



NIA Nonhuman Primate Scientific Merit Review Form (Prior to ACUC Approval)

PART I: Investigator Completes

Protocol Number:	Redacted by agreement
Protocol Title:	Assessment of primate aging: effects of caloric modification
Principal Investigator:	Redacted by agreement

1. **Relevance of this Research:** Please explain how the research is relevant to human and/or animal health and how this project will advance the state of science.

Calorie restriction without malnutrition is the most reliable intervention shown, in many species, to slow the biological aging process. For nearly 100 years, this has fueled intense interest among the scientific community due to the obvious potential impact for humans. When this project began in 1987, it was a landmark endeavor to unravel the physiological mechanisms underlying the beneficial effects of CR in a species closely related to humans. More than 100 publications have resulted and we are continuing the investigation with tissue samples from all the subjects.

2. **Background/Rationale for Use of Nonhuman Primates:** Please provide details of the scientific basis for why nonhuman primates are required for this project instead of a lower species or humans.

Our long-term study of CR in rhesus monkeys has been ongoing for over three decades. In addition, it is one of only two studies of its kind ever to exist, which is aimed at answering questions about how CR modulates lifespan and healthspan in a mammalian species. Though rodents are useful to help our understanding of basic physiology, rhesus monkeys are longer-lived, thereby sharing similar aging patterns with humans. They also develop age-associated pathologies at similar rates and trajectories as humans. But, most importantly, rhesus monkeys share 93% genetic homology to humans.

Currently 16 monkeys from the original cohort remain and will be monitored for the course of their natural life. No new animals are being added to this project and no invasive experiments are planned.

3. **Experimental Design:** Provide a copy of the draft Animal Study Proposal OR briefly explain the experimental design and specify all procedures performed on the nonhuman primates as part of the research. The description should allow the reviewers to understand the experimental timeline of an animal from its entry into the experiment to the endpoint of the study.

- a. Include a justification for the number of animals to be used and

b. Explain how pain and distress are addressed in this protocol.

ASP Provided: Yes ☒ No ☐

Brief Explanation (Complete, only if ASP isn't provided):

<div>Redacted by agreement</div> PI Signature:	Date: 11/06/2020
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PART 2: Nonhuman Primate Scientific Merit Review Committee Completes

Scientific Merit Review Committee Chairperson: (Cannot be a Principal or Associate Investigator on the proposal under review.) Type name: <div>Redacted by agreement</div> Affiliation: NIA	
Request is for a minor amendment. If yes, committee review isn't required.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Scientific Review Committee Participants (List names): * <div>Redacted by agreement</div> * *	Date discussed: 11/23/2020

Yes	No	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The proposed research is designed to develop knowledge necessary to improve human and/or animal health and well-being.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The Study Objectives are clearly stated and scientifically meritorious.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental methods are reasonable and well justified.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	There is a clear and rational explanation for using NHPs and the proposed species is the appropriate experimental model for the study.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The number of animals required is well-justified and sufficient to achieve the Study Objectives.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental endpoints are as humane as possible consistent with obtaining valid results and achieving the Study Objectives.

Summary of Scientific Merit Review Discussion:

The presentation by

Redacted by agreement

 was very informative and well organized. I have no additional comments.

Scientific Review Committee Vote:

This is a scientifically meritorious study and ready for ACUC review:

☒ Yes ☐ No

Respond to PI <input type="checkbox"/>	Date:
Copy provided to the ACUC <input type="checkbox"/>	Date:
Copy provided to the Scientific Director <input type="checkbox"/>	Date:



NIA Nonhuman Primate Scientific Merit Review Form (Prior to ACUC Approval)

PART I: Investigator Completes

Protocol Number:	Redacted by agreement
Protocol Title:	Assessment of primate aging: effects of caloric modification
Principal Investigator:	Redacted by agreement

1. Relevance of this Research: Please explain how the research is relevant to human and/or animal health and how this project will advance the state of science.

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2. Background/Rationale for Use of Nonhuman Primates: Please provide details of the scientific basis for why nonhuman primates are required for this project instead of a lower species or humans.

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Currently 16 monkeys from the original cohort remain and will be monitored for the course of their natural life. No new animals are being added to this project and no invasive experiments are planned.

3. Experimental Design: Provide a copy of the draft Animal Study Proposal OR briefly explain the experimental design and specify all procedures performed on the nonhuman primates as part of the research. The description should allow the reviewers to understand the experimental timeline of an animal from its entry into the experiment to the endpoint of the study.

a. Include a justification for the number of animals to be used and

b. Explain how pain and distress are addressed in this protocol.

ASP Provided: Yes ☒ No ☐

Brief Explanation (Complete, only if ASP isn't provided):

<div>Redacted by agreement</div> PI Signature:	Date: 11/06/2020
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PART 2: Nonhuman Primate Scientific Merit Review Committee Completes

Scientific Merit Review Committee Chairperson: (Cannot be a Principal or Associate Investigator on the proposal under review.) Type name: Affiliation:	
Request is for a minor amendment. If yes, committee review isn't required.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Scientific Review Committee Participants (List names): <div>Redacted by agreement</div>	Date discussed: 11/22/20

Yes	No	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The proposed research is designed to develop knowledge necessary to improve human and/or animal health and well-being.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The Study Objectives are clearly stated and scientifically meritorious.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental methods are reasonable and well justified.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	There is a clear and rational explanation for using NHPs and the proposed species is the appropriate experimental model for the study.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The number of animals required is well-justified and sufficient to achieve the Study Objectives.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental endpoints are as humane as possible consistent with obtaining valid results and achieving the Study Objectives.

Summary of Scientific Merit Review Discussion:

Questions regarding husbandry conditions were asked and answered appropriately. Information about endpoint criteria addressed and found appropriate.

Scientific Review Committee Vote:

This is a scientifically meritorious study and ready for ACUC review:

☒ Yes ☐ No

Respond to PI <input type="checkbox"/>	Date:
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Copy provided to the ACUC <input type="checkbox"/>	Date:
Copy provided to the Scientific Director <input type="checkbox"/>	Date:

b. Explain how pain and distress are addressed in this protocol.

ASP Provided: Yes ☒ No ☐

Brief Explanation (Complete, only if ASP isn't provided):

<div>Redacted by agreement</div>	Date: 11/06/2020
PI Signature:	

PART 2: Nonhuman Primate Scientific Merit Review Committee Completes

Scientific Merit Review Committee Chairperson: (Cannot be a Principal or Associate Investigator on the proposal under review.) Type name: <div>Redacted by agreement</div> Affiliation: NIA	
Request is for a minor amendment. If yes, committee review isn't required.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Scientific Review Committee Participants (List names): * <div>Redacted by agreement</div> * *	Date discussed:

Yes	No	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The proposed research is designed to develop knowledge necessary to improve human and/or animal health and well-being.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The Study Objectives are clearly stated and scientifically meritorious.
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<input checked="" type="checkbox"/>	<input type="checkbox"/>	The number of animals required is well-justified and sufficient to achieve the Study Objectives.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental endpoints are as humane as possible consistent with obtaining valid results and achieving the Study Objectives.

Summary of Scientific Merit Review Discussion:

Saline restriction in Aging study for NHPs

Scientific Review Committee Vote:

This is a scientifically meritorious study and ready for ACUC review:

☒ Yes ☐ No

Respond to PI <input checked="" type="checkbox"/>	Date: 11/23/2020
Copy provided to the ACUC <input checked="" type="checkbox"/>	Date: 11/23/2020
Copy provided to the Scientific Director <input checked="" type="checkbox"/>	Date: 11/23/2020



NIA Nonhuman Primate Scientific Merit Review Form (Prior to ACUC Approval)

PART I: Investigator Completes

Protocol Number:	Redacted by agreement
Protocol Title:	Aging interventions in rhesus monkeys
Principal Investigator:	Redacted by agreement

1. Relevance of this Research: Please explain how the research is relevant to human and/or animal health and how this project will advance the state of science.

This animal study protocol provides the framework for the work of the Nonhuman Primate (NHP) Core. The Core serves as a translational aging model resource for intramural and extramural investigators, conducts short-term in vivo research projects, and maintains a tissue bank. All individual procedures described in the ASP are needed for research projects and sample collections. The samples are used by collaborators for various projects including the evaluation of age-related changes in skeletal muscle, immune function, inflammatory profile, the gut microbiota, markers of cardiac disease, metabolomics, proteomics, assay development, and samples of COVID-19 related research. A list of relevant publications in high impact journal is attached and attests to the value of this important resource.

Additionally, under this ASP domain, the Core conducts short-term in vivo studies to characterize physiological parameters associated with aging and possible interventions to slow the process. Projects have included drug development trials, pharmacokinetic trials, metabolic effects of compounds previously assessed in the NIA Intervention Testing Program in rodents, and exercise effects on serum markers of memory. All new projects will be submitted as amendments and reviewed individually. The current ASP describes three ongoing studies, as follows:

1. Cardiovascular function in NHPs: This experiment will help establish potential links between changes in gene expression in cardiac tissue and age-related cardiac dysfunction. This study will provide the basis for mechanistic experiments aimed at establishing whether miRNAs modulated by aging have an effect on myocardial function, and thus, lay the groundwork for interventions to combat cardiovascular dysfunction in humans.
2. Muscle and Exercise in NHPs: Loss of muscle mass with age contributes to loss of mobility and independence. Activity can counteract deleterious effects on muscle but the mechanism for activity induced preservation of muscle protein is unclear. By examining the role of RNA splicing and the inflammatory response to activity, this study in monkeys will provide a better understanding of how to target interventions in humans to counteract muscle wasting.

3. Treating pre-diabetes in NHPs: Type II diabetes occurs spontaneously in rhesus monkeys at rates approximating the human population. Managing diabetic monkeys in the research setting is challenging, thus limiting their use for translational studies. This project aims to document clinical outcomes following treatment with newer FDA approved diabetes drugs to support a needed research model for the treatment and management of human diabetes.

2. Background/Rationale for Use of Nonhuman Primates: Please provide details of the scientific basis for why nonhuman primates are required for this project instead of a lower species or humans.

The purpose of the NHP Core is to provide translational model for aging research that is clinically relevant to humans. Rhesus monkeys are approximately 93% genetically similar to humans and parallel human morphology, physiology, and behavior changes with age. They allow us to explore physiological declines associated with aging in a controlled environment that is not possible with human studies but in a species that is closely related. Projects within the Core are bridging the bench to bedside gap.

3. Experimental Design: Provide a copy of the draft Animal Study Proposal OR briefly explain the experimental design and specify all procedures performed on the nonhuman primates as part of the research. The description should allow the reviewers to understand the experimental timeline of an animal from its entry into the experiment to the endpoint of the study.

- Include a justification for the number of animals to be used and
- Explain how pain and distress are addressed in this protocol.

ASP Provided: Yes ☒ No ☐

Brief Explanation (Complete, only if ASP isn't provided):

<div>Redacted by agreement</div> PI Signature:	Date: 11/30/2020
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PART 2: Nonhuman Primate Scientific Merit Review Committee Completes

Scientific Merit Review Committee Chairperson: (Cannot be a Principal or Associate Investigator on the proposal under review.) Type name: Affiliation:	
Request is for a minor amendment. If yes, committee review isn't required.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Scientific Review Committee Participants (List names): <div>Redacted by agreement</div>	Date discussed: 12/11/2020

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*	

Yes	No	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The proposed research is designed to develop knowledge necessary to improve human and/or animal health and well-being.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The Study Objectives are clearly stated and scientifically meritorious.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental methods are reasonable and well justified.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	There is a clear and rational explanation for using NHPs and the proposed species is the appropriate experimental model for the study.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The number of animals required is well-justified and sufficient to achieve the Study Objectives.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental endpoints are as humane as possible consistent with obtaining valid results and achieving the Study Objectives.

Summary of Scientific Merit Review Discussion:

This application clearly outlines the rationale and description of use for the rhesus macaque core for use by NIA intramural and extramural researchers. While the protocol is expansive the scientific rationale for including all protocols that may be used is well-explained and clear. During the discussion, questions were addressed to the PI that focused on the design of particularly projects, the animal husbandry and the relationship between veterinary care staff and research staff. My comments in particular addressed the goals of project 3 (pre-diabetic intervention) and whether animal care took approaches that differed broadly based on age (that is, do geriatric monkeys receive specific standard of care that differs from younger) or whether all treated on case-by-case basis. In response to both, PI presented clear answers that clarified questions I made on the proposal that had good scientific rationale. In the case of the first, PI clarified that role and approaches veterinary staff used for pre-diabetic intervention and how research into alternative approaches could benefit both research and the care of animals. In regard to the later, PI clarified that research staff & veterinary staff make clear decisions based on individual animals and long-term care and husbandry of animals makes it clear the needs for individuals. Overall, the scientific rationale for the core is solid and this protocol should move forward to animal use committee for review.

Scientific Review Committee Vote:

This is a scientifically meritorious study and ready for ACUC review:

☒ Yes ☐ No

Respond to PI <input type="checkbox"/>	Date:
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Copy provided to the ACUC <input type="checkbox"/>	Date:
Copy provided to the Scientific Director <input type="checkbox"/>	Date:



NIA Nonhuman Primate Scientific Merit Review Form (Prior to ACUC Approval)

PART I: Investigator Completes

Protocol Number:	Redacted by agreement
Protocol Title:	Aging interventions in rhesus monkeys
Principal Investigator:	Redacted by agreement

1. Relevance of this Research: Please explain how the research is relevant to human and/or animal health and how this project will advance the state of science.

This animal study protocol provides the framework for the work of the Nonhuman Primate (NHP) Core. The Core serves as a translational aging model resource for intramural and extramural investigators, conducts short-term in vivo research projects, and maintains a tissue bank. All individual procedures described in the ASP are needed for research projects and sample collections. The samples are used by collaborators for various projects including the evaluation of age-related changes in skeletal muscle, immune function, inflammatory profile, the gut microbiota, markers of cardiac disease, metabolomics, proteomics, assay development, and samples of COVID-19 related research. A list of relevant publications in high impact journal is attached and attests to the value of this important resource.

Additionally, under this ASP domain, the Core conducts short-term in vivo studies to characterize physiological parameters associated with aging and possible interventions to slow the process. Projects have included drug development trials, pharmacokinetic trials, metabolic effects of compounds previously assessed in the NIA Intervention Testing Program in rodents, and exercise effects on serum markers of memory. All new projects will be submitted as amendments and reviewed individually. The current ASP describes three on-going studies, as follows:

1. Cardiovascular function in NHPs: This experiment will help establish potential links between changes in gene expression in cardiac tissue and age-related cardiac dysfunction. This study will provide the basis for mechanistic experiments aimed at establishing whether miRNAs modulated by aging have an effect on myocardial function, and thus, lay the groundwork for interventions to combat cardiovascular dysfunction in humans.
2. Muscle and Exercise in NHPs: Loss of muscle mass with age contributes to loss of mobility and independence. Activity can counteract deleterious affects on muscle but the mechanism for activity induced preservation of muscle protein is unclear. By examining the role of RNA splicing and the inflammatory response to activity, this study in monkeys will provide a better understanding of how to target interventions in humans to counteract muscle wasting.

3. Treating pre-diabetes in NHPs: Type II diabetes occurs spontaneously in rhesus monkeys at rates approximating the human population. Managing diabetic monkeys in the research setting is challenging, thus limiting their use for translational studies. This project aims to document clinical outcomes following treatment with newer FDA approved diabetes drugs to support a needed research model for the treatment and management of human diabetes.
2. Background/Rationale for Use of Nonhuman Primates: Please provide details of the scientific basis for why nonhuman primates are required for this project instead of a lower species or humans.
- The purpose of the NHP Core is to provide translational model for aging research that is clinically relevant to humans. Rhesus monkeys are approximately 93% genetically similar to humans and parallel human morphology, physiology, and behavior changes with age. They allow us to explore physiological declines associated with aging in a controlled environment that is not possible with human studies but in a species that is closely related. Projects within the Core are bridging the bench to bedside gap.
3. Experimental Design: Provide a copy of the draft Animal Study Proposal OR briefly explain the experimental design and specify all procedures performed on the nonhuman primates as part of the research. The description should allow the reviewers to understand the experimental timeline of an animal from its entry into the experiment to the endpoint of the study.
- Include a justification for the number of animals to be used and
 - Explain how pain and distress are addressed in this protocol.

ASP Provided: Yes ☒ No ☐

Brief Explanation (Complete, only if ASP isn't provided):

<div style="border: 1px solid black; padding: 2px; width: fit-content;">Redacted by agreement</div>	Date: 11/30/2020
PI Signature:	

PART 2: Nonhuman Primate Scientific Merit Review Committee Completes

Scientific Merit Review Committee Chairperson: (Cannot be a Principal or Associate Investigator on the proposal under review.) Type name: Affiliation:	
Request is for a minor amendment. If yes, committee review isn't required.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Scientific Review Committee Participants (List names): *	Date discussed: 12/11/20

Redacted by agreement	
*	

Yes	No	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The proposed research is designed to develop knowledge necessary to improve human and/or animal health and well-being.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	The Study Objectives are clearly stated and scientifically meritorious.
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<input checked="" type="checkbox"/>	<input type="checkbox"/>	The experimental endpoints are as humane as possible consistent with obtaining valid results and achieving the Study Objectives.

Summary of Scientific Merit Review Discussion:

The reviewers did not have any scientific concerns with the NIA NHP Core resource and the three proposed projects: (1) cardiovascular function in NHPs, (2) Muscle and exercise in NHPs and (3) Treating pre-diabetes in NHPs. The only issue raised by this reviewer was the specific criteria that will use to house experimental animals alone or in pairs. The issue was explained initially by

Redacted by agreement

and will be addressed at a later date by

Redacted by agreement

Scientific Review Committee Vote:

This is a scientifically meritorious study and ready for ACUC review:

☒ Yes ☐ No

Respond to PI <input checked="" type="checkbox"/>	Date: 12/14/2020
Copy provided to the ACUC <input checked="" type="checkbox"/>	Date: 12/14/2020
Copy provided to the Scientific Director <input checked="" type="checkbox"/>	Date: 12/14/2020



NIA Nonhuman Primate Scientific Merit Review Form (Prior to ACUC Approval)

PART I: Investigator Completes

Protocol Number:	Redacted by agreement
Protocol Title:	Aging interventions in rhesus monkeys
Principal Investigator:	Redacted by agreement

1. **Relevance of this Research:** Please explain how the research is relevant to human and/or animal health and how this project will advance the state of science.

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 - b. Explain how pain and distress are addressed in this protocol.

ASP Provided: Yes ☒ No ☐

Brief Explanation (Complete, only if ASP isn't provided):

<div style="border: 1px solid black; width: 100%; height: 100%; text-align: center; font-size: small;">Redacted by agreement</div>	Date: 11/30/2020
PI Signature:	

PART 2: Nonhuman Primate Scientific Merit Review Committee Completes

Scientific Merit Review Committee Chairperson: <small>(Cannot be a Principal or Associate Investigator on the proposal under review.)</small> Type name: <div style="border: 1px solid black; width: 150px; height: 1.2em; display: inline-block; vertical-align: middle;">Redacted by agreement</div> Affiliation:	
Request is for a minor amendment. If yes, committee review isn't required.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Scientific Review Committee Participants (List names): * <div style="border: 1px solid black; width: 150px; height: 1.2em; display: inline-block; vertical-align: middle;">Redacted by agreement</div>	Date discussed:

*	Redacted by agreement	
*		

Yes	No	
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95% versus 93% homologous to human → Connected by PI
Summary of Scientific Merit Review Discussion:
 Is body condition part of physical → Yes
 A robust discussion occurred and the SMRC approved the study.

Scientific Review Committee Vote:

Redacted by agreement

12/11/2020

This is a scientifically meritorious study and ready for ACUC review:

☒ Yes ☐ No

Respond to PI <input type="checkbox"/>	Date:
Copy provided to the ACUC <input type="checkbox"/>	Date:
Copy provided to the Scientific Director <input type="checkbox"/>	Date: