

DAMON RUNYON CLINICAL INVESTIGATOR CONTINUATION GRANT AWARD STATEMENT

FUNDING

At the beginning of each award year a budget is required. Awards are in the amount of \$150,000 per year in stipend for the Clinical Investigator. Funds are intended to be flexible and can be used for a variety of scientific needs, including the Investigator's salary, salaries for professional and technical personnel, special equipment, supplies, and other miscellaneous items required to conduct the proposed research. *No part of this award may be used for institutional overhead.*

PERCENT EFFORT

The Investigator must commit 80% of his/her full-time professional effort to the conduct of research and research career development.

SCIENTIFIC PROGRESS REPORTING

Both the Clinical Investigator and mentor must submit signed annual progress reports due on the 15th day of the final month of each year of funding and signed final progress reports no later than 60 days after the completion of the award. In addition to written reports, Clinical Investigators will present oral progress reports during the second year of the award.

All reports are kept strictly confidential. The goal of the reports is three-fold. First, the reports serve as an auditing tool to monitor research progress and assure that the research is on target with the funded project. Second, the reports allow the Foundation to perform regular program evaluations including issues related to mentoring, areas of study, concurrent funding, networking opportunities, career development and award impact. Third, the reports provide an opportunity to identify specific parts of the Clinical Investigators' research (*e.g.*, fundamental advance, clinical trial development, patient-related anecdote, publications) that the Foundation may highlight in various media outlets. In fact, we would appreciate contact from Investigators at anytime to share such information.

Annual Progress Reports Instructions

The Clinical Investigator's annual report includes:

1. A **summary of research** performed during the award year and evaluation of the results. The summary should be technical, but targeted to a general scientific audience. The summary should be sufficiently detailed such that the Clinical Investigator's research activities over the award year are clearly described. Figures and references can be included if appropriate. If the research differs from the originally funded proposal, please provide an explanation. The report must be signed by the Clinical Investigator and by the Mentor(s) and should not exceed four pages.
2. A one-paragraph **lay summary**, for the public, detailing the research performed over the award year.
3. An up-to-date **curriculum vitae** including:
 - a. A bibliography of publications from the award year (please submit pdf copies of reprints).
 - b. An updated **list of current and pending funding**.

- c. A list of conferences and seminars attended and presentations given during the award year.
- d. Changes in the Clinical Investigator's responsibilities or title (tenure/promotion, leadership positions, consultant work, etc.).
4. Brief **comments on the most important accomplishment** over the past year. Also, please address any issues or concerns regarding career development, obstacles to success or mentoring of physician-scientists to which the Foundation might respond.
5. A brief description of the Clinical Investigator's current **research and office space allocation**.
6. Annual **budget**.
7. A completed **intellectual property disclosure** form (attached).

Please email these items (with scanned copies of signed forms, where applicable) as attachments to cait.ahearn@damonrunyon.org.

Mentor's Yearly Report:

Summarizes the Investigator's progress in becoming an independent clinical investigator in the field of human disease-oriented clinical and translational research.

Final Progress Report Instructions:

The Clinical Investigator's final report includes:

1. A **summary of research** performed during the award and evaluation of the results. The summary should be technical, but targeted to a general scientific audience. The summary should be sufficiently detailed such that the Clinical Investigator's research activities are clearly described. Figures and references can be included if appropriate. If the research differs from the originally funded proposal, please provide an explanation. The report must be signed by the Clinical Investigator and by the mentor(s) and should not exceed four pages.
2. A one-paragraph **lay summary**, for the public, detailing the accomplishments over the term of the award, including how the research has impacted the cancer field.
3. An up-to-date **curriculum vitae** including:
 - a. A bibliography of all publications resulting from the Clinical Investigator's research (please submit pdf copies of reprints).
 - b. An updated **list of current and pending funding**.
 - c. A list of conferences and seminars attended and presentations given during the award year.
 - d. Changes in the Clinical Investigator's responsibilities or title (tenure/promotion, leadership positions, consultant work, etc.).
4. A **statement indicating how the award made a difference in the Clinical Investigator's career**.
5. Brief **comments on the most important accomplishment** over the award term. Please address any issues or concerns regarding career development, obstacles to success, or mentoring of physician-scientists to which the Foundation might respond.
6. A completed **intellectual property disclosure** form.

Please email these items (with scanned copies of signed forms, where applicable) as attachments to cait.ahearn@damonrunyon.org.

Mentor's Final Report

Summarizes the Investigator's progress in becoming an independent clinical investigator in the field of human disease-oriented clinical and translational research.

FINANCIAL REPORTING

The institution's financial officer must maintain a separate account for the Clinical Investigator and this account must be available for audit by representatives of the Damon Runyon Cancer Research Foundation. None of the funds awarded can be used for indirect costs. Reports of expenditures must be submitted to the

Foundation within 30 days of the end of each award year. Upon termination or expiration of the award, a final report of expenditures with the refund of any unexpended balance must be submitted within 30 days.

Annual Financial Expenditure Report Preparation Guidelines:

- Please use the Foundation's form for the report (it is available on our website or can be requested from awards@damonrunyon.org).
- No part of this award may be used for institutional overhead.
- Any balance carried forward from the previous year should be denoted on the form where indicated. (Remaining balances of both stipend and research allowance may be carried forward **to be used the following year as research allowance only.**)
- The Investigator may request that a portion of the year's stipend be reallocated for use as research allowance. If such a request has been approved, please indicate the resulting amounts for the stipend and research allowance after this reallocation.
- Funds covering stipend and/or fringe benefits for anyone other than the Investigator are extracted from the research allowance. Please provide their names and position titles in the breakdown section or as an attachment.
- Itemize supplies by category (please attach additional pages, if necessary).
- Identify each item of equipment with an acquisition cost of more than \$500 by name, date of purchase and price.
- If patient costs are requested, include under 'Other Costs'.
- If the research allowance was used for travel, please provide the following details:
 - name and position title of attendee, if other than Investigator
 - name and location of scientific meeting or conference attended
 - dates of meeting/conference
 - use of funds- restricted to registration fee, lodging, meals, transportation (if by train or plane, must be coach class ticket only).

No-Cost Extensions: The Foundation may allow no-cost extensions for up to six months after the expiration of the award. A financial report must be submitted to the Foundation 30 days after the completion of the award. If there is an unexpended balance, the Investigator may submit a written request to allow a no-cost extension for the award. If the no cost extension is approved, at the end of the six-month period, a final financial report is due with the return of any unexpended balance.

INVENTION POLICY

The Damon Runyon Cancer Research Foundation ("DRCRF") encourages the rapid development and commercialization of promising new biomedical technologies for the public benefit. In furtherance of DRCRF's mission of supporting high quality cancer research, DRCRF requires that revenue derived from Intellectual Property be shared with DRCRF in accordance with this policy. "Intellectual Property" is defined as any invention, discovery, improvement, work of authorship (excluding books or chapters of books) or other work product resulting from the performance of any research funded, in whole or in part, by DRCRF.

Unless otherwise agreed, title to Intellectual Property shall reside with the grantee institution pursuant to the grantee institution's intellectual property ownership and licensing policies. DRCRF will be entitled to share in any revenues, including consideration in any form ("revenues"), arising out of the licensing or other exploitation of Intellectual Property. DRCRF's share of revenues will be determined as a share of "Distributable Net Income," in accordance with the following:

DRCRF's share of Distributable Net Income will be a percentage calculated by dividing (a) the amount of costs paid by DRCRF for the research that resulted in the Intellectual Property, by (b) the aggregate amount of costs provided by all funders (including DRCRF). For the purposes of determining Distributable Net

Income, the grantee institution may include overhead for which it has not received funding from other sources using its current approved NIH indirect cost rate. It will not include any out-of-pocket expenses taken into account in determining “Net Income.”

“Net Income” is defined as gross revenues resulting from any licensing, assignment or other commercialization agreement or arrangement involving to any extent the Intellectual Property, less any non-reimbursed out-of-pocket expenses incurred by the grantee institution in protecting or marketing the Intellectual Property.

“Distributable Net Income” is defined as Net Income, less distributions to inventors in accordance with the grantee institution’s policies.

Upon the expiration of a DRCRF award, the grantee institution shall, or shall cause the Awardee and, where applicable, the Sponsor or Mentor, to complete DRCRF’s standard Intellectual Property Disclosure Form to indicate whether any Intellectual Property was developed in the performance of the relevant DRCRF-funded research. If Intellectual Property was so developed, the grantee institution shall thereafter complete DRCRF’s standard Intellectual Property Annual Update form to indicate the status of any patents and copyrights and applications therefore, licensing, assignment or other commercialization of the Intellectual Property. Prior to generation of Net Income from any Intellectual Property, DRCRF and the grantee institution will enter into a revenue sharing agreement in a timely fashion.

All information of a confidential nature disclosed to the DRCRF will be held in strict confidence and will not be disclosed to any third party without the prior written consent of the grantee institution. The grantee institution agrees to use diligent efforts in obtaining patent and/or copyright protection, as applicable, and in commercializing the Intellectual Property.

PUBLICATIONS/PRESENTATIONS

Publications (including abstracts of presentations at scientific or clinical meetings) resulting from projects supported by the Foundation must carry the following acknowledgment: “Name of Awardee is a Damon Runyon Clinical Investigator supported (in part) by the Damon Runyon Cancer Research Foundation (CI-___).” Awardees should identify themselves as Damon Runyon Clinical Investigators when presenting their work at professional conferences or accepting professional honors or awards.

Publicity

Media coverage is to the advantage of both the Clinical Investigator's institution and the Damon Runyon Cancer Research Foundation. The Foundation is prepared to assist in any publicity related to the award.

TAX STATUS OF CLINICAL INVESTIGATOR AWARDS

The Damon Runyon Cancer Research Foundation, a tax-exempt, non-profit corporation, was founded for, and continues to retain as its sole purpose, the advancement of cancer research. No other benefit to, or service for, the Foundation is expected or sought in return of Clinical Investigator support. Any questions related to the tax status of the Clinical Investigator Award should be discussed by the Clinical Investigator with their personal tax advisor.

TERMINATION

Upon premature termination of a Clinical Investigator Award, the Foundation should be notified immediately. A final report of expenditures must be submitted within 30 days, along with the refund of any unexpended balance. Progress reports are also required within 30 days (follow instructions for “Investigator’s Final Report”).

Should the Clinical Investigator wish to discontinue the project, leave the designated institution or modify any agreement of the award letter, he or she must seek approval from the Damon Runyon Cancer Research Foundation in advance. Failure to comply with this requirement may jeopardize any future awards to the grantee institution by the Foundation.

PARENTAL LEAVE POLICY

The Damon Runyon Foundation will allow up to 12 weeks of paid parental leave for birth/adoptive parents consistent with their institution's policy. The Foundation should be notified of the leave.

MEDICAL SCHOOL LOAN REPAYMENT PROGRAM FOR CLINICAL INVESTIGATORS

The Damon Runyon Clinical Investigator Award is designed to encourage and assist greater numbers of physicians to become clinical investigators and conduct patient-oriented research. As part of this award program, the Damon Runyon Cancer Research Foundation (the "Foundation") will pay up to \$100,000 of outstanding medical school loans of Damon Runyon Clinical Investigator Award recipients pursuant to the below policy.

Qualifying loans: Debt incurred for tuition and direct educational expenses during medical school and any interest thereon. (Loans for general items or living expenses, *e.g.*, housing, transportation, and consumables, do not qualify for this program.) Loans must be from a government entity, academic institution, or commercial or chartered lending institution. Qualifying medical school loans, which have been combined or refinanced with non-qualifying loans, are not eligible for the loan repayment program.

Eligibility and amount of support: Debt and interest thereon will be paid up to an amount equal to One Hundred Thousand Dollars (\$100,000) in the aggregate over the five-year award period with amounts not to exceed Twenty Thousand Dollars (\$20,000) in any one-year period, if the following conditions are met:

- (i) Participants in this program must be current holders of the Damon Runyon Clinical Investigator Award in good standing.
 - (ii) Participants in this program must submit documentation regarding the loans (*e.g.*, receipts and supporting documents for tuition and directly related expenses, loan agreements, and payment information) to the Foundation within one month of acceptance of a Clinical Investigator Award to determine whether they qualify for this program. Documentation of loan status and payment information must be provided to the Foundation annually, no later than one month prior to the award renewal date, as a condition of continued participation.
 - (iii) Participants enrolled in NIH-sponsored loan repayment programs or any other debt relief programs must disclose the details of such agreements to the Foundation.
 - (iv) Participants must agree in writing to refund all amounts paid under this loan repayment program if they terminate the Clinical Investigator Award prior to completion of the five-year term.
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Payments: For each year of eligibility, the Foundation will pay directly to each lender an amount representing the total payments owed by the participant for all qualifying loans for that year up to an aggregate maximum of \$20,000 ("Annual Debt Payments"). If the participant has qualifying loans with annual payments in excess of \$20,000, the Foundation, in its discretion, will determine which loans it will pay. Upon the successful completion of the Clinical Investigator Award, the Foundation will pay the lending institutions the difference between the total amount already paid under the loan repayment program and \$100,000 ("Final Payment"). If the participant does not demonstrate a continuing commitment to clinical research upon the completion of the Clinical Investigator Award, the Foundation reserves the right to withhold the Final Payment.

Consolidated loans: The Foundation will make repayments on consolidated loans that were originally obtained for qualifying medical school expenses but not when they have been combined or refinanced with non-qualifying loans. Participants must submit the loan agreement for consolidated loans as well as loan agreements for each of the underlying loans.

Leave without pay: Loan repayments will not be made during leaves of absence unless written permission is granted by the Foundation.

Obligations not qualifying for repayment: (i) Loans not obtained from a government entity, academic institution, or a commercial or other chartered lending institution such as loans from friends, relatives, or other individuals. (ii) Delinquent loans, loans in default, loans not current in their payment schedule, or loans already repaid. (iii) Late fees, penalty fees, additional interest charges, or collection costs.

Reimbursement for increased income tax liabilities: Loan repayments made to lenders represent taxable income to program participants. This income will be reported annually to the IRS and may result in an increase in participants' Federal, State, and Local tax liabilities. To offset tax liability increases, the Foundation will approximate the added liability using the applicable tax rates each year and pay this amount directly to the participant at the time of each repayment ("Additional Tax Payment"). For purposes of the foregoing, the assumed tax rate shall be determined by the Foundation, in its sole discretion, and may or may not equal the tax rate that actually applies to the participant.

Payback Agreement: If a participant in this program terminates his or her Clinical Investigator Award prior to the end of the five-year term, the Foundation shall, in its sole discretion, be entitled to require repayment by the participant of all Annual Debt Payments and Additional Tax Payments. This payback will be paid over the same period of time and in the same amounts as the initial payments by the Foundation. The Foundation reserves the right to waive this payback requirement if the participant continues in clinical investigation after early termination of the Clinical Investigator Award.

Updating Information

The Foundation requests the most current information pertaining to change of address or position of the Clinical Investigator, mentor and executive or fiscal officers of the institution in order to maintain an up-to-date database.