BCRF BREAST CANCER RESEARCH FOUNDATION

Precision Prevention Initiative

2018 REQUEST FOR PROPOSALS

RFA Contents

Summary and goals of the program

Breast cancer mortality is at its lowest level in 30 years. This success has largely been fueled by advances in early detection and treatment. In contrast, our approach to cancer prevention has not progressed at nearly the same rate, as illustrated by the steady rates of breast cancer incidence over the same period.

At BCRF, we want to create a future in which women can benefit from the wide range of innovative strategies that can propel prevention as well as treatment, with advances in individual risk assessment, surveillance and risk reduction, using the tools of precision medicine, artificial intelligence, epidemiology and immunology to reduce the incidence of breast cancer with all possible speed.

The field of cancer prevention will evolve quickly as emerging technologies continue to be incorporated into all areas of precision medicine research. BCRF has long been at the vanguard of breast cancer research, playing a role in every major advance in clinical care. We now aim to take the lead in precision prevention.

The Precision Prevention Initiative (PPI) was conceived out of this vision. The overarching goal of this multiyear program is to fuel innovation and accelerate breast cancer prevention research by challenging the research community to think boldly; to explore multidisciplinary approaches to get the answers in less time, utilize new technologies or identify new ways to examine available data, and to build or enhance infrastructure, resources and tools that will facilitate innovation in prevention research for years to come. This inaugural RFA is launched with generous underwriting from Blizzard Entertainment. The PPI is intended to be a multi-year initiative for which BCRF is committed to fundraising to support continued efforts.

Through teleconference focus groups and an in-person think tank, the PPI steering committee identified three primary areas for impact: 1) Risk Assessment and Stratification; 2) Biomarkers; 3) Interventions.

For the 2019 funding period, BCRF is requesting applications that focus on **prevention of the most aggressive breast cancers – those with the greatest likelihood of causing death.** Projects should integrate multiple disciplines and where possible, to include areas of expertise and/or methodologies not normally associated with prevention or cancer research.

Two award opportunities are being offered: One-year pilot grants and 3-year multidisciplinary grants.

High-risk/high-reward concepts are encouraged.

Key Dates for 2018-19 application

Application submission period opens:	December 17, 2018
Letter of Intent (LOI) Due:	Feb 11, 2019
Scientific review of LOIs:	February 15 – March 1, 2019

The following dates are subject to change

Invitation to submit full proposals:	Notifications by March 8, 2019
Full Proposal due:	April 19, 2019 (invited LOI's only)
Scientific review of full proposals:	April 24 – May 10
Award notification date:	May 17, 2019
Award Start Date:	June 15, 2019

About the Breast Cancer Research Foundation

The Breast Cancer Research Foundation (BCRF) is dedicated to being the end of breast cancer by advancing the world's most promising research. Founded by Evelyn H. Lauder in 1993, BCRF-funded investigators have been deeply involved in every major breakthrough in breast cancer prevention, diagnosis, treatment and survivorship. This year, BCRF awarded $63 million to support the work of nearly 300 scientists at leading medical and academic institutions across 14 countries, making BCRF the largest private funder of breast cancer research worldwide. Visit www.bcrf.org to learn more.

Program Guidelines

Applications for the 2019 funding period should address the challenges and gaps in primary prevention of aggressive breast cancers with a focus in one or more of the following categories:

- Risk Assessment/Stratification
- Biomarkers
- Interventions

Eligibility Requirements

- Principal investigators on the research team must hold a primary academic faculty position of assistant professor or higher.
- Applications for multi-year awards must involve three or more investigators representing different scientific disciplines.
- Grantees will be responsible for data management, statistical analysis and quality assurance processes associated with their research and for all other aspects of study management required for a regulatory sponsor, and will comply with all applicable laws, regulations, rules, industry guidance, and Good Clinical or Laboratory Practice.

Institution Requirements

Applicant institutions must be non-profit research institutions with the appropriate resources and support required to execute the proposed research. All subcontracted institutions must meet the same criteria and agree to the award conditions and policies and procedures of BCRF as outlined in the award contract.

Institutional Assurances

Clinical Trials/Human Subjects Research: As a condition of support, institutions and investigators must provide documentation of both the initial IRB/Ethical Committee approval and annual renewals of that approval, as applicable. IRBs must include date of approval and expiration, project title, primary investigator name and list BCRF as a funder. No award can be initiated without documented IRB approval and patient informed consent documentation (ICD), as applicable.

Research involving animals: The USDA Animal Welfare Act and the NIH Public Health Service Policy on the Humane Care and Use of Animals require that institutions conducting research with animals establish an Institutional Animal Care and Use Committee (IACUC). Institutions and Investigators must provide documentation of IACUC approval and annual reviews of animal use protocols. Approval letters must include the date of approval and expiration, project title, primary investigator name and name BCRF as a funder. No award can be initiated without documented IACUC approval, as applicable.

Data Sharing: Data generated by funding through the Precision Prevention Initiative is expected to be made available to the research community to the fullest extent possible within local regulations and

policies. A detailed data sharing plan or explanation for why data cannot be shared must be provided in the full proposal. Please refer to https://grants.nih.gov/policy/sharing.htm for guidelines.

Publication: All abstracts, manuscripts, and presentations of a study conducted under an approved award must be shared with BCRF. BCRF does not have veto privilege over the reporting of study results.

For more information, please refer to the **Frequently Asked Questions** or contact BCRF directly.

PPI Contacts:
Karin Lilja, PhD, Scientific Program Manager: klilja@bcrf.org (646-497-2641)
Sarah Boll, MSWL, Senior Program Manager: sboll@bcrf.org (646-497-2628)

To Apply

All letters of intent and applications must be submitted through the BCRF Grants Portal: https://www.grantinterface.com/Common/LogOn.aspx?urlkey=bcrfcure. If you already have an account, use your username and password to log in. If you do not have an account, you will need to create one by clicking on "create account." After logging in, click the apply button on the top menu. Then click the blue apply button next to the "2018-2019 Precision Prevention Initiative."
A few helpful hints:

- Add administrator@grantinterface.com to your safe sender list. Many of our grant related emails (eg. submission confirmations, award notices, and follow-up reminders) come from this address. Click here for instructions for your email client.
- Helpful new user tutorials: Video or Written

Pilot grants. Pilot grants are intended to provide interested parties the opportunity to develop pilot data to support a fully developed multidisciplinary concept. These awards are for a single year but must have for up to $100,000 and can be submitted by an individual investigator or team.
Proposal requirements:

- A working title for the planned project
- A short description of the project, including
    - Background, significance, short- and long-term goals;
    - Research plan, expected outcome and how the pilot data will facilitate a larger multidiscipline effort in breast cancer prevention research;
    - Areas of expertise and resources required to conduct the proposed research;
    - Budget (including no more than 20% in indirect cost allocations.);
    - If the concept is submitted by more than one investigator, names and biosketches of co-investigators is required.

Three-year grants These are multi-disciplinary grants with awards from $500,000 - $750,000 per year. These awards must involve three or more investigators representing different scientific disciplines.
Proposal requirements

- Milestone timeline identifying both short- and long-term measurable milestones with defined metrics of success.
- Laboratory-based studies should have a clear translational path.
- Intervention studies should include a path to implementation.
- All studies should include a data sharing plan that outlines how the data can be accessed by the research community and where it will be housed.

- Projects may be supplemental to current funding but must expand the grant holder's research question in a new direction relevant to this RFA.
- Biosketches for co-investigators and key personnel
- Letters of institution support
- Letters of collaboration from co-investigators and collaborators

Proposal Components

Letter of Intent:

The online LOI for both pilot and 3-year applications are submitted on the same form, requiring the following information:

- Applicant details
- Selection of pilot of 3-year grant
- Project title
- Amount requested and expected duration of project
- Keywords and research categories
- Lay and Scientific Abstracts
- Study concept: A narrative of no more than 2-3 pages describing the rationale for the proposed work, study design, study population, endpoints, expertise, and planned resources.
- Proposed budget and justifications.
- Investigator biosketches in NIH (short) format (no more than 5 pages, no CVs)

The letters of intent will be reviewed by a panel of expert reviewers. Selected applicants from the LOI stage will be invited to submit full proposals.

Full application

Detailed instructions will be provided to those invited to submit a full proposal. Applicants should expect to submit the following:

- **Lay abstract:** No more than 250 words, written for review by a lay advocate and to be shared with BCRF donors and constituents. The lay abstract should succinctly outline the reason for the study, innovations, and how it will impact prevention of aggressive breast cancers.
- **Research Proposal**: The proposal section should be no more than 10 pages including references and must include the following sections under separate headings:
    - **Background/Rationale**: This section should state the need and scientific rationale supporting the proposed research and study design, explain how it is innovative and its impact on breast cancer prevention.
    - **Hypothesis**
    - **Specific Aims**
    - **Methods/Research Plan,** including details of how each area of expertise contributes to the study design.
    - **Feasibility Plan:** including details related to available resources and those that will require permission to access
    - **Study Timeline with milestone tracker** (outline of expected deliverables and outcomes)**:** All studies should be feasible within the study timeline and not assume the opportunity for renewal. For multi-year proposals, the study timeline should be commensurate with requested budget for each year.

- **Statistical Plan** including detailed statistical design describing endpoints (including secondary and other descriptive endpoints, clinical or lab correlatives), stratification plans as applicable, sample size with power justifications, analysis (including plan for interim analysis), expected accrual rate (if applicable) and time for accrual (if applicable).
- **Data Sharing Plan**
- **Clinical Significance:** Pre-clinical studies should demonstrate a clear path to clinical translation and intervention trials should include a plan for implementation (even if implementation is not intended to be part of the original project)
- **Budget and Justifications:** Budgets should realistically align with work proposed for each year. Large unexpended balances at the end of a budget year will delay subsequent payment.
- **Study Personnel and Expertise**: Detail study personnel, level of effort and how each will contribute to the study.
- **Biosketches:** For key personnel only
- **Letters of institution support and collaboration:** Letters of institution support should verify available resources as described in the proposal and indicate they can accept BCRF terms and conditions without modifications. Multi-institution awards require letters of support from each institution. Letters of collaboration should include details of shared resources and/or expertise as described in the proposal and acceptance of BCRF terms and conditions.

Appendix A: Frequently asked questions

Request for applications

Do I have to already be funded by BCRF to be eligible for this RFA? No. While applicants may be currently funded BCRF Investigators or may wish to collaborate with currently funded BCRF Investigators, the RFA is open to all applicants who meet the eligibility requirements.

Do I have to be at a U.S. institution? No. International applications will be accepted.

Will multi-institution applications be accepted? Yes. Applications involving multiple institutions should have MTAs or other agreements in place to avoid delays in execution of work (Though not required at time of application submission, agreements will be required before payment is issued). Each participating institution must be willing to accept BCRF award conditions, policies and procedures. See Appendix B: BCRF Award Conditions, Policies and Procedures

How will awards be paid? Awards will be paid via wire transfer after the investigators and institution officials have completed a payment request form and accepted BCRF Terms and Conditions. Awards to multi-institution collaborations will be paid to the submitting institution. Split payments to participating institutions is not possible.

What is the selection process of LOI and full proposals? A Steering Committee and Special Review Committee have been established to oversee the PPI program and to review LOI and full proposals. Each LOI and full proposal will be reviewed by at least two qualified reviewers. Ad hoc reviewers may be added, as needed, to ensure appropriate scientific expertise for rigorous evaluation of all letters of intent and full proposals. The Steering Committee will consider the reviews from the Special Review Committee and make recommendations for funding. The BCRF Board of Directors with make final decisions based on the Steering Committee recommendations.

What is BCRF's Data Sharing policy? BCRF does not have a formal data sharing policy at this time but recommends applicants and applicant institutions adhere to NIH policies. The requirements of a data sharing policy for this RFA are intended to accelerate the goals of the initiative by making data freely available to other PPI awardees and the research community.

Using the BCRF grants portal

How do I submit my letter of intent? All letters of intent and full proposals are submitted through the BCRF Grants Portal at: https://www.grantinterface.com/bcrfcure/Common/LogOn.aspx.

Can I save my application and finish it later? Yes. You can select "Save" at the bottom of application form. IMPORTATNT: To return to a saved application, go to your dashboard, select the application under "processes" and click on the edit link to continue the application. DO NOT GO TO THE APPLY PAGE TO RETURN TO A SAVED APPLICATION. THIS WILL START A NEW (BLANK) APPLICATION.

Can I print my application? Yes. At the top left of the page, there is a link to "Application Packet." This will download the application form and your entries as a PDF file. Documents that were uploaded in the form will be at the end of the form pages. You can print the form or save it for your records. DO NOT EMAIL OR MAIL PROPOSALS TO BCRF.

I can't log into the BCRF portal. Be sure you are going to the correct site here: https://www.grantinterface.com/bcrfcure/Common/LogOn.aspx

I get an error message when I try to log in to the BCRF grants portal. We recommend trying a different browser if you get an error message when you try to log on, Chrome seems to work best.

I can't remember my password to log into the BCRF grants portal. To reset your password, click on "Forgot Password" to receive instructions to reset your password. Be sure to check your junk mail folder if you do not receive instructions.

What if I need to change my contact or institution information? To edit your contact information, click on your name in the top menu and click "edit organization." Be sure to SAVE the new information. NOTE: Organization name cannot be edited. BCRF uses the institution name as it appears in the organization box for internal reports only. It is not used for payment or correspondence. This is the institution name, as it will appear in any system-generated emails.

Can my assistant or grants administrator submit documents on my behalf? Only the registered portal account holder can submit documents or be assigned follow ups. The software does not currently allow multiple users with unique log in information on the same account. If someone else is submitting documents on the grantee's behalf, they will need the email address (this is the log in) and password for the registered account holder.

Can my assistant or grant administrator to be copied on any emails regarding my grant? Please note that while BCRF will do its best to copy relevant parties in grant correspondence, it is the responsibility of the grantee to forward important emails to others in their organization responsible for completing an action. All batch emails or automated reminders will go the registered portal user only.

I have other questions about using the portal not listed here. Please review this tutorial on how to start and edit applications (video: https://drive.google.com/file/d/0B8P9ImR-APIbOVI5YVBFUWpXbnc/view), written: https://docs.google.com/document/d/1HyVKOrd9FiHscI3tsupIHKpwzcrMRqwWF43t4zXK9NY/edit).

If you still have questions, contact the BCRF grants team at grants@bcrf.org

Appendix B: Policies and Procedures

The following award conditions, policies and procedure are for the 2018-19 grant year and are subject to change.

I. Award Conditions

1. The granted funds will be used solely for clinical and/or translational research described in the Beneficiary's submitted proposal. Substantive changes in the direction of the research project should be discussed with BCRF staff.
2. The maximum overhead allocation permitted will be twenty percent (20%) of the total direct costs.
3. All publications based wholly or partially on research supported by Breast Cancer Research Foundation (BCRF) granted funds must be acknowledged by the inclusion of the following statement: "(Supported) (Supported in part) by (a grant) (grants) from the Breast Cancer Research Foundation." If the award(s) referenced were issued in 2016 or later, include the BCRF award ID that was provided with your grant agreement (BCRF-YY-XXX). BCRF should be listed as "Breast Cancer Research Foundation" in the Beneficiary's Annual Report, and BCRF would be grateful if its support was also acknowledged in interviews, institution press releases, or other public discussions of the related research. Investigators can identify themselves as or ask to be identified as a "BCRF Investigator" in those public discussions.
4. At least eighty percent (80%) of funds received from BCRF must be expended by the end of the grant year, as a requirement for applying for future grants.
5. By accepting this award, the grant recipient and sponsoring institution agree to adhere to these Grant Award Conditions, including the intellectual property policy.
6. The grant recipient must provide a statement of financial conflict of interest prior to contract initiation.
7. The grant recipient should understand that she/he may be invited to attend BCRF-related events or asked to accommodate a donor request on behalf of BCRF, with the clear understanding that BCRF will not require attendance or participation as a condition of the award. BCRF will make every effort to minimize the frequency of such invitations, to coordinate scheduling with the grant recipient's availability, and to reimburse reasonable travel expenses associated with attendance at such events/requests.

II. Policies and Procedures

1. Only the investigator(s) addressed in the invitation to submit a proposal is(are) considered BCRF investigators upon approval of the award. All approved BCRF investigators have the following privileges:
    a. A researcher profile on the BCRF website (http://www.bcrf.org/researchers)
    b. Included on grantee lists and announcements
    c. Invited to attend the annual October Luncheon and Symposium
2. Award Cycle
    a. BCRF applications are by invitation only by the Scientific Advisory Board.
    b. Unless otherwise stated, each BCRF award is for one year, typically from October 1 to September 30. In May of each year, the BCRF Scientific Advisory Board (SAB) invites renewal applications from current grantees based on progress, available funds and program priorities. If invited, renewal applications are due by June 15 and are submitted through the BCRF grants portal.
    c. New awards that are initiated outside of the October 1-September 30 cycle, will start and end based on the date of contract execution or other agreed to date. If considered for renewal, a partial pro-rated award may be offered to extend the grant term to the end of the current BCRF grant year (September 30). As an example, an award that starts

March 1, 2016 and ends February 28, 2017, may be offered a pro-rated award from March 1 through September 30, 2017. The supplemental award will be treated as an amendment to the current award extending the grant term and award amount. In this example, the awardee would be invited to submit a renewal proposal in June for an award that would start October 1, 2017.

3. Reporting and Communication
    a. All reports and deliverables are submitted through the BCRF grants portal as follow ups to the award.
    b. Grant-related correspondence will be sent from the portal email server only to the investigator holding the BCRF portal account. **The party receiving this communication is responsible for forwarding information about deadlines and instructions to the party(ies) responsible for completing the required action.**
    c. Unless otherwise notified by BCRF, an annual progress and financial report is required to assess progress and eligibility for renewal. This report should describe progress to date and must show actual (not estimated) disbursement of funds, including overhead allocation, and provide explanations for significant variance from the approved budget.
    d. Final financial reports are due within 60 days of the end of the grant year. Balances greater than 20 percent of the awarded budget require justification and detailed plans to spend down the balance and must be approved by BCRF. <u>March payment for the current year may be withheld if a final financial report for the previous year is not provided.</u>
4. Budgets, no cost extensions and carry forward balances
    a. All budgets and financial reporting are in US dollars at the current exchange rate. Investigators should not adjust the award budget based on exchange rate in their BCRF reports. If a balance or over expenditure occurs due to exchange rates, this should be noted in the justifications. Any refunds on awards must be paid in US dollars at the current exchange rate.
    b. BCRF does not impose spending restrictions in any budget categories. However, major equipment (i.e. capitol purchases) are not considered a part of research budget and should be discussed with BCRF.
    c. Travel funds greater than $5,000 per year should include detailed justifications. Travel funds to attend BCRF events are not allowed as these expenses are paid for or reimbursed by BCRF.
    d. BCRF funds may be used for postdoc salaries. Visa costs are permissible but should be discussed with BCRF. Tuition for graduate students is not allowed.
    e. Pre-award spending is not allowed without prior approval from BCRF.
    f. BCRF does not require pre-approval for common budget reallocations, but we appreciate notification of any significant changes to the budget so that we can keep our records current. A budget reallocation template is included in the budget and financial report template.
    g. End of year balances of less than 20% of the awarded budget do not require BCRF approval to be carried forward to a renewing award but must be reported on subsequent financial reports. Unspent funds should not be returned to BCRF if the awardee has received continued funding from BCRF.
    h. Balances may be carried forward to a renewing award.
    i. No cost extensions (NCE) may be granted in cases where awardees are not receiving renewal money and need to extend their current award.

j. In rare cases of balances over 50% of previous year's award, BCRF may offer a current grantee an NCE award in lieu of renewed funding in a particular year. These decisions are made at the discretion of BCRF and are based on large balances or other circumstances that have delayed progress. This does not disqualify the grantee for renewed funds in the next funding cycle or alter his/her privileges as a BCRF investigator outlined in Section II.1.
k. Indirect costs may not be applied to balances carried forward to subsequent years.
l. Carry forward of negative balances is not permitted without prior approval from BCRF.
m. Balances on past awards that are still active must be reported annually. Awards will have scheduled follow ups until the balance is spent down or applied to a current award.

5. Sub awards
    a. BCRF terms and conditions apply to sub awarded institutions.
    b. Indirect cost rate may not be collected by both the prime and the sub award institutions.
    c. BCRF does not require a detailed budget or financial report for the sub award but reserves the right to request one.
6. Payments
    a. BCRF payments are to one institution only. Payments to support the effort of co-investigators at other institutions are handled as subcontracts between the institutions.
    b. BCRF awards are split into two equal payments that are paid on the first day of October and March, respectively unless otherwise indicated in the award letter.
    c. All award payments are made by wire transfer in US dollars.
7. Conduct of Research
    a. **Studies involving Human Subjects**. BCRF assumes that all US grantee institutions are compliant with the Federal Policy for the Protection of Human Subjects, HHS regulations, 45 CFR part 46. Copies of IRB approval letters are requested on applicable proposal applications.
    b. **Studies involving animals**. BCRF assumes that all US grantee institutions are compliant with the NIH's Office of Laboratory Animal Welfare and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. Copies of IACUC approval letters are requested on applicable proposal applications.
    c. **International awards.** BCRF assumes non-US investigators are compliant with institution policies and local laws regarding human and animal research. If available, copies of the appropriate approval letter should be provided. Approval letters not in English should be accompanied by a cover letter in English stating compliance.
    d. Studies should be conducted pursuant to Good Laboratory Practice and/or Good Clinical Practice.
8. Intellectual property and Financial Conflicts of Interest
    a. BCRF's policy on intellectual property is regularly reviewed to be in line with policies of similar private funders of biomedical research. Requests for modification of the policy are considered only if specific terms are incompatible with institution policy and on the recommendation of BCRF legal counsel. A mutually accepted intellectual property policy is required prior to contract initiation. A copy of the final policy will be provided with award execution.
    b. A statement of financial conflict of interest is required prior to contract initiation. BCRF assumes that all US grantee institutions are in compliance with the NIH guidelines

(Federal Register 42 CFR 50.603; 45 CFR 94.3) on financial conflict of interest reporting and management and does not require institution documents outlining this compliance.

9. Changes of Institution or Primary Investigator (PI)
    a. Changes to or addition of PI(s) on an existing or renewing award must be approved by the BCRF Scientific Advisory Board. Requests to add or change a PI should be sent via email to Sarah Boll (mailto:sboll@bcrf.org) or Karin Lilja (mailto:sboll@bcrf.org)
    b. Transfer of a BCRF award is not allowed.
    c. Changes of primary institution must be approved by BCRF before transfer of award. Please contact BCRF as soon as the new appointment is confirmed. The following items are required:
        i. Letter from BCRF investigator with effective end date at current institution and start date at new institution. This can be provided via email notification.
        ii. Letter from new institution acknowledging faculty appointment and start date. Prepared on institution letterhead and signed by department head.
        iii. Letter from old institution relinquishing award. Prepared on institution letter head and signed by authorized institution official.
        iv. Final financial report from old institution showing all charges against the award and final unspent balance
        v. Return of unspent funds to BCRF
        vi. Submission of new proposal by investigator. In some cases, BCRF may be able to transfer the original award to a new account in the portal.
        vii. New institution contacts and payment form.
        viii. Signed grant acceptance letter from new institution.

Upon receipt and review of the above documents, the unspent balance will be paid to the new institution on behalf of the PI.

III. Conflict of Interest

At the time of award acceptance, the Breast Cancer Research Foundation requires awardees to declare Significant Financial Interests, Fiduciary Relationships, and Executive Positions:

1. That could reasonably give the appearance of being affected or actually be affected by the research for which BCRF funding is sought; or
2. in entities whose interests would reasonably appear to be affected by the research.

DEFINITIONS

As defined in the NIH guidelines on financial conflict of interest (Federal Register 42 CFR 50.603; 45 CFR 94.3), **Significant Financial Interest** means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
    a. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
    b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the

Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Fiduciary Relationship exists when an Investigator is obligated to act in the best interests of another entity because of a position that the Investigator holds with such other entity. The other entity can be either for profit or not-for profit; it can be a corporation, partnership or other form of organization. Positions that often give rise to Fiduciary Relationships include service in an Executive Position or as a member of the Board of Directors or other governing body. For purposes of this policy, Fiduciary Relationships arising from an Investigator's primary employment by a not-for-profit academic institution, research center or hospital/health care institution are not included.

Executive Position means any position which includes fiduciary and other responsibilities for a material segment of the operation or management of a business. It specifically includes positions with the titles of "Scientific Director" and "Medical Director."