

ADDGENE, INC.
RETROSPECTIVE REVIEW & MITIGATION REPORT

A Retrospective Review must be performed upon discovery that a financial conflict of interest (FCOI) has not been timely disclosed or managed (see Addgene's "[Conducting a Retrospective Review](#)" procedure). The purpose of this review is to determine the influence of potential bias on the federally funded research.

RETROSPECTIVE REVIEWS MUST BE COMPLETED WITHIN 120 DAYS OF DISCOVERY

BASIS FOR RETROSPECTIVE REVIEW

	Failure by Investigator or Senior / Key Personnel to disclose Significant Financial Interest(s) that is determined by Addgene to constitute a FCOI
	Failure by Addgene to review or manage the FCOI
	Failure by Investigator or Senior / Key Personnel to comply with the FCOI Management Plan
	Other:

RESEARCH PROJECT INFORMATION

Research / Project No.:	Research / Project Title:
Lead Investigator:	Email:

INDIVIDUAL WITH FINANCIAL CONFLICT OF INTEREST

Name:	Role / Job Title:
Start Date:	End Date:
Discovery Date of Untimely Disclosure / Management:	
Description of Responsibilities / Duties:	

DESCRIPTION OF FINANCIAL CONFLICT OF INTEREST

Entity Name:	Affiliation w/ Entity:
--------------	------------------------

Actual or Estimated Value of Remuneration:
Description of Remuneration:

<p align="center">RETROSPECTIVE REVIEW METHODOLOGY</p> <p align="center">(Tick corner of each box as applicable, add / delete as necessary)</p>
--

	Ad hoc committee formed to investigate reason(s) / cause of failure (as noted in "Basis for Retrospective Review" above)	
Retrospective Review Committee (RRC) Members		
Name:	Job Title:	
Name:	Job Title:	
Name:	Job Title:	
Name:	Job Title:	
Name:	Job Title:	

	Various personnel were interviewed	
Interviewees		
Name:	Job Title:	
Date(s) of Interview:		
Reason for Interview:		
Name:	Job Title:	
Date(s) of Interview:		
Reason for Interview:		
Name:	Job Title:	
Date(s) of Interview:		
Reason for Interview:		
Name:	Job Title:	
Date(s) of Interview:		
Reason for Interview:		

CONCLUSION OF THE REVIEW

After careful consideration of the RRC's report and findings, Addgene's Board of Directors determined, by vote, that:

No Bias. There is no reasonable basis on which to conclude bias has occurred.

Bias. There is a reasonable basis on which to conclude bias has occurred. A **Mitigation Report** must be completed and submitted along with this report.

Composition of Addgene's Board of Directors

Name:

Organization:

Name:

Organization:

Name:

Organization:

Name:

Organization:

Name:

Organization:

Name:

Organization:

Name:

Organization:

Name:

Organization:

CERTIFICATION

We, the undersigned, have reviewed the contents of this report and submit, under the penalty of perjury, that the information above is true, complete and accurate to the best of our knowledge.

On Behalf of Addgene's FCOI Team:

Signature: _____ Date: _____

Printed Name: _____

On Behalf of the RRC:

Signature: _____ Date: _____

Printed Name: _____

Executive Director:

Signature: _____ Date: _____

Printed Name: _____

ADDGENE, INC.
MITIGATION REPORT

Upon reviewing the findings of the Retrospective Review Committee, Addgene's Board of Directors have determined that there is a **reasonable basis** on which to conclude that the untimely disclosure or management of a financial conflict of interest (FCOI) has caused, created, or led to bias in a federally funded research project. This form sets forth the steps Addgene will take to eliminate or mitigate the effect of the bias.

NATURE OF THE FINANCIAL CONFLICT OF INTEREST

Name:	Role / Job Title:
Start Date:	End Date:
Discovery Date of Untimely Disclosure / Management:	
Description of Responsibilities / Duties:	
Entity Name:	Affiliation w/ Entity:
Actual or Estimated Value of Remuneration:	
Description of Remuneration:	

RETROSPECTIVE REVIEW METHODOLOGIES & FINDINGS

	a copy of the Retrospective Review is attached
--	--

BIAS IMPACT

Description of harm caused, or could be caused, by the bias, including any supportive qualitative and quantitative data (attach additional pages as needed):
Impacted stage(s) of the research project:

Severity of Bias Impact:	
	Research integrity is salvageable. Bias can be eliminated. See Plan of Action below.
	Research integrity is salvageable. Bias can be mitigated. See Plan of Action below.
	The integrity of the research cannot be salvaged. Bias cannot be eliminated nor mitigated.

PLAN OF ACTION

Addgene **has taken** following actions to eliminate or mitigate the effect of bias on the research project.

Addgene **will take** the following actions to eliminate or mitigate the effect of bias on the research project.

On Behalf of Addgene's FCOI Team:

Signature: _____ Date: _____

Printed Name: _____

On Behalf of Addgene's Board of Directors

Signature: _____ Date: _____

Printed Name: _____

Executive Director:

Signature: _____ Date: _____

Printed Name: _____