I hope you are reassured by this letter that the NIH does, in fact, have very rigorous processes in place to investigate and address concerns about the welfare of animals. The NIH remains committed to protecting animals while, at the same time, advancing biomedical research. Thank you for your ongoing interest in the NIH's research efforts. A similar response has been sent to the other co-signers of your letter.

Sincerely yours,



Francis S. Collins, M.D., Ph.D.
Director