



## **GRANT POLICIES**

***RUNX1* Research Program – American Cancer Society  
Leukemia Exploration and Prevention (LEAP) Grant Program**

**EFFECTIVE AUGUST 2024**

**ELECTRONIC APPLICATION DEADLINE: October 29, 2024**

**AMERICAN CANCER SOCIETY, INC.  
Extramural Discovery Science Department**

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## **MISSION**

The **American Cancer Society**'s mission is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer.

The ***RUNX1* Research Program**'s mission is to improve the quality of life and prevent blood cancer in individuals with *RUNX1* familial platelet disorder (*RUNX1*-FPD).

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## 1. DESCRIPTION OF THE LEUKEMIA EXPLORATION AND PREVENTION (LEAP) RFA

Clonal hematopoiesis (CH) is unequivocally associated with hematologic malignancies (HM) and therefore considered a precancerous condition. While in the general population CH is common in the elderly (more than 10% in 70 years+), the overall risk of malignant transformation is low. However, in high-risk populations, like those with germline predispositions to hematologic malignancies (HM), CH rates are much higher, and the risk of HM development is significantly greater.

*RUNX1* familial platelet disorder (*RUNX1*-FPD), a rare heritable disease caused by germline *RUNX1* mutations, represents such a high-risk population. Individuals with *RUNX1*-FPD have a 35-50% lifetime risk of hematologic malignancies (HM) and the most common HM is acute myeloid leukemia, the second deadliest HM. Despite the established link between *RUNX1*-FPD and hematologic malignancies, there remains a significant gap in understanding the cell non-autonomous factors that contribute to clonal evolution and malignant transformation, as well as the precise mechanistic pathways by which *RUNX1* mutations promote cancer development. This knowledge gap impedes the development of targeted strategies for early intervention and prevention. A deeper understanding of how extrinsic signals and the broader microenvironment interact with intrinsic *RUNX1* mutations is critical to uncovering novel therapeutic targets.

The *RUNX1*-FPD community of families is in urgent need of cancer interception and prevention therapies. Grant proposals are investigator-initiated and pursue questions specifically designed to enable the discovery of cancer interception or prevention therapies for *RUNX1*-FPD hematologic malignancies.

### Applicants must propose research projects in one of the two areas of focus below:

- A. This area is focused on deepening our understanding of the mechanisms that cause each leukemogenic step, beginning with germline *RUNX1*-mutated hematopoietic stem/progenitor cells (HSPCs) that acquire deleterious somatic mutations and expand overtime culminating in overt *RUNX1*-mutated leukemia. Projects should consider experimental designs that address both cell-autonomous and cell non-autonomous factors.
- B. This area of the LEAP grant program is committed to supporting high-risk projects with strong scientific rationale to pursue a cancer interception treatment. Projects could focus on preclinical studies and/or clinical trials designed to test innovative approaches to treatment. This can include repurposing existing regulatory-approved treatments or novel therapeutics. The intent here is to act on behalf of the urgency felt by the patient community.

## 2. ACS RESEARCH PRIORITY AREAS

The American Cancer Society has established six areas to prioritize the research we fund to help advance our mission. These include:

- **Etiology** – Supports research into the causes of cancer and the incidence, initiation, and biology of early onset cancers. To accelerate progress in understanding the causes of cancer, this priority area supports research to identify early, inherited, somatic, molecular, behavioral, environmental, and societal causes and risk factors impacting cancer incidence, progression, and mortality.
- **Obesity/Healthy Eating and Active Living (HEAL)** – Supports research on diet, metabolism, physical activity, and nutrition-related factors to better understand these factors roles in cancer risk, progression, treatment, and survivorship. Studies can span the research continuum (i.e., from molecular to population).

- **Screening and Diagnosis** – Supports research on cancer screening and early detection, diagnostics, prognostics, and risk assessment. Studies can span the research continuum (i.e., from molecular to population-based).
- **Treatment** – Supports research to develop new cancer treatments, targets, and systems to monitor and treat resistant disease, to enhance opportunities in immunotherapy and precision medicine, and to improve models and test interventions for prevention, tumor dormancy, recurrence, resistance, and metastasis. Studies could also seek to establish predictive preclinical models to streamline clinical testing of combination or multi-modal therapies by funding research on tumor microenvironment, heterogeneity, microbiome, and immune escape or improve timely access to treatment, increase participation rates of diverse populations in clinical trials, and advance our understanding of barriers to receipt of timely and high-quality treatment.
- **Survivorship** – Supports research that focuses on improving the survivorship journey for cancer survivors and their caregivers including physical, emotional, financial, spiritual, and supportive services, including care delivery, from diagnosis through the balance of life. Research may address access barriers to high quality, equitable cancer care, treatment-related outcomes, palliative care, and communication research.
- **Health Equity across the Cancer Control Continuum** – The American Cancer Society believes that everyone should have a fair and just opportunity to prevent, find, treat, and survive cancer. Societal issues such as poverty, education, social injustices, unequal distribution of resources and power underpin profound inequities. These macro-environmental conditions where people are born, grow, live, work and age along with the available systems supporting health are known as the social determinants of health (SDOH). The SDOH are interrelated and extend across the life span to impact health. This area of research addresses the interplay between SDOH and access to high quality care and services across the cancer continuum and solutions to achieve optimal outcomes for all.

**Applicants are expected to explain how their proposed research integrates into at least one of the above research priorities and advances the goals of the LEAP RFA.**

### **3. AWARDS TO BE FUNDED UNDER THE RFA**

The LEAP RFA offers two distinct funding opportunities for independent investigators at all career ranks. Principal Investigators (PIs) funded under this RFA will become members of a Collaborative Learning Community, where there is an expectation to engage with members through the sharing of scientific advances, ideas, and resources to accelerate the translation of research discoveries to clinical impact.

#### **A. LEAP - TEAM AWARD**

**Description:** Supports a team research project that aligns with one of the LEAP program research topics. The application must clearly articulate how the team will synergize to accelerate scientific advancement and clinical benefit. Applicants must clearly demonstrate the assembly of an interdisciplinary team with diverse expertise, ensuring a comprehensive approach to addressing the research objectives.

**We define an interdisciplinary team as one having well-justified representation of diverse research skills and perspectives, not merely team members representing different departments.**

**Research Team:** Each team must consist of one Lead PI and at least one Team Principal.

- **Lead PI** (no multi- or co-PIs allowed)
  - **Eligibility:** An independent investigator with a full-time faculty at an eligible US academic institution or non-profit appointment at any career stage.
  - **Roles:** Serves as the team leader and primary point of contact for the application and award, ensures the team complies with the terms of the award, and oversees all organization assurances and certifications.
- **Team Principal**
  - **Eligibility:** An independent investigator with a full-time faculty at an eligible US academic institution or non-profit appointment at any career stage, who will provide diverse expertise and collaboratively move a subproject forward.
  - **Roles:** Leads a component of the research based on their area(s) of expertise and, together with the Lead PI, shares authority for scientific leadership.
  - A minimum of 1 team principal must be proposed in the grant application.

Additional investigators and team members can be added to the research team as needed. See the LEAP RFA Instructions document for information on Key Personnel definitions.

**Budget and Award Period:** Awards are for up to \$430,000 direct costs per year for up to 4 years (\$1,720,000 direct costs), plus 10% allowable indirect costs.

Personnel may receive salary support up to the National Institutes of Health salary cap, prorated according to their percent effort on the project. Budgets submitted must be realistic estimates of the funds required for the proposed research.

**Expenditures:** The Society is flexible in response to the changing needs of a research program. The Lead Principal Investigator and Team Principal(s) may make minor alterations (changes <\$15,000/year) within the approved budget except where such expenditures conflict with the policies of the Society.

Major changes in expenditures (>\$15,000 per year) require written approval from your Scientific Director. For permanent equipment, the annual threshold requiring written approval is >\$5,000. The Lead PI should contact the Scientific Director for guidance.

**Research Intent:** Awards for team science are designed to foster a collaborative, integrated research process and promote transformational research advances with the potential for rapid clinical translation. Teams must consist of investigators from different disciplines aiming to integrate areas of expertise to address their proposed aims (see bolded definition above).

These awards have a collaborative and interdisciplinary emphasis, involving meaningful collaboration between participants. Applications must include a description of the rationale and nature of the proposed collaboration, the specific role of all investigators, and synergistic opportunities. Evidence of prior productive collaborations between members of the team is helpful. New teams should provide evidence of synergy among disciplines and areas of translational research that foster innovation pertaining to the proposed research.

**Resubmissions:** Unfunded Team applications to the LEAP RFA can only be resubmitted (up to 2 times) if the RFA is re-issued. The Team PI may be able to submit the project (or part of the project) to a standard grant mechanism, but only if they meet the eligibility criteria for that mechanism. In this instance the application will be considered a new application.

**Organizational Assurances:** The Lead PI and his or her institution must ensure that organizational assurances and certifications from all team member institutions are obtained. The assurances and certifications are made and verified by the signature of the institutional official signing the application.

These may include:

- **IRB and/or IACUC Approvals.** If applicable, these approvals are required with documentation provided within 3 months of grant activation.
- **Human Subjects or Vertebrate Animals.** All activities involving either human or vertebrate animals as subjects must be approved by an appropriate institutional committee and documentation provided within 3 months of grant activation.
- **HHS Compliance.** Compliance with current US Department of Health and Human Services research subjects' protection regulations.
- **ACS Guidelines.** These include conflict of interest, recombinant DNA, and scientific misconduct and are required.

The institution of the Lead PI is responsible for the accuracy, validity, and conformity with the most current institutional guidelines for all administrative, fiscal, and scientific information in the application.

The institutional official signing the application further certifies that the Lead Institution will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The Lead Institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

For funded grants, it is the responsibility of the institution to immediately report to ACS any action including recertification or loss of IRB approval that occurs during the term of the award that is related to the work described in the grant application.

**By accepting an award, the Lead PI agrees to the Guidelines for Maintaining Research and Peer Review Integrity that can be found in the Appendix of these policies.**

## **B. LEAP-RESEARCH SCHOLAR GRANT**

**Description:** Research Scholar Grants (RSG) provide support for independent, self-directed researchers including clinician scientists. The scope of the application must align with one of the two LEAP program research areas. These grants typically contribute to the cost of salaries, consumable supplies, and other miscellaneous items required for the research. The application must convey the commitment of the institution to the applicant and the proposed research activities. The Society will only recognize one PI, who is responsible and accountable for overseeing the project.

**Eligibility:** Applicants must be independent, self-directed researchers or clinician scientists. Any career stage is allowed, and there is no citizenship requirement. The PI's institution must provide space and other resources customary for independent investigators. There is no limit to the level of extramural funding, as long as there are no overlapping scientific objectives.

**Resubmissions:** Unfunded RSG applications to the LEAP RFA may be resubmitted if the RFA is re-issued. Alternatively, unfunded LEAP-RSG applications could be resubmitted (up to 2 times) during our standard peer review cycles, but this does not assure the same reviewers. The applicant must meet the eligibility criteria for our [standard RSG](#).

**Budget and Award Period:** Awards are for up to 4 years at \$215,000 per year direct costs, plus 10% allowable indirect costs.

Equipment that equals or exceeds \$5,000 with a useful life of more than one year, is not included in the direct cost total used to calculate indirect costs.

Personnel may receive salary support up to the National Institutes of Health salary cap, prorated according to their percent effort on the project. Budgets submitted must be realistic estimates of the funds required for the proposed research.

**Expenditures:** The Society is flexible in response to the changing needs of a research program. The PI may make minor alterations (changes <\$15,000/year) within the approved budget except where such expenditures conflict with the policies of the Society.

Major changes in expenditures (>\$15,000 per year) require written approval from your Scientific Director. However, for permanent equipment, the annual threshold requiring written approval is >\$5,000. Contact your Scientific Director for guidance.

#### **4. AUTHORITY FOR MAKING GRANTS**

All ACS grants and awards are made by the Chief Executive Officer on behalf of the Society's Board of Directors.

#### **5. SOURCE OF FUNDS**

Funding for the LEAP RFA is made possible by a generous donation from the *RUNX1* Research Program along with public donations to the ACS collected annually from our many dedicated volunteers. To disseminate information about the Society's Extramural Discovery Science Program to volunteers and the public, grantees may occasionally be asked to give brief presentations to professional and lay audiences.

#### **6. WHO MAY APPLY**

The Society will allow only one individual designated as PI, responsible and accountable for the overall conduct of the project (i.e., no co-principal investigators).

Applicants, who may include current ACS grantees, may submit only one application in response to this RFA.

The ACS does not fund projects that overlap with other funded projects. Projects are considered to overlap if there are any shared *Specific Aims or areas of the budget*. Scientific Directors make final decisions regarding any questions of overlap. In cases of overlap, the PI may accept only one award if both are approved for funding. The ACS does not negotiate partial funding of grants with overlapping specific aims.

The only exceptions are:

- Funds provided by the institution as start-up support to develop a new laboratory; and
- Awards that provide only salary support for the Principal Investigator. In the latter case, if the salary support for the PI's contribution to the project is covered by the other agency, no additional salary support for the PI may be requested from the American Cancer Society.

#### **Guidelines for "Independence"**

The LEAP-Team and LEAP-RSG grant mechanisms require the applicant to be an independent investigator. The ACS uses the guidelines below to evaluate "independence." The details below are meant to capture many of the characteristics of independent research positions.

*Administrative independence* is typically demonstrated by a full-time faculty appointment (normally equivalent to Assistant Professor); a tenure-track position; allocated office and/or laboratory space; a start-up package; and institutional commitment defined and verified in a letter of support from a department chair or equivalent.

Evidence of *scientific independence* could include prior grant funding and senior-author publications.

Specific evidence of an applicant's independence may include:

- **Degree(s):** PhD, MD, or terminal degree in the field of specialty.
- **Title/Appointment:** Assistant Professor (or higher); Research Assistant Professor; or comparable position (i.e., Assistant Member). Individuals with the rank of Instructor may apply if that rank confers principal investigator status at their institution.
- **Training Experience:** In most disciplines, applicants will have completed a period of postdoctoral or other research training.
- **Space:** Committed independent research facilities.
- **Publications:** Corresponding or senior authorship for publications in the investigator's main area of research interest. This is desirable but not required.
- **Institutional support:** At least partially through hard-money, or money for start-up or equipment.

## 7. TOBACCO-INDUSTRY FUNDING POLICY

Scientific investigators or individuals who are funded for any project by the tobacco industry, or whose named mentors are so funded, are not eligible for ACS grants. Any of these who accept tobacco-industry funding during the term of a grant must inform the Society, whereupon the grant will be terminated.

### **Tobacco industry funding includes:**

- Funds from a company that is engaged, or whose affiliates are engaged, in the manufacture of tobacco produced for human use;
- Funds in the name of a tobacco brand, whether or not the brand name is used solely for tobacco goods; and
- Funds from a body set up by the tobacco industry or by 1 or more companies in the industry.

### **The following do not constitute tobacco industry funding:**

- Legacies funds from tobacco industry investments (unless the name of a tobacco company or cigarette brand is associated with them).
- Funds from a trust or foundation established with assets related to the tobacco industry, but which no longer have any connection with the industry, even though the entity may bear a name that for historical reasons is associated with the tobacco industry.

Tobacco industry funding is defined for purposes of Society grants and awards applicants and recipients as money provided or used for any costs for research, including personnel, consumables, equipment, buildings, travel, meetings, and conferences, or operating costs for laboratories and offices. It does not include meetings or conferences unrelated to a particular research project.

## 8. COLLABORATIONS WITH ACS INTRAMURAL SCIENTISTS (IF APPLICABLE)

ACS Discovery intramural scientists and their staff ([Surveillance and Health Equity](#); [Population Science](#)) may participate in grants and contracts in many ways, including:

- Serving as unpaid consultants, collaborators, co-investigators, or mentors. Intramural scientists may not serve as a principal investigator on an ACS grant or contract.
- Contributing to the conceptualization, design, execution, or interpretation of a research study.
- Having primary responsibility for a specific aim within a standard research grant mechanism.
- Developing or contributing data for an extramural collaboration.



- Participating in a multi-institutional collaborative arrangement with extramural researchers for clinical, prevention, or epidemiological studies.

ACS intramural scientists may not receive salary support, but can receive travel expenses, or other funds from ACS-funded grants or contracts.

In most cases, the use of ACS research resources requires that at least one ACS intramural scientist be included as a collaborator on the grant application. Therefore, prior to submission of an application, the collaboration between extramural scientists and intramural scientists must be established according to the policies and procedures of ACS intramural research.

Intramural and extramural scientists may have access to reagents, laboratory equipment, and/or data to conduct the extramurally funded portion of the research, as established in their collaborative agreement.

While intramural scientists may write a description of the work to be performed by the intramural department, they may not write an applicant's grant application or contract proposal. However, the intramural scientist(s) should review and approve sections relevant to the collaboration.

ACS intramural scientist participation must comply with disclosure, non-disclosure, and conflict-of-interest regulations.

## **9. ELIGIBLE INSTITUTIONS AND INSTITUTIONAL RESPONSIBILITIES**

The Society's grants and awards are made to not-for-profit institutions physically located within the US and its territories. Eligible institutions should be able to provide:

- A current letter from the Internal Revenue Service conferring nonprofit status;
- Evidence of an active research program with a track record of extramural funding and publications in peer reviewed journals; and
- Documentation of appropriate resources and infrastructure to support the proposed research. These include, but are not limited to:
  - Adequate facilities and services;
  - Fiscal and grants management infrastructure to ensure compliance with ACS policies, and with federal policies regarding protections for human and animal subjects (e.g., a sponsored-projects office or a contract with an IRB or IACUC);
  - A process for appointment and promotion equivalent to those in academic settings for staff scientists; and
  - Evidence of education, training, and mentoring for fellows and beginning researchers appropriate to the grant mechanism.

Grant applications will not be accepted, nor will grants be made, for research conducted at

- For-profit institutions;
- Federal government agencies (including the National Laboratories);
- Organizations supported entirely by the federal government;
- Organizations that primarily benefit federal government entities, such as foundations operated by or for the benefit of Veterans Affairs Medical Centers (VAMC). However, qualified academic institutions may submit applications on behalf of a VAMC if a Dean's Committee Memorandum of Affiliation is in effect between the 2 institutions.

The American Cancer Society does not assume responsibility for the conduct of the activities that the grant supports, or for the acts of the grant recipient, because both are under the direction and control of the grantee institution and subject to its medical and scientific policies.

Every grantee institution must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an institutional review board (IRB), as specified by the National Institutes of Health Office for Human Research Protections of the US Department of Health and Human Services (DHHS).

Furthermore, applicants, applicant institutions, and grantee institutions must adhere to DHHS guidelines as well as ACS guidelines regarding conflicts of interest, recombinant DNA, scientific misconduct, and all other applicable ACS policies and procedures.

To signify agreement with all ACS policies and procedures, an application for a grant must bear the e-signature of the principal investigator. Space is provided for e-signatures for the departmental chair (or equivalent) and institutional official to accommodate institution-specific requirements for proposal submissions, but neither are required for submission to ACS. Note: the PI must enable other users' access to the application on ProposalCentral to permit their e-signatures.

Once a grant is awarded, an institutional official signature's is required signifying institutional agreement with all ACS policies and procedures. The institution is responsible for verifying that all documentation related to the grant is correct, including all representations made by any named researcher (e.g., position or title). Further, the institution is responsible for verifying that the grantee is either a US citizen or permanent resident with a Resident Alien Card ("Green Card") where applicable. If the award does not require US citizenship or permanent residency, the institution is responsible for documenting the grantee's legal eligibility to work in the US for the duration of the award.

It is the responsibility of the institution to immediately report to ACS any finding that any information presented to ACS in connection with the application and/or grant is false. It is also the responsibility of the institution to immediately report to ACS any action including recertification, loss of certification, breach of contract, misconduct, or change in employment status for a named researcher with the institution. This includes administrative leave, which may occur during the term of any award pertinent to the work described in the grant application.

Failure to abide by the terms above, or by any other ACS policy or procedure, may result in suspension or cancellation of the grant, at the sole discretion of ACS.

**By accepting an American Cancer Society award, you agree to the Guidelines for Maintaining Research and Peer Review Integrity found in the Appendix of these policies.**

## **10. PEER REVIEW OF APPLICATIONS**

Applications submitted in response to this RFA will be assigned to the most appropriate peer review committee based on the proposed project. Each application will be assigned to at least 2 scientific reviewers and one community research partner (usually no formal training as a scientist or health professional but has a strong personal interest in advancing the effort to control and prevent cancer through research) for independent and confidential review.

The peer review committee will use application evaluation criteria that vary depending on the grant mechanism. See the LEAP RFA Applicant Instructions for details.

After the peer review committee discusses and votes to rank the most competitive applications, it provides its recommendations, along with critiques of the applications and fundable scores, to be utilized for making funding decisions.

No voting member of a peer review committee or of the Council may be a member of the Society's staff or Board of Directors.

Typically, the ACS allows resubmissions for research grant applications. However, resubmission to this RFA will only be offered if additional funds remain unspent following review.

Resubmitted applications are reviewed in the same detail as new applications and compete with them on an equal basis.

## **11. APPLICATION DEADLINES**

Applications for grants and awards under the LEAP RFA must be submitted electronically via ProposalCentral by **11:59 PM ET on October 29, 2024**. If there is an option for resubmissions, details about the second application deadline will be communicated to applicants in a timely fashion.

No supplemental materials will be accepted after the deadline unless requested by ACS staff.

## **12. NOTIFICATION OF APPLICATION RECEIPT AND REVIEW**

Approximately one month after receipt of the application, applicants will receive an email acknowledgement providing an application number, the assigned peer review committee, and the name of their Scientific Director with contact information. This email will be sent to the address in the professional profile supplied at the time of submission in ProposalCentral. Be certain the email address listed in your professional profile is active, since it will be used to notify you throughout the review and award process.

**Post-Review Notification.** Applicants will receive the reviewers' critiques approximately 4-6 weeks after peer review. Funding decisions will be communicated to applicants approximately 10-12 weeks after peer review.

## **13. GRANT MANAGEMENT AND PAYMENTS**

New grantees will receive a packet of information with instructions for activating the award. The activation form as well as other important information about the grant can also be found at <https://ProposalCentral.com/> (select the Award tab to see the Post Award Management site).

Grant payments will be made at the end of each month. The ACS makes all payments to the sponsoring institution via electronic funds transfer or via a mailed check depending on the preference selected on the grant activation form.

Acknowledgement of payment by the sponsoring institution is not required. Continued funding by ACS throughout the grant period is contingent upon the institution's compliance with all terms related to the grant; failure to comply with all the grant terms may result in a suspension or cancellation of the grant, to be determined by ACS at its sole discretion.

Personnel compensated in whole or in part with funds from the ACS are not employees of the Society. Consequently, institutions are responsible for issuing appropriate IRS tax filings for all individuals receiving compensation from ACS grants, and for withholding and paying all required federal, state, and local payroll taxes for such compensation. Any tax consequences are the responsibility of the individual recipient and the sponsoring institution. We advise all grant and award recipients to consult a tax advisor regarding the status of their awards.

## **14. PROGRESS REPORTS AND REVIEW**

Timely scientific and financial reports represent a critical part of responsible stewardship of the donated dollars. We greatly appreciate your efforts to assist us in fulfilling these important commitments. Information in the annual and final scientific reports, as well as possibly from the Structured Technical Abstract, may be shared with donors under a Non-Disclosure Agreement.

Therefore, do not include proprietary or confidential information. To access the necessary forms for bi-annual and final progress reports, please go to <https://proposalcentral.com/>.

1. An annual progress report must be submitted each year within 60 days after the first and subsequent anniversaries of the start date of the grant.
2. The final progress report should cover the entire grant period. In the event a grant has been extended without additional funds, the final report is not due until 60 days after the official termination date of the grant. If the grant is terminated early, a final report must still be completed within 60 days of the termination date.
3. Grantees must submit reports in a timely manner. If this is not possible, a grantee must make a written request to extend the reporting deadline. Noncompliance may result in the withholding of payment on all grants in effect at the recipient institution until reports are received.
4. Please note that up-to-date annual reports **are required** when requesting any grant modifications, including transfer of institutions and no-cost extensions.
5. Grantees must attend the annual [RRP Scientific Conference](#) and be prepared to present an overview of the progress made on the LEAP grant project. RRP will cover the costs of attendance.
6. During the grant term, Grantees are expected to meet with RRP at least once per year to discuss progress.
7. A formal review of each LEAP grant will occur after 2 years. At this time, the project's progress will be assessed, and PIs will have the opportunity to adjust the project's specific aims if necessary for the remaining 2 years of the LEAP grant. If it is determined at that time that the project has not made significant progress or that the preliminary findings generated are no longer warrant further investigations, the Parties may terminate funding of the LEAP Grant at this juncture.

## 15. PUBLICATIONS AND OTHER GRANT-RELATED COMMUNICATIONS

*When and how to acknowledge your grant:*

Publications resulting from research supported through this RFA must contain the following acknowledgment: "Supported by [name of grant and number] from the American Cancer Society and the *RUNX1* Research Program". When there are multiple sources of support, the acknowledgment should read "Supported in part by [name of grant and number] from the American Cancer Society and the *RUNX1* Research Program," along with references to other funding sources.

The support from both funding partners should also be acknowledged by the grantee and the institution in all public communication of work resulting from this grant, including scientific abstracts (where permitted), posters at scientific meetings, press releases or other media communications, and internet-based communications.

Although there is no formal ACS approval process for publications by Society grantees, it is helpful to notify your Scientific Director when manuscripts have been accepted for publication. This will allow ample time for additional public or Society-wide notifications. If your institution plans a press release involving any of your Society-supported research, please notify the ACS and RRP communications representatives (contact information on your award letter) and your Scientific Director in advance.

ACS and RRP grant to you a limited, revocable, non-transferable license to use the ACS and RRP logos (as shown below) in association with your funded work. We encourage you to use it on scientific posters, Power Point presentations, and any other visual presentation about your funded work where

the ACS is noted as a funding source. In turn, you agree to provide any materials featuring the ACS and RRP logos upon our request.

Permission to use the logo is limited to the uses outlined in the above paragraph. It should not imply ACS or RRP's endorsement of products such as guidelines, websites, software for mobile devices (apps), tool kits, and so on.



## 16. FINANCIAL RECORDS AND REPORTS

A report of expenditures must be submitted within 90 days of the grant's expiration date shown in the award letter; annual financial reports are not required. Any change in terms, such as a no-cost extension, will alter a report's due date. The necessary forms can be found under the "Deliverables" tab at <https://proposalcentral.com/>.

Signatures of the PI and the institution's financial officer are required. Any unexpended funds must be returned to the Society.

Grantees must submit financial reports in a timely manner. If this is not possible, a grantee must make a written request to extend the reporting deadline. Noncompliance may result in the withholding of payment on all grants in effect at the recipient institution until reports are received.

Institutions must maintain separate accounts for each grant, with substantiating invoices available for audit by representatives of the ACS. The Society is not responsible for expenditures made prior to the start date of the grant, costs incurred after termination or cancellation of the grant, commitments against a grant not paid within 60 days following the expiration date, or any expenditures that exceed the total amount of the award. (See also Section 21, "Cancellation.")

## 17. EXPENDITURES

American Cancer Society *research grants* are not designed to cover the total cost of the research proposed or the investigator's entire compensation. The grantee's institution is expected to provide the required physical facilities and administrative services normally available at an institution.

For grants that allow indirect costs, the calculation of allowable indirect costs includes all budget items except permanent equipment.

The Society's *research grants* do NOT provide funds (direct budget) for such items as:

- **Administrative**
  - Secretarial or administrative salaries that are not specifically related to the research project.
  - Membership dues
- **Tuition, books, and fees**
  - Student tuition and fees (graduate or undergraduate).
  - Books and periodicals
- **Office or laboratory setup and expenses**
  - Office and laboratory furniture
  - Office equipment and supplies
  - Rental of office or laboratory space
  - Construction, renovation, or maintenance of buildings or laboratories
  - Service contracts for lab equipment

- **Other**
  - Recruiting and relocation expenses for personnel.
  - Non-medical services to patients (travel to a clinical site or patient incentives are allowable expenses)

Grant funds may be used for computers for research and PI's training purposes, which can be purchased with direct funds from the equipment budget. In addition, the Society's research grants may provide funds (direct budget) for foreign travel, but this requires pre-approval by your Scientific Office.

## **18. OWNERSHIP OF EQUIPMENT**

Equipment purchased under ACS research grants or grant extensions is for use by the PI and collaborators. Title of such equipment shall be vested in the institution at which the PI is conducting the research. In the event the ACS authorizes the transfer of a grant to another institution, equipment necessary for continuation of the research project purchased with the grant funds may be transferred to the new institution, and title to such equipment shall be vested in the new institution.

## **19. INTELLECTUAL PROPERTY RIGHTS**

As a not-for-profit organization supported by public contributions, the Society wishes to adopt policies and practices that enhance the likelihood that potentially beneficial discoveries and inventions will be exploited to the benefit of humankind. It is the desire of the Society that such inventions be administered in such a manner that they are brought into public use at the earliest possible time. The Society recognizes that often this may be best accomplished through patenting and/or licensing of such inventions. Accordingly, the Society has adopted the following patent policy that is binding on all Grantees and Not-for-profit Grantee Institutions (hereinafter "Grantee"), To the extent the Grantee Institution's own policies permit individual investigators to own any right, title or interest in any Funded Invention, the Grantee Institution shall ensure that each Investigator complies with the provisions of these terms and conditions with respect to such Funded Invention.

Acceptance of a Grant from the Society constitutes acceptance of the terms and conditions of this policy. In the event of any conflict between this policy and the Grantee's policy, the terms and conditions of this policy shall govern.

- A. All notices required pursuant to this policy shall be in writing, and in this policy, the following terms shall have the meaning set forth below.
  - i. "Invention" shall mean any potentially patentable discovery, material, method, process, product, program, software, or use.
  - ii. "Funded Invention" shall mean any Invention made in the course of research funded in whole or in part by a Society Grant.
  - iii. "Gross Income" shall mean gross royalty income received by Grantee in respect of a Funded Invention inclusive of income from a single sale of the Funded Invention, less a total of \$25,000 towards United States patent filing fees.
  - iv. "ACS Award" shall mean the total monetary amount of the Grant provided to the Grantee.
  
- B. The Grantee technology transfer officer shall provide the Society with an annual report for each Funded Invention. The annual report will be due by January 31 of each calendar year after an ACS Grant Award has been received. The annual report shall include a listing or description of the following information for each Funded Invention: (1) all issued patents and pending patent applications, (2) all licenses, leases, or other revenue generating agreements, (3) all gross revenue for each preceding calendar year, (4) the filing, publication and issuance or grant of any application for a patent or other statutory right for a Funded Invention, and (5) the latest stage of development of any product arising from each Funded Invention.

Grantee shall pay all costs and expenses incident to all applications for patents or other statutory rights and all patents and other statutory rights that issue thereon owned by Grantee (other than patent filing fees as provided for in Section A).

- C. Both the Society and Grantee, (the appropriate Grantee technology transfer officer managing Funded Invention), shall promptly inform the other of any suspected infringement of any patent covering a Funded Invention and of any misappropriation, misuse, theft, or breach of confidence relating to other proprietary rights in a Funded Invention. Grantee and Society will discuss in good faith further action to be taken in this regard.
- D. Grantee will license a Funded Invention in accordance with Grantee Policy and established practices.
- E. The Society waives the receipt of income until the Gross Income from the Funded Invention exceeds \$500,000.

Once the Gross Income from a Funded Invention exceeds \$500,000, Grantee funded through the LEAP RFA shall pay the Society annually 5% of Gross Income. Such payment shall be accompanied by an appropriate statement of account. The income to the ACS from grants awarded in association with the LEAP RFA will not exceed ten (10) times the amount of the total Award.

Payments shall be made on an annual basis by January 31, the year after the year that Income was received. Should Grantee not be able to make a payment by January 31 for any calendar year in which income was received, Grantee shall inform the Society at least seven days prior to missing a payment. Grantee shall have a grace period of 90 days to make the missed payment. Failure to make payments after the 90-day grace period will be deemed a breach of this agreement. The Society shall have the right to audit, at the Society's expense, the Grantee's books and records annually. The term of this Agreement shall extend until the expiration of the last to expire patent in any jurisdiction that covers the Funded Invention, or three years past decline of revenue to \$0, or once the cap has been met.

- F. Development and Commercialization of Funded Invention

The Society wishes to support and accelerate the commercialization and deployment of the results from Grantee's research. To help Grantee bring its Funded Invention to market as quickly as possible, Grantee shall inform The Society if Grantee decides to commercialize or seek investment in any Funded Invention. The Society requests that the Grantee offer The Society an opportunity to fund, facilitate, invest, or otherwise participate in such commercialization efforts via ACS BrightEdge, its impact venture capital fund (<https://www.acsbrightedge.org/>).

**Please note that the American Cancer Society is unable to renegotiate the terms of this agreement with any individual institution.**

## **20. REQUEST FOR GRANT MODIFICATIONS**

Please note that up-to-date annual reports are required prior to approval of any grant modifications including transfers and no-cost extensions. All Forms can be found under the Deliverables tab at <https://proposalcentral.com/>.

**Change of Institution:** Grantees may transfer their grant from one institution to another eligible institution only after receiving written approval from the Society. Grant recipients must request a transfer as soon as a final decision for changing institutions has been made. Contact the Program Office to alert the Scientific Director of your intent to transfer.

Prior to the formal transfer, the ACS must receive the following:



- A request for transfer in writing, indicating the anticipated transfer date.
- A statement from an administrative official at your original institution relinquishing the grant.
- Report of Expenditures from the original institution, together with a check for any unexpended funds. Payments to the new institution will not be initiated until a final accounting and a check for any unexpended funds have been received from the original institution and the Society has approved the transfer. The final accounting must be submitted within 60 days of the transfer request.
- Grant transfer forms (title page, contact information page, and assurances and certification page of the grant application) completed by the appropriate individuals at the new institution, indicating acceptance of the grant.

**For the LEAP-Team Members:**

- If the Team member is moving to an eligible institution, follow the steps above to request approval for the transfer and discuss how the transfer will impact the Team and the project.
- If the Team member is moving to an ineligible institution, then reach out to the Scientific Director to discuss how to fill the role or reallocate the budget.

**Change of Research Project or Team:** Applicants and grantees are not allowed to change the research project or team without prior approval from ACS and RRP. PIs (or for the Team award, the Lead PI) must notify the ACS Scientific Director immediately if there are any anticipated changes in team members or other research personnel. Please note that a request to change the research proposal or team may not be accepted and may result in termination of the grant.

**No Cost Extensions:** A No Cost Extension (NCE) can be requested for a LEAP-Research Scholar Grant and LEAP-Team Award. Before starting a request for the extension of a grant term without additional funds, notify your Scientific Director by email of your intent. A formal request should be uploaded onto ProposalCentral 60 days before the grant's expiration date using the NCE webform and NCE Budget and Justification forms located under the Deliverables tab on ProposalCentral. Include an estimate of the funds to be carried over into the extension, and an explanation for the delay (i.e., which specific aims remain incomplete and why). In general, a grant may be extended for up to one year if a programmatic need is justified and the funds to be carried over into the no-cost period do not exceed an amount equivalent to one year of support (direct plus indirect costs).

**Leave of Absence:** Requests for a leave of absence by PIs (all funding mechanisms) will be handled on a case-by-case basis. If possible, please contact the Scientific Director at least 30 days prior to the proposed beginning of leave.

**The Society reserves the right to deny requests for extensions, leaves of absence, or transfers.**

## 21. CANCELLATION OF GRANT

If a grant is to be canceled prior to the original termination date, contact your Scientific Director and submit the Request for Cancellation form found in the "Deliverables" section at <https://proposalcentral.com>. The ACS may cancel a grant at its sole discretion if the institution fails to comply with the terms and obligations related to the grant.

In the event a grant is canceled, the institution is only entitled to the prorated amount of the award accumulated between the start and termination dates. The Society assumes no responsibility for expenditures in excess of the prorated amount.

If an award is canceled after the initiation of the grant period, a final report will be due within 60 days of the termination date describing the work completed up to that point.



## **APPENDIX A: GUIDELINES FOR MAINTAINING RESEARCH AND PEER REVIEW INTEGRITY**

The American Cancer Society seeks excellence in the discovery and dissemination of knowledge regarding the cause, prevention, detection, diagnosis, treatment, survivorship, and health policy of cancer. This requires that all individuals affiliated with, or funded by, the American Cancer Society adhere to the highest standards of professional integrity. Volunteer grant reviewers for the American Cancer Society will also be held to the highest codes of conduct and integrity in performing their essential function of peer review.

The American Cancer Society provides grant funds for individuals at academic and other not-for-profit institutions to promote cancer-related training, research, and treatment. This represents a contractual relationship with such institutions, and it is an accepted responsibility and obligation of those institutions to provide policies and procedures for their faculty, staff, and students that address possible misconduct in training, research, and treatment of patients. Moreover, it is the responsibility and obligation of faculty, students, and staff engaged in scientific research and training to be aware of policies and procedures for addressing possible misconduct at their institutions, and to follow those procedures in reporting possible misconduct.

While questions of the integrity of applicants, grantees, and reviewers are very infrequent, they do occur. Ensuring that all questions regarding research integrity are handled in a discrete, but thorough, manner is the responsibility of the Scientific Program Directors managing the review process and portfolios of funded grants, and of the Senior Vice President for Extramural Discovery Science.

The actions of the Scientific Directors and the Senior Vice President for Extramural Discovery Science must insure:

- the confidentiality and anonymity of the individual raising the question of misconduct,
- the integrity of the American Cancer Society and its review processes,
- the rights of the individual accused of misconduct, and
- their own credibility and integrity.

### **Article I**

#### **Standards and Definitions:**

##### **1.1 Research Misconduct by Applicants or Grantees**

The American Cancer Society uses the following definitions related to scientific misconduct outlined in the Federal Guidelines [Federal Register, Vol. 65, No. 235, pg. 76260-76264].

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.<sup>1</sup>
- Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, biology, chemistry, psychology, natural sciences, social sciences, and statistics, and all research involving human subjects or animals.<sup>1</sup>
- Fabrication is defined as making up data or results and recording or reporting them.<sup>1</sup>

- Falsification is defined as manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.<sup>1</sup>
- The research record is defined as the record of data or results that embody the facts resulting from scientific inquiry. It includes, but is not limited to, research proposals, laboratory records (both physical and electronic), progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.<sup>1</sup>
- Plagiarism is defined as the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.<sup>1</sup>
- Reported Qualifications must be accurate (e.g., years since degree earned).

## **1.2 Research Misconduct by Peer Review Committee Members**

The American Cancer Society has adopted the following definitions of misconduct by members of a Peer Review Committee. Misconduct in review is defined as:

- Review for an application for which there is a clear conflict of interest (COI) between the reviewer and applicant. Examples of a COI include joint work on a recent publication, collaboration on a grant, or having trained together.
- Failure to notify ACS personnel of actual, potential, perceived, or potentially perceived conflicts of interest.
- Any communication pertaining to review-related materials between a reviewer and an applicant or applicant's mentor when the application includes an element of training.
- Any communication of the unpublished content of a grant application by a reviewer with any individual who is not a permanent or ad hoc member of the peer review committee to which an application is assigned, or who has not been approved by the Scientific Director for such communication.
- Any use of the unpublished content or concepts of a grant application in pursuit of scientific or career goals by a reviewer.
- Any review or use of the contents of a grant application by a reviewer who might have, or might be perceived to have, a conflict of interest with the applicant or his/her mentor, when the application includes an element of training.

## **1.3 Confidentiality Standard for Reviewers**

To preserve the integrity of the peer review process, all parties involved in the review process must adhere to the following practices regarding confidentiality and non-disclosure:

- Reviewers must not discuss applications reviewed with any individual not designated as a part of the review process, and especially not with applicants or their mentors in the case of training grants, either before or after the peer review meetings.

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<sup>1</sup> The above definitions are outlined in the Federal Guidelines [Federal Register, Vol.65, No.235, pg.: 76260-76264]

- Any inquiries to a peer review panel member regarding an application from an applicant, PI, Co-PI, consultant, or their mentor, to a member of a peer review committee or the ACS Council for Extramural Grants must be reported immediately to the Scientific Director.
- All materials related to the review process must be destroyed or given to the Program Manager at the end of the review meeting.
- For purposes of this standard, materials related to the review process include, but are not limited to paper, bound volumes, flash drives, electronic files accessed via the internet, and oral presentations or discussions.

#### **1.4 Conflict of Interest Standard for Reviewers**

To preserve the integrity of the peer review process, all participants in the process must adhere to these principles and practices:

- Reviewers must not be an employer or employee of an applicant and may not be employed by the same institution as an applicant within three years of the date of submission of an application.
- Reviewers must not be a party to any agreement for future employment or other agreement or arrangement with an applicant or any person listed as key personnel on an application.
- Reviewers must not have served as mentors or collaborators of an applicant within three years of the date of an application.
- Reviewers must not participate in the review of an application submitted by a standing member of a peer review committee serving on the same review committee, with the exception of Institutional Research Grants.
- Reviewers must not be under the health care of, or providing health care to, an applicant or any person listed as key personnel on an application.
- Reviewers must not have received, or have the potential to receive, direct financial benefit from the application.
- Reviewers must not be pursuing research projects which might be viewed as being in direct competition with applicants or their collaborators and colleagues. Nor should a reviewer have potential to receive direct benefit from an application's rejection for funding.
- Reviewers must not have any cause of action, dispute, or claim against, or any long-standing scientific or personal differences with, the applicant or any person listed as key personnel on an application.

### **Articles II**

Policies:

#### **2.1 Policy Governing Misconduct by Applicants and Grantees**

##### **2.1.1 Scientific Misconduct by Applicants:**

Any allegations of scientific misconduct must be brought to the immediate attention of the Scientific Director in charge of the Peer Review Committee that is responsible for reviewing the work in question. If possible, allegations of scientific misconduct on the part of an applicant in the submission of a grant proposal should be raised in advance of the review meeting. The Scientific Director will then bring the allegation to the attention of the Senior Vice President for Extramural Discovery Science at ACS. The Senior Vice President for Extramural Discovery Science will

evaluate the allegation and make a determination on the misconduct issue and the appropriate next steps to be taken to engage in further investigation or action in accordance with Article III, section 3.1.1, “Procedure for Handling Allegations of Scientific Misconduct by Applicants.”

#### 2.1.2 Scientific Misconduct by Grantees:

In instances where alleged scientific misconduct occurs after the awarding of a grant, such as in the publication of falsified data, the Scientific Director will bring the allegation to the attention of the Senior Vice President for Extramural Discovery Science at ACS. The Senior Vice President for Extramural Discovery Science will evaluate the allegation and make a determination of the appropriate steps to be taken to engage in further investigation or action as defined in Article III, section 3.1.2, “Procedure for Handling Allegations of Scientific Misconduct by Grantees.”

#### 2.1.3 Professional Misconduct by Grantees:

In instances where alleged professional misconduct occurs after the awarding of a grant, such as an allegation of sexual harassment by a principal investigator, the grantee should follow the reporting guidelines in Article III, section 3.1.3, “Procedure for Handling Allegations of Professional Misconduct by Grantees.”

## 2.2 Policy Governing Misconduct by Peer Review Committee Members

### 2.2.1 Confidentiality:

Confidentiality is at the heart of the peer review process and is imperative for objective evaluation and free expression in the review process. The applicant-reviewer relationship is a privileged alliance founded on the ethical rule of confidentiality. To maintain the essence and integrity of the peer review process, the Society and its appointed peer reviewers must ensure and be assured that the confidentiality of the applicant’s information, the contents of the grant application, and the proceedings of the review panel will be maintained. Such confidentiality adheres when a person discloses information to another with the understanding that the information will not be divulged to others without the consent of the party who disclosed the information, or as otherwise required by law. In the context of peer review, this rule upholds the applicants’ rights to have the information they submit, whether in proposal form or in communications, kept confidential. The rule also ensures that those involved in the review process maintain their obligation to keep confidential any information concerning an application. In fact, the very existence of a submission should not be revealed (or confirmed), to anyone other than those within the review process unless and until the application is funded. To this end, all contents, evaluation and discussion of applications shall be confined to Peer Review Committee (PRC) members and ACS staff personnel (Scientific Director, Senior Vice President for Extramural Discovery Science, Program staff), responsible for managing the review process of that PRC. For these purposes, reviewers include all standing, stakeholder and ad hoc reviewers of PRCs and members of the Council for Extramural Grants. In rare and specific instances, discussion of applications with, or in the presence of, non-committee members can occur after obtaining the written consent of the Scientific Director. Reviewers must not discuss reviews with applicants or their mentors in the case of training grants, either before or after the review meetings. Reviewers also must not communicate the contents of any grant applications with individuals not associated with the review process. Any materials related to the review process must be disposed of at the meeting, and all final critiques given to the Scientific Director.

If an allegation of a breach of reviewer confidentiality is brought forward, that allegation will be communicated to the Senior Vice President for Extramural Discovery Science who will determine if an investigation of that allegation is warranted. The Senior Vice President for Extramural Discovery Science will then follow the appropriate steps as defined in Article III, section 3.2 “Procedure for Handling Reviewer Misconduct and Conflicts of Interest.”

### 2.2.2 Conflict of Interest:

An objective evaluation of grant proposals is essential to the peer review process. In achieving this goal, there must be no conflict of interest, apparent conflict of interest or pending future conflict of interest between any participant in the review process and the applicants or their collaborators and colleagues. In this setting, reviewers include standing, stakeholder and *ad hoc* Peer Review Committee (PRC) members and members of the ACS Council for Extramural Grants responsible for, and participating in, the review process. There are numerous bases for conflicts of interest, and these can include: employment, professional relationships, personal relationships, financial benefit, industry affiliation or other interests. The conflicts can be real or apparent. For Definitions of Conflict of Interest, refer to Section 1.5.

Reviewers may not make use of any of the contents of a grant for their own research purposes or those of their collaborators and colleagues. Reviewers must exercise proper due diligence in investigating and disclosing any potential conflict of interest that might exist between themselves and an applicant or the applicant's collaborators or mentors. The Conflict of Interest Statement attached as EXHIBIT A shall be submitted to the Society prior to the beginning of Peer Review.

If an allegation of a reviewer conflict of interest is brought forward, that allegation will be communicated to the Senior Vice President for Extramural Discovery Science who will determine if an investigation of that allegation is warranted. The Senior Vice President for Extramural Discovery Science will then follow the appropriate steps as defined in Article III, section 3.2, "Procedure for Handling Reviewer Misconduct and Conflicts of Interest".

### **Article III**

Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct:

To ensure the integrity of the peer review process and the integrity of ACS-sponsored research, it is necessary that the procedures for dealing with allegations of misconduct be clearly understood by all reviewers and ACS personnel. Procedures for handling allegations of misconduct by applicants, grantees and reviewers are detailed in the following sections.

#### **3.1 Procedures for Handling an Allegation of Scientific Misconduct by Applicants or Grantees**

##### **1.1.1 Procedure for Handling Allegations of Scientific Misconduct by Applicants:**

In the event that an allegation of scientific misconduct by an applicant is brought forward to a Scientific Director or other ACS staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation, the anonymity of the person against whom the allegation is made, and the integrity of the review process. The Scientific Director must immediately inform the Senior Vice President for Extramural Discovery Science of the allegation and provide all relevant information regarding the allegation. It is the Senior Vice President's responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the Senior Vice President's responsibility to contact the appropriate institutional office at the applicant's institution regarding the allegation. The Senior Vice President for Extramural Discovery Science will then serve as the point of contact between the ACS and the institutional official[s] handling issues of scientific misconduct.

If determined to be appropriate, the Senior Vice President for Extramural Discovery Science will forward an allegation of scientific misconduct and all pertinent information to the Research Integrity Officer at the institution sponsoring the grant application in question or at which the alleged scientific misconduct was carried out. If there is not a Research Integrity Officer, the Dean of the School in question or its chief academic officer will be contacted. In the instance that the person[s] making the allegation does not contact the American Cancer Society but raises the allegation of scientific misconduct with the appropriate institutional official according to their established

institutional procedures, it is the responsibility of the institution to contact the American Cancer Society regarding the allegation, any investigation of the allegation, and the outcome of that investigation. All such correspondence will be held in strict confidence and will not be made public by the American Cancer Society irrespective of the outcome of the investigation. The American Cancer Society assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of scientific misconduct. However, acceptance or nonacceptance of the findings of the institutional investigation is at the discretion of the Society, and additional clarification may be requested.

Allegations of scientific misconduct in a grant application may be made by individuals who are colleagues, trainees, or reviewers. In the instance that an allegation of scientific misconduct is made in reference to a grant application, the Senior Vice President for Extramural Discovery Science will contact the institutional official at the sponsoring research institution and seek to follow their established protocol for investigating such allegations. If an investigation is deemed necessary, it will be the responsibility of the sponsoring institution to carry out the investigation, to keep the ACS aware of the progress, and to report the outcome of the investigation to the Senior Vice President for Extramural Discovery Science. The written report should include findings, actions taken, and any pending actions.

In fairness to the applicant, the review process must continue while the allegation of scientific misconduct undergoes assessment. Review may continue either in the standing review committee or under the By-pass to Council review mechanism. Under no circumstance should a reviewer, Scientific Director, or ACS staff raise the issue of the allegation in a peer review meeting or meeting of ACS Council for Extramural Discovery Science. If that were to occur, review of that application could not be completed without bias; and review of the application must therefore be discontinued immediately and deferred to ad hoc reviewers or the ACS Council for Extramural Grants. If a reviewer suspects scientific misconduct, which is discovered at the time of the meeting, it is appropriate to request the Chair of the PRC or Council take a "break" and discuss the issue privately with the Scientific Director. The Scientific Director will then take the proscribed administrative steps following the adjournment of the review meeting.

The ACS will complete the process of peer review of the application but will suspend any administrative action which would result in funding of the award in question until the resolution of the investigation. At the conclusion of the investigation, the ACS will require the Office of Research Integrity or comparable entity at the applicant's sponsoring institution to provide a written statement detailing the results of the investigation including any actions taken, or actions pending. Failure of the institution to carry out such an investigation in a timely manner or to provide written results of the investigation will result in the administrative disapproval of the application. If the applicant is absolved of any scientific misconduct, the ACS will reinstitute administrative action that can result in funding for the award if it was approved and is within the pay-line established by ACS Council for Extramural Grants. In the instance that scientific misconduct has occurred, the ACS will administratively inactivate the application. Also, in the case of a finding of scientific misconduct, the investigator may no longer be eligible to participate in ACS funded awards, either as principal investigator, coinvestigator, collaborator, mentor, or consultant. The investigator also may not be eligible to serve in any capacity in reviewing ACS grant proposals.

### 3.1.2 Procedure for Handling Allegations of Scientific Misconduct by Grantees:

In the event that an allegation of scientific misconduct by a grantee is brought forward to a Scientific Director or other ACS staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation and the anonymity of the person against whom the allegation is made. The Scientific Director, or ACS staff contacted about the alleged scientific misconduct, must immediately inform the Senior Vice President for Extramural Discovery Science of the allegation and provide all relevant information

regarding the allegation. It is the Senior Vice President's responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the Senior Vice President for Extramural Discovery Science's responsibility to contact the appropriate institutional office at the applicant's institution regarding the allegation. The Senior Vice President for Extramural Discovery Science will then serve as the point of contact between the ACS and the institutional official[s] handling issues of scientific misconduct.

If determined to be appropriate, the Senior Vice President for Extramural Discovery Science will forward an allegation of scientific misconduct and all pertinent information to the Research Integrity Officer at the institution sponsoring the grant in question or at which the alleged scientific misconduct was carried out. If there is not a Research Integrity Officer, the Dean of the School in question or its chief academic officer will be contacted. In the instance that the person[s] making the allegation does not contact the American Cancer Society but raises the allegation of scientific misconduct with the appropriate institutional official according to their established institutional procedures, it is the responsibility of the institution to contact the American Cancer Society regarding the allegation, any investigation of the allegation, and the outcome of that investigation. All such correspondence will be held in strict confidence and will not be made public by the American Cancer Society irrespective of the outcome of the investigation. The American Cancer Society assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of scientific misconduct. However, failure of the institution to immediately notify ACS of an allegation and/or investigation of scientific misconduct, or to carry out an investigation in a timely manner, or to provide written results to include findings, action taken, or any pending actions of the investigation, is in non-conformance with the terms and obligations of the grant and may result in the suspension of ACS funds for all grants awarded at the institution, to be decided by ACS in its sole discretion. Acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the American Cancer Society, and additional clarification may be requested.

If the investigator has an active ACS award, funding of that award will be suspended until the allegation has either been confirmed or be proven to be erroneous. If the allegation is proven not to have merit, the award may be reinstated by ACS at the date of notification of those findings by the sponsoring institution. If the allegation of scientific misconduct is confirmed, the award will be terminated and any residual funds, as of the date of notification of the sponsoring institution of the allegation, must be returned to the ACS. In the case of a finding of scientific misconduct, the investigator may no longer be eligible to participate in ACS funded awards, either as principal investigator, co-investigator, collaborator, mentor, or consultant. The investigator may also not be eligible to serve in any capacity in reviewing ACS grant proposals.

The publication of data serves to further the interests of the scientific pursuit, and specifically in the case of the ACS, the pursuit of eliminating the burden of cancer. Therefore, it is incumbent on both the ACS and the scientific community to ensure that any instances of misrepresentation of findings in a scientific study are apparent to the scientific community. To that end, a finding of falsification or misrepresentation of data in a published forum must be reported to the editor-in-chief of the journal in which such data is reported. It is the responsibility of the Senior Vice President for Extramural Discovery Science to coordinate such notification with the appropriate sponsoring institutional official according to their established policies and in conjunction with the policies of the journal. If the sponsoring institution does not have a policy regarding notification of the journal, then the Senior Vice President for Extramural Discovery Science will notify the editor-in chief of the journal according to the journal's established policies. In the case of findings of falsification or misrepresentation of published data supported by ACS funds, any active grant[s] held by the responsible individual will be terminated and that individual may no longer be eligible for ACS funding via any mechanism as a principal investigator, co-investigator, collaborator, mentor, or consultant. That individual may also not be eligible to participate in ACS review in any capacity.

### 3.1.3 Procedure for Handling Professional Misconduct by Grantees:

For purposes of this subsection, the following definitions apply:

- Finding/Determination: (1) the final disposition of a matter under organizational policies and processes, to include the exhaustion of permissible appeals; or (2) a conviction of a sexual offense in a criminal court of law.
- Administrative leave/Administrative action: any temporary/interim suspension or permanent removal of an individual, or any administrative action imposed on an individual by the grantee under organizational policies or codes of conduct, statutes, regulations, or executive orders, relating to activities, including but not limited to, teaching, advising, mentoring, research, management/administrative duties, or presence on campus.

The grantee's institution is required to notify ACS (1) of any finding/determination regarding the principal investigator (PI) or co-PI that demonstrates a violation of grantee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, sexual assault, or other professional misconduct; and/or (2) if the PI or co-PI is placed on administrative leave or if any administrative action has been imposed on the PI or any co-PI by the awardee relating to any finding/determination or an investigation of an alleged violation of grantee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, sexual assault, or other professional misconduct. Such notification must be submitted to the Senior Vice President for Extramural Discovery Science within ten days of (1) the finding/determination, (2) the date of the placement of the PI or co-PI on administrative leave, or (3) the date of the imposition of an administrative action, whichever is sooner. Each notification must include the following information:

- ACS grant number;
- Name of individual being reported;
- Type of notification (choose one):
  - Finding/determination that the reported individual has been found to have violated grantee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault; or
  - Placement by the grantee of the reported individual on administrative leave or the imposition of any administrative action on the individual by the grantee relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault;
- Description of the finding/determination and action(s) taken, if any; and,
- Reason(s) for, and conditions of, placement of the individual on administrative leave or imposition of administrative action.

If (1) the institution notifies ACS of a finding of professional misconduct by a grantee, or (2) the institution notifies ACS that administrative action has been taken against a grantee because of a finding/determination that the grantee committed professional misconduct, ACS will consider the policy violation findings on a case-by-case basis. ACS may respond to a misconduct finding by, but not limited to, substituting or removing principal investigators or co-principal investigators, reducing award funding, and--where neither of those options are available or adequate--suspending or terminating awards. If the award is terminated, any residual funds, as of the date of notification, must be returned to ACS. The grantee may no longer be eligible to participate in ACS funded



awards, either as principal investigator, co-investigator, collaborator, mentor, or consultant. The grantee may also not be eligible to serve in any capacity in reviewing ACS grant proposals.

If the institution notifies ACS of administrative action taken against a grantee pending an investigation of an allegation of professional misconduct and the investigator has an active ACS award, funding of that award will be suspended until the allegation has either been confirmed or determined to be erroneous. If the allegation is determined not to have merit, the award may be reinstated by ACS at the date of notification of those findings by the sponsoring institution. If the allegation of professional misconduct is confirmed, ACS will consider the policy violation findings on a case-by-case basis. If the award is terminated, any residual funds, as of the date of notification, must be returned to the ACS. In the case of a finding of professional misconduct, the grantee may no longer be eligible to participate in ACS funded awards, either as principal investigator, co-investigator, collaborator, mentor, or consultant. The grantee may also not be eligible to serve in any capacity in reviewing ACS grant proposals.

Institutions are strongly encouraged to conduct a thorough review of these guidelines to determine whether these guidelines necessitate any changes to the institution's policies and procedures. Institutions should likewise ensure that, in carrying out their investigating, disciplinary, and reporting obligations under these guidelines, they are at all times in compliance with state and federal laws, regulations, and guidelines applicable to the institution.

### **3.2 Procedure for Handling Reviewer Misconduct and Conflicts of Interest**

In the event that an allegation of reviewer misconduct, such as failure to acknowledge a conflict of interest, is brought forward to a Scientific Director or other ACS staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation, the anonymity of the person against whom the allegation is made, and the integrity of the review process. The Scientific Director or other ACS staff contacted regarding the alleged misconduct must immediately inform the Senior Vice President for Extramural Discovery Science of the allegation and provide all relevant information regarding the allegation. It is the Senior Vice President for Extramural Discovery Science's responsibility to evaluate the likelihood of reviewer conflict of interest or misconduct; and, if warranted, it is the Senior Vice President for Extramural Discovery Science's responsibility to handle the investigation internally or to inform the appropriate institutional office at the reviewer's institution about the allegation if aspects of the reviewer misconduct violate any of the tenets of professional behavior established by that institution. The Senior Vice President for Extramural Discovery Science will then serve as the point of contact between the ACS and the institutional official handling issues of reviewer misconduct.

Some elements of reviewer misconduct represent conduct that will only have relevance for the appropriateness of the reviewer's role as a member of a peer review committee. For instance, if there is inappropriate communication between reviewer and applicant or an applicant's mentor or colleagues. In a case of this type, all elements of the investigation of the reviewer misconduct will be handled by ACS personnel at the discretion of the Senior Vice President for Extramural Discovery Science. In cases where a reviewer does not retain the confidentiality of the applicant's information or the content of his or her application, and makes that information available to a third party, it will be at the discretion of the Senior Vice President for Extramural Discovery Science to handle the issue internally at ACS or contact the Office of Research Integrity at the reviewer's institution, based upon an initial assessment of whether such conduct violates the rules of conduct established by that institution. For instance, if there is communication of the contents of a grant proposal by a reviewer to a competitor in the same field as the applicant, or if the reviewer makes use of findings or ideas in an application to further his or her own research interests. In the instance of such an allegation, the American Cancer Society assumes no responsibility for carrying out the investigation of scientific misconduct, or in determining an individual's innocence or guilt of the allegation of misconduct. It is the institution's responsibility to handle the misconduct according

to their established procedures, and to submit to the Society a written report that includes findings, actions taken, and any pending actions. However, acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the Society, and additional clarification may be requested. In any instance of a finding of reviewer misconduct, that individual may no longer be eligible to serve in any capacity in reviewing ACS grant proposals and may be barred from receiving any ACS grant funds.

**References:**

The American Cancer Society Confidentiality, Non-Disclosure Rules and Conflict of Interest: Information for Reviewers of Grant Applications, Version 6/3/2005.

“Confidentiality in Peer Review” (section 3.7.1). Pugh MB, ed. American Medical Association Manual of Style: a guide for authors and editors. 9th ed. Baltimore, MD: Williams & Wilkins; 1997:136-137.

Federal Register, Vol. 65, No. 235, pg. 76260-76264.

## APPENDIX B: INSTRUCTIONS FOR SUBMITTING DELIVERABLES

### GRANT ACTIVATION FORMS ANNUAL PROGRESS/FINAL REPORTS TRANSFER REQUEST CHANGE OF INSTITUTION CHANGE OF TERM EXTENSION OF TERM GRANT CANCELLATION CHANGE OF PRINCIPAL INVESTIGATOR REPORTS OF EXPENDITURES

The American Cancer Society subscribes to the Altum ProposalCentral **Post Award Management System** to facilitate management ACS grants. The system is designed to collect and store grant information from grantees. Grantees are asked to keep their ProposalCentral profile current for the duration of the grant.

The site will house all reports, requests and correspondence pertaining to a grant and is accessible to both ACS staff and grantees. Grantees may provide access to others at their institution (e.g. grants officers) using the instructions provided below.

All awardees of an ACS grant will need to upload deliverables to ProposalCentral. The first deliverable we will be collecting through the **Post Award Management System** is the “Activation Form.” For the Activation Form **only**, please also email Greta McShan at [greta.mcshan@cancer.org](mailto:greta.mcshan@cancer.org) and cc: [grants@cancer.org](mailto:grants@cancer.org) notifying her that you have uploaded your Grant Activation Form.

#### **Uploading an Award Deliverable**

- Log onto <https://proposalcentral.com/>
- **PI must enter their ProposalCentral username and password in “Applicant Login” to access their award detail information**
- Click on the “Awarded” link or “all Proposal” link
- In the Status column, click on the “Award Details” link
- On the Award Details screen, click on the “Deliverables” link at the bottom of the screen
- The schedule of deliverables due for the award is shown chronologically
- Click “Save” to upload the deliverable. You can replace the uploaded document with another document by clicking “Browse” again, selecting a different document from your computer files and clicking “Save” (adding description of deliverable is optional).
- Click “Close”

#### **Send Email (Correspondence) to an ACS Administrator**

- To send correspondence to a Scientific Director at the ACS, click the “Correspondence” link from the Award Details screen
- From this page, you can see any correspondence that has already been sent by clicking the blue link in the Message column
- Use the “Respond” link to respond directly to a message you have received
- To send a new message, click “Send Correspondence to Scientific Director” at the top of the page

- Select the administrator(s) who should receive the correspondence email
- Enter a subject and text for the correspondence in the spaces provided
- Click the "Send Email" button to send the email(s) to the selected administrator

Once an application is awarded it moves from ProposalCentral into the Post Award Management System. People who previously had access to your application in ProposalCentral will not have access to your awarded grant in the Post Award Management System. You may need to allow access to different users than those listed in ProposalCentral to enable them to upload various reports on your behalf.

**To grant another user access to your award and submit deliverables**

- Person(s) must be a registered user on ProposalCentral. If they are not, ask them to register as a new user at: <https://proposalcentral.com/>
- Once user is registered, from Award Detail screen click "Contacts" and "User Access" link
- Click on "Manage User Access to Award" at the top of the screen
- Enter and confirm email address of person
- Click on "Add" button
- Change the Permissions role from View to Administrator
- Click on "Save" button to activate access for new person

**To upload other documents/deliverables such as Publications, CV, etc.:**

- Click the "Add Deliverable" link on the Award Deliverable screen. Select "Other" from the drop-down menu next to "Deliverable Type" from the pop-up screen
- Type in the "Deliverable Description" (i.e., Publications; CV; etc.)
- Click "Browse" to upload their document
- Click "Save"

Additional information and help can be obtained through ProposalCentral customer support desk:

By phone: 1-800-875-2562 toll free

By email: [pcsupport@altum.com](mailto:pcsupport@altum.com)