

Damon Runyon Clinical Investigator Award Statement

Please contact the Damon Runyon Cancer Research Foundation at 212.455.0520 or awards@damonrunyon.org to accept or decline the award.

The **grantee institution**, **Clinical Investigator Award recipient** and **mentor** must sign the attached award acceptance form and return it to the Foundation within ten (10) working days following notification.

The Clinical Investigator Award recipient must send the Foundation a brief paragraph describing in layman's terms how the project is relevant to cancer and to which specific types of cancer the work relates (please e-mail an additional copy to awards@damonrunyon.org). Also required are two 3 x 5 inch digital photographs (jpg at 300 dpi) of the recipient in a clinical setting, which may be used for fundraising purposes or to publicize the Foundation's programs.

Relationship of Parties

Awards are made to the institutions to support the Clinical Investigator and the project set forth in his/her application. It is understood by all parties that this award in no way constitutes an employer-employee relationship between the Damon Runyon Cancer Research Foundation and the recipient.

Percent Effort

The Investigator must commit 80% of his/her full-time professional effort to the conduct of research and research career development during the entire course of the award. Other responsibilities may not exceed 20% effort.

Usage of Funds

At the beginning of each award year a budget is required. The \$450,000 award will be for a period of three years. Funding in the amount of \$150,000 will be allocated to the awardee's institution each year for the support of the Clinical Investigator. Funds are intended to be flexible and can be used for a variety of scientific needs including the Investigator's stipend and/or fringe benefits (up to \$100,000), salaries for professional and technical personnel, special equipment, supplies and other miscellaneous items required to conduct the proposed research. **No part of this grant can be used for indirect costs or institutional overhead.**

Other Sources of Funding

At the beginning of each award year, Investigators must submit a list of all current and pending funding sources, including the specific aims of each grant and the degree of overlap with their Damon Runyon funded research project. Scientific or budgetary overlap with other funded projects is not allowed. Therefore, it is critical that all current and pending grant support for the Investigator's research be reported to the Foundation and the relationship of that support to the Damon Runyon funded project be explained.

Investigators may receive funding from other sources; however, no other physician-scientist career development award from a private source (non-federal government) may be held concurrently with the

Clinical Investigator Award. Physician-scientist career development awards from the federal government including the National Institutes of Health (*e.g.*, K-08, K-12, K-23), the Department of Defense, and the U.S. Department of Veterans Affairs are allowed. During the award period, Investigators are encouraged to seek funding through an NIH Research Project Grant (R01). Please notify the Foundation immediately of any additional funding you receive.

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 Investigators contacting us at any time to share such information.

Annual Progress Reports Instructions

The Clinical Investigator's annual report includes:

1. A completed questionnaire on the Investigator's progress, institutional commitment and mentorship.
2. 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.
3. A statement addressing where the Investigator is in advancing his/her research to translation.
4. A brief description of collaborations and partnerships related to the Damon Runyon-funded research, with either academic and/or industry scientists. Please identify your collaborator(s) and his/her academic/industrial affiliation(s).
5. A one-paragraph **lay summary**, for the public, detailing the research performed over the award year.
6. An up-to-date **NIH biosketch** 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.).
7. 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.
8. A brief description of the Clinical Investigator's current **research and office space allocation**.
9. Annual **budget**.
10. A completed **intellectual property disclosure** form (attached).

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.

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

Final Progress Report Instructions:

The Clinical Investigator's final report includes:

1. A completed questionnaire on the Investigator's progress, institutional commitment and mentorship.
2. 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.
3. A statement addressing where the Investigator is in advancing his/her research to translation.
4. A brief description of collaborations and partnerships related to the Damon Runyon-funded research, with either academic and/or industry scientists. Please identify your collaborator(s) and his/her academic/industrial affiliation(s).
5. 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.
6. An up-to-date **NIH biosketch** 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.).
7. A **statement indicating how the award made a difference in the Clinical Investigator's career**.
8. 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.
9. A completed **intellectual property disclosure** form.

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.

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

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 60 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 60 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).
- Up to \$100,000 may be used for the Investigator's stipend and/or fringe benefits annually.

- 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.
 - To report funds covering stipend and/or fringe benefits for anyone other than the Investigator, 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 \$1,500 by name, date of purchase and price.
 - If patient costs are requested, include under ‘Other Costs’.
 - 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).
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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 60 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.

Confidentiality Agreement:

Investigators may not enter into confidentiality agreements that prevent or delay them from publishing and/or presenting their Damon Runyon-supported research.

INTELLECTUAL PROPERTY POLICY

All research grants, fellowships and other awards made by the Damon Runyon Cancer Research Foundation (“DRCRF”) are subject to this policy. By accepting an award from DRCRF for a research project, the grantee and the institution(s) agree to be bound by the terms and conditions of this policy.

An essential part of DRCRF’s mission is to accelerate the translation of scientific breakthroughs into new diagnostic tools and treatments for cancer, and DRCRF recognizes that discoveries having commercial application or value may arise out of research supported by DRCRF. It is DRCRF’s intent that these discoveries are widely disseminated and become available for the public benefit at the earliest possible time. This policy sets forth DRCRF’s rights with respect to discoveries funded, in whole or in part, by DRCRF that have commercial application or value.

For purposes of this policy, “Intellectual Property” is defined as any invention, data, material, method, product, process, program, discovery, improvement, copyrightable work (excluding scientific publications) or other work product resulting from the performance of any research funded, in whole or in part, by DRCRF.

1. Unless otherwise agreed, title to Intellectual Property will reside with the grantee institution pursuant to the grantee institution’s intellectual property policies.
2. The grantee institution will, at its own expense, use diligent efforts to obtain patent and/or copyright protection, as applicable, for the Intellectual Property and to grant licensees under such Intellectual Property to third parties to commercialize the discoveries disclosed or claimed in the Intellectual Property in a thorough and diligent manner.
3. The grantee institution will inform DRCRF in writing promptly upon the filing of any patent application constituting Intellectual Property and the execution of any license agreement under which rights to practice such

Intellectual Property commercially are granted to a third party. In addition, the grantee institution will provide DRCRF, on an annual basis, a written report describing the status of all patent rights constituting Intellectual Property, information regarding any licenses to commercialize the discoveries disclosed or claimed in the Intellectual Property, including consideration received under such licenses, and status of efforts by any licensees to commercialize the discoveries.

4. DRCRF will be entitled to receive a portion of all consideration, in any form, received by the grantee institution that arise out of the licensing or other exploitation of Intellectual Property, after amounts are distributed to individual inventors (but not distributions to institutional departments or laboratories) in accordance with the grantee institution's written policies. The portion of such consideration to which DRCRF will be entitled will be equal to the quotient obtained by dividing (a) the amount of the award made by DRCRF for the research that resulted in the Intellectual Property by (b) all direct costs provided by funding sources, including DRCRF, for the research that resulted in the Intellectual Property, but in no event will Damon Runyon's portion exceed 50%. For clarity, costs associated with the recruiting of scientific staff, laboratory start-up costs and other infrastructure costs may not be included in the foregoing calculation.

5. The grantee institution will be entitled to credit the following against any amounts due to DRCRF under this policy:

(a) an amount equal to the product obtained by multiplying (a) the amount of the award made by DRCRF for the research that resulted in the Intellectual Property and (b) the grantee institution's approved NIH indirect cost rate at the time the award was made; and

(b) the reasonable, out-of-pocket costs incurred by the grantee institution for the preparation, filing and prosecution of patent rights included in the Intellectual Property that have not been reimbursed by a third party.

6. DRCRF and the grantee institution will negotiate in good faith and execute a royalty-sharing agreement consistent with the terms of this policy promptly following the filing of any patent application constituting Intellectual Property, and before any rights are granted to a third party to commercialize the discoveries disclosed or claimed in the Intellectual Property.

7. All information of a confidential nature disclosed to DRCRF pursuant to this policy will be maintained in confidence by DRCRF and will not be disclosed to any third party without the prior written consent of the grantee institution.

Publicity

Media coverage is to the advantage of both the host institution and the Damon Runyon Cancer Research Foundation. In media releases resulting from projects supported by the Foundation, identify yourself as "Name of Awardee, Damon Runyon Clinical Investigator." Please notify the Foundation as soon as possible of all media releases. The Foundation is willing and able to assist in any publicity related to the award.

Publications/Presentations/Website

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 scientific conferences or accepting professional honors or awards, and on their websites.

Public Access Policy

Damon Runyon Cancer Research Foundation ("Damon Runyon") funds biomedical research in order to better understand the causes of cancer and to advance its prevention, diagnosis and treatment. The main output of this research is new knowledge. To ensure this knowledge can be accessed, read, applied, and built

upon in fulfillment of our goals, Damon Runyon expects its researchers to disseminate their findings, including publishing in peer-reviewed journals.

In addition, it is a condition of Damon Runyon funding that all peer-reviewed articles supported in whole or in part by its grants must be made available in the PubMed Central online archive. PubMed Central is a database of full-text biomedical journal articles available online without a fee, hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated, making it easier for scientists worldwide to pursue biomedical research. It also makes this information accessible to Damon Runyon and its donors, as well as patients, clinicians, educators, students and others.

Damon Runyon award recipients are required to deposit an electronic copy of their final peer-reviewed manuscripts in PubMed Central immediately upon acceptance for journal publication and take the steps necessary to link that manuscript to the appropriate Damon Runyon grant. The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal publication. This requirement applies to all Damon Runyon grants awarded after July 1, 2013.

Damon Runyon is part of the Health Research Alliance (HRA), a national consortium of non-governmental, not-for-profit funders of biomedical research and training. HRA has made arrangements so that PubMed Central will accept deposits of manuscripts and publications resulting from research funded by HRA member organizations. All Damon Runyon award recipients are required to create an account with HRA through its Public Access Initiative. Someone from our awards team will be contacting you with information on how to create your HRA account.

Damon Runyon award recipients must acknowledge Damon Runyon support in every article arising from such funding. The acknowledgement statement must include the applicable Damon Runyon grant number. This will enable Damon Runyon to link the published outputs of research to the support it has provided.

Damon Runyon also encourages award recipients to publish in peer-reviewed open access journals with a policy of immediate availability of the published version without restriction, and permits use of non-salary/stipend grant funds to pay associated publication fees.

Open Access Fee Reimbursement Policy

Damon Runyon encourages and enables our scientists to publish in open access journals, which facilitates more rapid dissemination and broad use of their publications. To do so, **we have established an annual fund of \$25,000 that is available on a first-come, first-served basis to current awardees to pay fees incurred by publishing in open access journals.**

- The publication must be based on Damon Runyon-funded research.
- Publications 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-___).”
- Requests must be submitted during the Damon Runyon award period, or within 18 months of the award end date.
- Scientists should submit a written request to us with 1) a copy of the invoice or receipt for publication fees from the journal, 2) PDF copy of the accepted publication, and 3) active URL link to the publication.

All requests will be reviewed. If approved and there is money remaining in the fund, we will reimburse you for these fees.

Termination

Upon early termination of a Clinical Investigator Award, the Foundation should be notified immediately. A final report of expenditures must be submitted within 60 days, along with the refund of any unexpended balance. (No-cost extensions do not apply to early terminated awards.) Progress reports are also required within 60 days (follow instructions for “Investigator’s Final Report”).

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 in advance 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. **Note:** qualified candidates must first apply to the NIH loan Repayment Program in order to be eligible for loan repayment from Damon Runyon.

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 three-year award period with amounts not to exceed Thirty Thousand Dollars (\$30,000) 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 three-year term.

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 \$30,000 (“Annual Debt Payments”). If the participant has qualifying loans with annual payments in excess of \$30,000, 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 three-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.

Modifications to the Award

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 result in immediate termination of the award and may jeopardize any future awards to the grantee institution by the Foundation.