

THEORYLAB™ (TLC) COLLABORATIVE PILOT GRANT POLICIES

Effective April 2024

ELECTRONIC APPLICATION DEADLINE: July 15, 2024

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American Cancer Society, Inc. Extramural Discovery Science

Website: http://www.cancer.org

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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.

THEORYLAB COLLABORATIVE GRANT POLICIES

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1. THEORYLAB COLLABORATIVE GRANT DESCRIPTION

The TheoryLab Collaborative (TLC) Grant mechanism is intended to provide pilot grant support for collaborative cancer research projects between members of the ACS research ecosystem, including current and former grantees and ACS scientists. Our goal is to invest in our ACS scientific community to enable the formation of new and interdisciplinary collaborations and test out a new idea or concept. The proposed project can focus anywhere along the cancer research continuum but must be collaborative and interdisciplinary. We highly encourage investigators to form new collaborations, if possible and appropriate. However, existing collaborators may continue to work together, but must submit an idea that is distinct from previous collaborative projects.

2. APPLICATION DEADLINE

Electronic applications must be submitted via ProposalCentral by **11:59 PM EST** on **the due date**. No supplemental materials will be accepted after the deadline unless requested by staff for administrative purposes or when requested by the reviewers.

KEY DATES

| Application Deadline | Peer Review Meeting | Award Notification | Grant Activation |
|----------------------|---------------------|---------------------------|-------------------------|
| July 15, 2024 | September 2024 | November 2024 | January 1, 2025 |

3. ELIGIBILITY

A. ELIGIBLE INSTITUTIONS

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 for grant mechanisms limited to early career researchers; and
 - Evidence of education, training, and mentoring for fellows and beginning researchers if appropriate for 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 (except postdoctoral fellowship applications);
- 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.

B. ELIGIBILITY REQUIREMENTS FOR CO-PIs

- Both PIs (maximum of 2) must hold a doctorate degree (M.D., Ph.D., or equivalent) and have a faculty position or equivalent independent research position at an eligible institution. There are no citizenship restrictions.
- Both co-Pls must be a member of TheoryLab and meet at least one of the following criteria:
 - Have held or currently hold an ACS research grant for independent investigators; a MRSG or CSDG award; or IRG or IDG sub-awards. Grantees who received Pfizer-ACS grants are also eligible.
 - Past recipients of the following grants are eligible provided that they have a full-time faculty position and are independent: Postdoctoral Fellowships and ACS Training Grants and Scholarships. <u>Note:</u> Current ACS postdoctoral fellows and scholarship grantees are ineligible to apply.
 - ACS scientists in the Surveillance and Health Equity Science or Population Science departments.
- TLC Co-PIs may be at the same institution, but they are required to be in different disciplines/departments.
- TLC Co-PIs may be current or past collaborators on projects, but the proposed TLC project must be different than an existing or past collaborative project.
- One TLC Co-PI can be an ACS scientist, a scientist at a federal government agency, or a scientist in industry if they are members of TheoryLab. However, they cannot accept compensation (see Section 4A. Budget and Award Period).
- An applicant may only be part of one TLC co-PI pair per submission window.

Applicants who are unsure of their eligibility should reach out to the program contact for the TLC grant mechanism.

4. COLLABORATIONS WITH ACS DISCOVERY SCIENTISTS (IF APPLICABLE)

In addition to serving as a co-PI under the TLC program, ACS Discovery intramural scientists and their staff (<u>Surveillance and Health Equity</u>; <u>Population Science</u>) 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.

5. GRANT TERMS

A. BUDGET AND AWARD PERIOD

The maximum allowable budget is \$61,200 for a 1-year period to be split between the 2 co-Pls; this includes \$600 for each co-Pl to travel to facilitate in-person discussion and collaboration. If the co-Pls are at the same institution, these funds can go toward attending a conference, workshop, etc., by the Pls or a member of the team working on the project. The co-Pls are not required to split the award evenly but can divide the budget according to the needs of the work to be done by each co-Pl.

It is permissible for one Co-PI to be an ACS scientist in the Surveillance and Health Equity Science or Population Science departments, but they cannot receive salary support from an ACS EDS grant. One co-PI could also be a scientist at a Federal agency; however, they cannot receive grant funds or salary support. In this instance, the total budget allowed is \$40,600 which is restricted to the Co-PI at an academic institution or eligible non-profit institution.

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.

B. 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 of 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.

C. EXPENDITURES

ACS research grants are not designed to cover the total cost of the research proposed nor 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.

The Society is flexible in response to the changing needs of a research program. The principal investigator may make minor budget alterations; changes less than \$15,000 per year do not require written approval from your Scientific Director.

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

These grants do not allow indirect costs and direct funds cannot be used for the following:

- Administrative salaries, not specifically related to the research project
- Student tuition and student fees, including graduate and undergraduate
- Membership dues
- Office or laboratory furniture
- Office equipment or supplies
- · Rental of office or laboratory space
- Recruiting or relocation expenses
- Construction, renovation, or maintenance of buildings and laboratories
- Non-medical services to patients (travel to a clinical site or patient incentives are allowable expenses)

D. RESEARCH PROGESS REPORTS

Research progress reports represent a critical part of responsible stewardship of the donated dollars. We greatly appreciate your efforts to assist us in fulfilling this important commitment to our donors.

We encourage TLC Co-PIs to share interim updates about their projects with the TheoryLab community.

Final Progress Reports. To access the necessary forms for final progress reports, please go to https://proposalcentral.com.

- 1. Final reports are due within 60 days after the grant has terminated. The final report should cover the entire grant period. If the grant is terminated early, a final report must still be completed within 60 days of the termination date. This report should be co-written, and each Co-PI will submit the same final report.
- 2. Both Co-Pls will give a virtual presentation for the TheoryLab community 6 months after the grant ends, detailing the outcomes, challenges, and future work of the project. Grantees will then post the slides from the presentation in TheoryLab to further engage with the community.
- 3. The ACS considers it important that scientists communicate the results of their research to a wide range of communities. In addition to research progress, the final report should also include plans for sharing your research and research findings with your (non-academic) community members.

E. FINANICAL RECORDS AND REPORTS

Financial reports. To access the necessary forms, go to https://proposalcentral.com/. A report of expenditures must be submitted by each Co-PI within 90 days of the expiration date of the

grant as indicated in the award letter. Signatures of the Principal Investigator and the institution's financial officer are required from each respective institution of the Co-Pls. Any unexpended funds must be returned to the ACS.

Reports are to be submitted in a timely manner. If this is not possible, a written request to extend the reporting deadline must be made.

Institutions must maintain accounts for each grant, with substantiating invoices available for audit by representatives of the ACS. The ACS is not responsible for expenditures such as these:

- 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
- Any expenditure that exceeds the total amount of the award

6. OWNERSHIP OF EQUIPMENT

Equipment purchased under the American Cancer Society research grants or extensions thereof is for the use of the principal investigator and collaborators. Title of such equipment shall be vested in the institution at which the principal investigator 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. Title to such equipment shall be vested in the new institution.

7. PUBLICATIONS AND OTHER RESEARCH COMMUNICATION

Publications resulting from research or training activities supported by this award must contain the following acknowledgment: "Supported by (insert name of grant and number) from the American Cancer Society."

If there are multiple sources of support, the acknowledgment should read "Supported in part by (insert name of grant and number) from the American Cancer Society." along with references to other funding sources.

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

Investigators should **notify their ACS Scientific Director when manuscripts have been accepted for publication**. This will allow ample time to consider and coordinate any additional public or ACS-wide notifications.

ACS grants a limited, revocable, non-transferable license to use the ACS logo (as shown at the end of this document) about the funded work. We encourage grantees and institutions to use the ACS logo on any scientific poster, PowerPoint presentation, or any other visual presentation about the funded work where the ACS is noted as a funding source. In turn, the grantee and institution agree to provide when requested by the ACS any materials featuring their logos. Permission to use the logo is limited to the uses outlined above.



8. NOTIFICATION OF CHANGES

Change of research project or team. Once the grant is submitted, applicants are not allowed to change the research project or team without prior approval from ACS. The Co-PIs must notify their program office immediately if there are any changes to the research project, 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.

9. INSTITUTIONAL RESPONSIBILITIES

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. The institution of the 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.

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.

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). 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.

The institution is required to ensure IRB approval is obtained for the grant to start, and the approval documentation is uploaded into ProposalCentral within 3 months of grant activation. Furthermore, IACUC approval must be obtained before animal work begins. An IACUC approval letter must be uploaded to ProposalCentral within 3 months of grant activation.

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. RENEWALS AND EXTENSIONS OF AWARDED GRANTS

These grants are not renewable.

No Cost Extensions (NCE) for up to 6-months may be requested by the co-PIs. The NCE Request form should be uploaded to the Deliverables tab on ProposalCentral at least 30 days before the end of the grant. The PI will be notified if the NCE is granted. Typically, the total dollar amount that is allowed to be carried over must be equal to or less than 6 months of direct costs. The PI will be notified if the NCE request is approved.

TLC grantees should refer to the All Grant Polices for details regarding:

- Cancellation of Grant
- Change of Term
- Grant Modifications
- Grant Transfer to New Institution
- Intellectual Property Rights
- Notification of Application Receipt and Review
- Authority for Making Grants
- Source of Funds
- Research Priority Areas
- Tobacco Industry Funding Policy

APPENDIX A: GUIDELINES FOR MAINTAINING RESEARCH AND PEER REVIEW INTEGRITY

I. Scope and Policy Statement

The American Cancer Society (the "Society" or "ACS") seeks excellence in the discovery and dissemination of knowledge regarding the cause, prevention, detection and 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 patient care. 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. 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. It is the responsibility of the Program Directors managing the review process and portfolios of funded grants and the responsibility of the Senior Vice President for Extramural Discovery Science to ensure that all questions regarding research integrity are handled in a discreet, but thorough manner. The actions of the Program Directors and the Senior Vice President for Extramural Discovery Science must ensure the confidentiality and anonymity of the individual raising the question of misconduct; ensure the integrity of the American Cancer Society and its review processes; ensure the rights of the individual accused of misconduct; and ensure their own credibility and integrity.

<u>Article I</u>

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:

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- 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, statistics, and research involving human subjects or
 animals.
- Fabrication is defined as making up data or results and recording or reporting them.

- 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.
- The research record is defined as the record of data or results that embody the facts resulting from scientific inquiry, and 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.
- 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.
- Reported credentials and qualifications must be accurately represented in all documents submitted to the Society (e.g., degrees earned, years since degree earned).

1.2 Research Misconduct by Peer Review Committee Members

The American Cancer Society has adopted the following definitions of misconduct in review 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. See Section 1.5.
- Failure to notify ACS personnel of actual, potential, perceived or potentially perceived conflicts of interest.
- Any communication pertaining to review related materials between a member[s] of a
 peer review committee and an applicant, or the mentor of an applicant, in the case of
 applications with an element of training as part of the application. See Section 1.4
- Any communication of the unpublished content of a grant application by a member or members of a peer review committee 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 Program 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 member of a peer review committee.
- Any review of, or use of, the contents of a grant application by a member or members of a peer review committee who might have, or be perceived to have, a conflict of interest with the applicant or his/her mentor, in the case of applications with an element of training as part of the application.

1.3 Professional Misconduct by Applicants, Grantees and Reviewers due to Harassment and/or Sexual Harassment

The American Cancer Society is committed to providing an environment that is free of discrimination and will not tolerate unlawful harassment of persons by others, including supervisors, volunteers, coworkers, grantees, reviewers or contractors. The American Cancer Society has adopted the following definitions of harassment and sexual harassment as forms of professional misconduct in addition to those definitions provided in sections 1.1 and 1.2 above:

- Harassment is unwelcomed conduct that is based on race, color, religion, ethnic or national origin, gender, age, disability, sexual orientation, gender identity, veteran status, caregiver status, and/or genetic information or any other factor that is a prohibited consideration under applicable law. Harassment becomes unlawful where (a) enduring the offensive conduct becomes a condition of continued employment, or (b) the conduct is severe or pervasive enough to create a work environment that a reasonable person would consider intimidating, hostile, or abusive.
- Sexual harassment is a form of discrimination and is therefore prohibited. Sexual
 harassment includes, but is not limited to, unwelcome sexual advances, requests for
 sexual favors, and other verbal or physical contact of a sexual nature, when:
 - Submission to such conduct is either an explicit or implicit term or condition of employment (e.g., promotion, training, or overtime assignments).
 - Submission to or rejection of the conduct is used as a basis for making employment decisions (e.g., hiring, promotion, or termination).
 - The conduct has the purpose or effect of interfering with an individual's work performance or creating an intimidating, hostile, or offensive work environment.

While it is not possible to list all those additional circumstances that may constitute sexual harassment, the following are some examples of conduct which, if unwelcome, may constitute sexual harassment depending upon the totality of the circumstances, including the severity of the conduct and its pervasiveness:

- Unwelcome sexual advances whether they involve physical touching or not
- Sexual epithets, jokes, written or oral references to sexual conduct, gossip regarding one's sex life; comments on an individual's body, comments about an individual's sexual activity, deficiencies, or prowess
- Displaying or distributing sexually suggestive objects, pictures, cartoons
- Unwelcome leering, whistling, brushing against the body, sexual gestures, suggestive or insulting comments
- Inquiries into one's sexual experiences
- Discussion of one's sexual activities

1.4 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.
- Any inquiries to a peer review panel member regarding an application from an applicant,
 PI, Co- PIs, consultants or their mentor, to a member of a Peer Review Committee or
 ACS Council for Extramural Grants must be reported immediately to the Program Director.

- All materials related to the review process must be destroyed or given to the Program staff 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, compact disks (CDs), flash drives, electronic files accessed via the internet, or oral presentations or discussions.

1.5 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 agreements or arrangements 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 3 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.
- 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 applicant or any person listed as key personnel on an application if the application was funded.
- Reviewers must not be pursuing research projects which might be viewed as being in direct competition with applicants or their collaborators and colleagues; nor have the potential to receive direct benefit from failure of the application to be funded.
- Reviewers must not have any cause of action against, any dispute with, any longstanding scientific or personal differences with, or any claim whatsoever against the applicant or any person listed as key personnel on an application.

Article 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 Program 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

Program 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 Program 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 (Program 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 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 Program 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 Program 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 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

3.1.1 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 Program 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 Program 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 non- acceptance 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, Program Director or ACS staff raise the issue of the allegation in a peer review meeting or meeting of ACS Council for Extramural Grants. 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 Program Director. The Program 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 investigationincluding any actions taken, or actions pending. Failure of the institution to carry out such an investigation in atimely 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, co- investigator, 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 Program 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 Program 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 officerwill be contacted. In the instance that the person[s] making the allegation does not contact the AmericanCancer 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 reinstituted by ACS at the date of notification of those findings by the sponsoringinstitution. If the allegation of scientific misconduct is confirmed, the award will be terminated and anyresidual 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-inchief 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 Pl or co-Pl 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 notlimited to, substituting or removing principal investigators or co-principal investigators, reducing awardfunding, 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 reinstituted 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 Program 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 Program 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

American Cancer Society (ACS) grants are managed using the Altum <u>ProposalCentral</u> Post Award Management System (PAMS). Grantees are asked to keep their ProposalCentral profile current for the duration of the grant. Grantees should refer to the Policies for their grant for information on required deliverables and allowable grant modifications.

Award deliverables can be accessed from the "award" area by selecting "award details" in ProposalCentral. Templates can be downloaded from the "Deliverables Templates" section at the bottom of the "Deliverables" section.

Completing a deliverable

- Download and save the template to your computer and complete it.
- To submit grant deliverables and other documents, click the "Upload" link next to the scheduled deliverable.
- Click "Browse" button to select the file from your computer.
- 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 then click "Save" (Adding description of deliverable is optional)

Adding a deliverable

- Click "Add Deliverable" on the Award Deliverables screen.
- Select the appropriate form from the drop-down menu next to "Deliverable Type" from the pop-up screen. If the form is not listed, select "Other" from the dropdown menu.
- Type in the "Deliverable Description" (e.g., IRB approval, Publications, No-Cost Extension, etc.)
- Select the date in which you are uploading the deliverable.
- Click "Save"
- Once deliverable option is added, return to the deliverable screen to upload added deliverable.

Required Deliverables

- 1. Grant Activation Form
 - Submit ~1 month before the grant start date.
 - Download from "Deliverables Templates," complete, and upload in the "Deliverables" section.
 - **Please Note**: By signing and submitting the <u>activation form</u>, the grantee institution certifies that IRB and/or IACUC approval has been received, if required.

Notify Greta McShan, the grants manager, via email at greta.mcshan@cancer.org after uploading the form.

2. Progress Reporting

- Required research and IP progress reports are pre-populated under the Deliverables area of the award profile.
- The TTO officer at the PI's institution is required to submit the IP progress report.
- 3. Report of Expenditures
 - Pre-populated under Deliverables

Send Email (Correspondence) to an ACS Administrator

- Click the "Correspondence" link from the Award Details screen
- Use the "Respond" link to respond directly to a message you have received

- To send a new message, click "Send Correspondence to Program Director" at the top of the page and select the administrator(s) who should receive the email
- Compose your message and send the email to the selected administrator(s)

Allow user access to your award and to submit deliverables

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. All awardees of an ACS grant <u>must</u> allow the institution's grants and contracts office access to their award information in ProposalCentral. You may need to allow access to additional users to enable them to upload reports on your behalf.

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

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

By phone: 1-800-875-2562 toll free By email: pcsupport@altum.com