Cure RTD
Riboflavin Transporter Deficiency Foundation
www.cureRTD.org

Cure RTD Foundation Research Grant Policies

A. Protecting the rights and welfare of human research participants is a top priority of the Cure RTD Foundation, Inc. (CureRTD). Federal regulation and CureRTD policy require that all institutions maintain appropriate policies and procedures for the protection of human subjects. In addition, CureRTD encourages a research environment in which ethical and productive investigation is valued. If applicable, a copy of the informed consent form for any human subjects for the project as well as proof of current project approval by an Institutional Review Board (IRB) (or a similar oversight group) must be provided to CureRTD before funding for a project will be released by CureRTD.

B. Similarly, it is a CureRTD policy that all projects must conform to regulations for the safe and humane treatment of animals (see Addendum A). Specifically, CureRTD stipulates that animals can be used in CureRTD-funded research only when no other means of obtaining scientifically sound, valid and useful results are available. Furthermore, only the minimum number of appropriate animals required to obtain and validate results should be used; and in cases requiring the death of an animal, only the most appropriate and humane form of animal sacrifice consistent with the purpose of the research shall be employed. If applicable, a copy of proof of current project approval by the institution's Animal Use and Protection Committee (IACUC or a similar oversight group) must be provided to the CureRTD before any funding for the project will be released by CureRTD.

C. It is CureRTD's expectation that any results and accomplishments from research it has funded will be made public (preferably through a high quality, peer-reviewed journal article) in order to maximize progress toward improved understanding, treatments and ultimately the discovery of a cure for RTD.

D. CureRTD also expects that Materials resulting from research funded by the organization will be made available to other researchers on a reasonable and quick basis. "Materials" means reagents useful for scientific or preclinical investigation, animal and cellular models and any other physical inventions useful in further scientific or preclinical work other than intellectual property that are at least partially funded by this award and unencumbered by either i) existing University intellectual property or contractual obligations as of the Project Start and/or ii) subsequent University intellectual property or contractual obligations related to work that was not funded by CureRTD. CureRTD considers an optional one-year period of exclusivity for the creator laboratory to be reasonable, and distribution should be able to commence with the first publication. Furthermore, it is expected that such Materials will be made available to noncommercial laboratories at cost and to commercial enterprises for a reasonable licensing fee.

E. CureRTD recognizes that in the effort to develop therapies for RTD the grant recipient may need to maintain confidentiality so that intellectual property rights can be preserved and patent applications filed appropriately. The grant recipient may enter into a for-profit enterprise to pursue and/or commercialize discoveries made in whole or in part with funding from CureRTD. For those situations where a for-profit enterprise is anticipated or the grant recipient is part of a forprofit company, please see Addendum B.

F. CureRTD will not challenge any decisions concerning patent applications that might be made by a grantee for inventions resulting from work performed under a CureRTD research grant. All inventions or discoveries made in whole or in part with funding from CureRTD must be reported to CureRTD at the earliest practical time. The grantee also must notify CureRTD immediately of any decision to apply for a patent or other legal protection. This information will be kept confidential.

G. CureRTD will forward funds for the project to the institution every six months in accordance with the project's approved budget. A five- to 10-page progress-to-date package will be sent by the grantee at the end of nine months to the Science Board for review. The subsequent year(s) of funding will not be activated prior to a review of the nine-month progress report and an explanation of any changes that the work necessitates or changes in specific aims for the next year. The progress report is required at nine months after the start of each award year.

H. In any published report of research funded in part or in whole by a CureRTD research grant, CureRTD must be cited as a source of funds, and CureRTD must be sent a copy of the published material or paper. If an affiliate of the CureRTD has provided funds for a CureRTD research grant, then the CureRTD affiliate must be cited by name in addition to CureRTD in any published report. The specifics of citation of acknowledgement will be noted in the initial award letter.

I. Within 60 days of the end of the grant period, it is required that a report by the Principal Investigator on the research that resulted from the CureRTD grant be sent to CureRTD. In addition, a layman's summary (which can be published by CureRTD as is or in edited form) must be submitted.

J. A final detailed accounting of the funds spent is required to be sent to CureRTD within 60 days of the end of the grant period. If the grant period is longer than one year, then annual financial reports must be filed with CureRTD on the grant commencement date anniversary. At the end of the grant period, any unused funds must be returned to CureRTD, unless a letter explaining the situation and requesting an extension of the grant period (without additional funds) is submitted at least 90 days ahead of the end of the grant period and approved by CureRTD.

K. Any change in a budget category equal to or greater than 10% of the total research grant amount must be requested ahead of time by the Principal Investigator to CureRTD in writing and must be approved by CureRTD before being executed.

L. CureRTD must be notified immediately if there is to be any change of either the Principal Investigator or the Institution with which he/she is associated. Furthermore, if the Principal Investigator is to be absent from the grantee Institution for a time of more than 30 days, then CureRTD must be notified. CureRTD reserves the right to request a written status report on the progress of the research project as well as an accounting of the funds spent as of the request

date and to determine the final dispensation of any research grant funds remaining in any such situations.

M. CureRTD reserves the right to suspend or cancel a grant at any time at its sole discretion for failure to abide by CureRTD policies governing research grants. Upon receipt of notice of project suspension or cancellation by the Institution, CureRTD 's financial support of further work on the project will cease. At that point, the Principal Investigator must prepare and submit a project status report to CureRTD, while the grantee's institution must submit a complete accounting of funds expended to date. All unused funds must be returned to CureRTD immediately upon its request. A grantee may terminate a grant by sending notice in writing to CureRTD, providing CureRTD with both a written accounting of funds expended to date and a project status report sufficient in detail for a third party to replicate and continue the research project, and returning all unused funds to CureRTD.

N. To properly evaluate the applications, each research grant application will be reviewed by members of the CureRTD Scientific and Medical Advisory Board (SMAB) who have not also submitted applications in that grant cycle. Outside reviewers may be utilized as well, if the subject matter of a particular application warrants enlisting outside expertise. The applicant should furnish CureRTD with a list of three individuals who would be appropriate outside reviewers. These individuals must be qualified to review your application, have not worked with you during the last three years, and have no conflict of interest. In addition, the applicant should make known to CureRTD at the time of application submission if there are any CureRTD SMAB members or other outside experts whose review of the application would constitute a conflict of interest.

O. Some information about research grants awarded by CureRTD will be made available to its constituents and to the general public. This information will include the title of the project, the Principal Investigator, the grantee Institution, the amount of the grant award, and the abstract provided as part of the grant application. No privileged or confidential information or trade secrets previously identified as such to CureRTD will be divulged.

P. The nature of this arrangement is a funding agreement; no employment or agency relationship is hereby created.

Q. The Principal Investigator and the grantee Institution indemnify, defend and hold harmless CureRTD, its Board, officers, agents, advisors and constituents from any claim, judgment, award, damage, settlement, liability, negligence or malpractice arising from research or investigation related to this CureRTD research grant.

Addendum A

USE OF ANIMALS IN BIOMEDICAL RESEARCH

Because the use of animals in biomedical research continues to be necessary to achieve scientifically sound and valid results, the National Health Council requires all its voluntary health agency members that conduct and/or fund biomedical research that involves the use of animals to have a Board-approved written policy that adheres to the following principles:

It is a CureRTD policy that all projects must conform to regulations for the safe and humane treatment of animals. Specifically, CureRTD stipulates that animals can be used in CureRTD funded research only when no other means of obtaining scientifically sound, valid and useful results are available. Furthermore, only the minimum number of appropriate animals required to obtain and validate results should be used; and in cases requiring the death of an animal, only the most appropriate and humane form of animal sacrifice consistent with the purpose of the research shall be employed. If applicable, a copy of proof of current project approval by the institution's Animal Use and Protection Committee (or a similar oversight group) must be provided to CureRTD before any funding for the project will be released by CureRTD.

This policy was adopted by the Cure RTD Foundation Board of Directors and will be distributed to all researchers working with animals on behalf of the Cure RTD Foundation.

Addendum B

CURERTD RESEARCH GRANT PROGRAM AND AWARDEES AT FOR-PROFIT INSTITUTIONS OR ANTICIPATING FOR-PROFIT INVOLVEMENT

Because the development of pharmaceuticals to treat human disease often requires the participation of for-profit biotechnology or pharmaceutical companies, Cure RTD Foundation (CureRTD) recognizes that special considerations may need to be implemented. For example, to maintain intellectual property rights that allow commercialization, the need to publish may be delayed for some period of time. Often the researcher will need to patent discoveries to preserve commercial viability. In consideration of these special circumstances with a for-profit enterprise, or with an awardee that licenses Intellectual Property or Materials, that receives funding from CureRTD the following is to be understood:

The mission of the Cure RTD Foundation is to save lives through education, advances in treatment, and finding a cure for Riboflavin Transporter Deficiency (RTD). As a 501(c}(3), charitable organization, CureRTD intends to do all it can to encourage the commercial development of safe and effective treatments for RTD. CureRTD understands that the cost for developing commercial products for extremely rare diseases that also meet regulatory requirements may exceed the revenues.

The awardee of a CureRTD Research Grant that is part of a for-profit enterprise or a University that licenses Intellectual Property or Materials will adhere to the CureRTD Research Grant Policies with the following clarification:

i. That publication of study results shall be sufficient to comply with the CureRTD policy that "Materials resulting from research funded by the organization will be made available to other researchers on a reasonable basis;"
ii. That it shall not be required, at the early stage of development, to make Materials resulting from research funded by the organization “available to noncommercial laboratories at cost and to commercial enterprises for a reasonable licensing fee.” After publication of study results describing Materials, then the usual requirements for allowing others to repeat the experiments of the published author will take precedence.
iii. Be expected to diligently pursue opportunities to license Materials and “Intellectual Property” that is funded, at least in part, by CureRTD. If the awardee does pursue licensing opportunities based on research funded, at least in part, by CureRTD, the awardee has an obligation to notify CureRTD as soon as practicable. If the awardee does not or chooses not to diligently pursue such licensing opportunities, the awardee will notify CureRTD such that CureRTD can pursue other options and will negotiate in good faith to permit use of the Intellectual Property by CureRTD or third parties identified by CureRTD.
iv. Agree that, if and when any Intellectual Property or Materials arise from work that was funded, at least in part by CureRTD, CureRTD shall: Share in any Net Revenue received from any Intellectual Property (the "IP Consideration"). “Net Revenue” means licensing fees, royalties, or any other income derived from Intellectual Property or Material (“Income”) less unreimbursed out of pocket expenses that are directly related to licensing or the filing prosecution, maintenance or enforcement of a patent for Intellectual Property or Material. In addition, the awardee shall not enter into any agreement that will derogate CureRTD's right to the IP Consideration and shall

notify CureRTD promptly and in writing of any license, lease, sale, or other agreement concerning an invention developed under the CureRTD Research Grant Program. CureRTD's participation shall be calculated on a pro rata basis, determined by multiplying any Net Revenue by a fraction, the numerator of which is CureRTD's grant amount, and the denominator of which is the total direct cost for the Intellectual Property, including all Intellectual Property patent and licensing costs. Notwithstanding the forgoing, the awardee's share pursuant to the forgoing calculation shall not be less than 50%.

v. Share in any Net Revenue, less unreimbursed out of pocket expenses directly related to review of Material encumbrances ("Material Revenue") received from licensing of a Material (the "Material Consideration"). CureRTD 's portion shall be calculated on a pro rata basis, determined by multiplying any Material Revenue by a fraction, the numerator of which is CureRTD's award amount, and the denominator of which is the total direct cost of the development of such Material, including patent and licensing costs. Notwithstanding the forgoing, the awardee's share pursuant to the forgoing calculation shall not be less than 50%.