

GRAY FOUNDATION

BASSER INITIATIVE @ GRAY FOUNDATION TEAM SCIENCE GRANTS

PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS

PROGRAM GUIDELINES

ABOUT THE BASSER INITIATIVE @ GRAY FOUNDATION

The Basser Initiative is a program of the Gray Foundation, which aims to support research, and improve treatment and prevention of BRCA-related cancers. These hereditary mutations affect both men and women, and can be passed down from either parent. BRCA mutations can increase lifetime risk for cancers including breast, ovarian, pancreatic, prostate, and melanoma.

TEAM SCIENCE GRANTS PROGRAM MISSION STATEMENT

The mission of the Basser Initiative Team Science Grant Program is to fund highly meritorious research projects that bring together the best minds in cancer research to develop new therapies, prevention approaches, and better understanding of the fundamental mechanisms at play in BRCA-related cancers. The funded research projects will be multidisciplinary and, preferably, multi-institutional.

GRANTS TERMS AND FUNDING

The funding will be for a period of 3-5 years for a total of up to \$3-5 million (up to \$1 million/year). The Foundation plans to award 2-4 grants.

DEADLINES

- LOI deadline: **December 17, 2018, at 12:00 pm ET**
- Full Application deadline (upon invitation): **March 1, 2019, at 12:00 pm ET**
- Projected start of grant term: **July 1, 2019**

APPLICANT ELIGIBILITY CRITERIA

- Principal Investigators must hold a medical or other doctoral degree and have a faculty appointment at an academic, medical, or research institution equivalent to an Assistant Professor, or higher.
- Applicants must be academic, medical, or research institutions anywhere in the world.
- For-profit enterprises are not eligible to apply, but may be listed as collaborators. However, no grant funds may be directed to collaborators working within a for-profit industry.
- Specific projects already receiving funding from the Gray Foundation or the Basser Center are not eligible (no overlap allowed).
- Applicants with questions about eligibility should contact the Gray Foundation (grants@grayfoundation.org) prior to submitting a Letter of Intent (LOI).

RESEARCH PROJECT CRITERIA

The goal of the Basser Initiative @ Gray Foundation is to fund projects led by **multidisciplinary teams of researchers** that will perform highly innovative research focused on the following areas of BRCA research:

Prevention of BRCA-related cancers

- **Understanding biology of early lesions and carriers (including the microenvironment) to determine targets for prevention**
- **Understanding immune surveillance**
- **Study of immune targets (for vaccine)**
- **New technologies (imaging, pathological, genetic, immune health, etc) for risk stratification and early detection**
- Development of strategies for personalized risk assessment
- Development of better biomarkers
- Improved risk reduction strategies

Clinical research on BRCA cancers

- **Clinical trials infrastructure initiative involving multiple sites. To allow the prioritization of BRCA1/2 specific trials at funded sites and allow for rapid onboarding of investigator-initiated studies (with drug costs from companies).**
- **A biorepository for serial plasma, tumor and normal tissue samples (multiple sites required)**
- Understanding the role of the immune response. Is it different in BRCA cancers?
- Strategies to better understand and overcome resistance to platinum agents and PARPi
- Development of new combinations of PARPi with other agents (other targeted agents, immune therapy, chemotherapy)
- Effects of sequence of agents and drug dosing choices.

Basic science of BRCA cancers

- **Description of the events (environmental, genetic, epigenetic) that explain the tissue tropism of BRCA mutant tumors. Could this impact preventative and therapeutic modalities?**
- Functions of the BRCA proteins in genome integrity control
- Determinants for viability and therapeutic response in BRCA mutant cancers at the cellular, biochemical, organismal level (cell autonomous and non-cell autonomous mechanisms)
- Can BRCA tumors stimulate an effective anti-tumor immune response?

Grants will fund proposals that have significant potential for translational impact and hold great promise for advancing the Gray Foundation's goal of improving and saving the lives of patients with BRCA-related cancers.

Proposals including biobanking and the use/generation of a BRCA cancer registry are highly encouraged.

EVALUATION

The Gray Foundation Scientific Committee will review all LOIs and will identify a subset that will be invited for the submission of a Full Proposal. Invited Full Proposals will also be reviewed by the Gray Foundation Scientific Committee, which will provide recommendation for funding.

The following criteria will be considered for each application:

- **Innovation.** Does the project utilize novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- **Significance.** Does the project address an important problem or a critical barrier to progress in the field of BRCA research? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions in BRCA cancers?
- **Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project within the grant term?
- **Clinical/Translational Potential.** Does the work hold great promise for improving and/or saving the lives of BRCA patients?
- **Investigators/Team/Environment.** Are the investigators well suited to the project? Do they have an ongoing record of accomplishments that have advanced their field(s)? Do collaborators appropriately fulfill a critical need of the project? Is the research environment appropriate?

GRANT POLICIES

Changes to Application. After the submission deadline, applicants are not permitted to change the project nor the Investigator proposed in the LOIs or Full Proposals. Once approved, projects can be modified as research progresses, but material changes require consultation with the Gray Foundation and may affect future grant payments.

Grant Agreement. A Grant Agreement will be executed between the Gray Foundation and the grantee institution setting forth the terms and conditions of the grant.

Initiation of the Research Project. The grantee must agree to initiate the research project described in the proposal on or about the time the first grant payment is received by the grantee. If the grantee is unable to commence the research project at

that time, the grantee must contact the Gray Foundation to discuss the timeline for the project.

Use of Funds. The grant funds may be used for direct research expenses attributable to the proposed research, which may include the following:

- A percentage of the salary and benefits expenses (limited to 20 percent of the total budget) of the grantee and any collaborators (no grant funds may be directed to collaborators working within government institutions or for-profit industry)
- Salary and benefits expenses of postdoctoral or clinical fellows, research assistants, or technicians
- Equipment, supplies, and other laboratory or clinical expenses
- Travel expenses relevant to the research project
- Expenses related to publication page charges

Tuition and professional membership dues are not allowable expenses.

Any indirect costs charged by the institution will be negotiated, but the indirect costs cannot exceed 10% of the total budget.

Payments. Annual installment payments will initiate upon execution of the Grant Agreement. Each payment is contingent upon grantee's compliance with the Grant Agreement, including the timely submission of progress and financial reports, and the Foundation's satisfaction with the progress of the project.

Reporting Requirements. Progress Reports, including a financial accounting of expenditures, are to be submitted twice a year, with the first one due 6 months after the beginning of the grant term. Templates for the completion of the reports will be provided to the grantees at least one month prior to the report due dates.

A final written progress and financial accounting report will be submitted no later than sixty (60) days after the ending date of the grant term. Detailed instructions on completion of a satisfactory progress and financial report will be provided prior to the report due date.

Grant termination. Failure to comply with the Grant Agreement, including the timely submission of progress and financial reports, or to achieve satisfactory progress toward the project's pre-defined milestones and deliverables may result in the termination of the grant.

Intellectual Property. Any intellectual property derived from the research funded by the grant will be the property of the grantee and/or its assigns. To the fullest extent permitted by the grantee's institutional policies, the grantee will use any income received by the grantee from the licensing of inventions resulting in whole or in part from the grant, net of any expenses and any payments owed to researchers pursuant to the grantee's royalty sharing arrangements, to support BRCA-related research at the

grantee institution. The grantee will report to the Gray Foundation on the receipt and use of such income at least annually.

Publications and Acknowledgment of Support. Subject to the Gray Foundation's approval, the grantee agrees to acknowledge the grant in any written public statement, press release, article, or announcement associated with the project, including articles appearing in scientific journals and other publications, and to otherwise acknowledge the grant in a similar manner to other grants. When acknowledging the grant, the grantee will refer to the grant as part of the Gray Foundation's "Basser Initiative."

Indemnification. The grantee will agree to indemnify the Foundation and its personnel from and against any and all liabilities arising from the project or the actions or omissions of the grantee and its personnel.

Organizational Assurances. It is the responsibility of the grantee to ensure that organizational assurances/certifications are obtained.

For research involving human subjects, the grantee will certify the following:

- The proposed research project has been reviewed and approved in writing by an accredited university or medical school Institutional Review Board (IRB) constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services (HHS) and approved by HHS, or by the Association for the Accreditation of Human Research Protection Programs (in the absence of an HHS-approved university or medical school IRB).
- The grantee will secure a legally acceptable informed consent from all human subjects taking part in any research supervised by such grantee funded in whole or in part by this grant in accordance with and to the extent required by current regulations promulgated by and approved by HHS. IRB certification should be documented by submitting a copy of the institutional letter of approval, which identifies the grantee and grant-associated members responsible for the relevant component, project title, the Gray Foundation as the funding agency, the date of approval, and is signed by the IRB Chair or equivalent responsible institutional official. The project must have been reviewed and approved by the IRB Chair or an equivalent responsible institutional official. Prior IRB certification for another project cannot be substituted, but can be officially amended to include the proposed project.

For research involving animals, the institution will ensure compliance with applicable chapters of the Public Health Service Animal Welfare Policy, the NIH Manual for Grants and Contracts, and any and all requirements of the institution concerning animal welfare. Certification by the Institution Animal Care and Use Committee (IACUC) or equivalent will be documented by submitting a copy of the institutional letter of approval, which identifies the grantee, project title, the Gray Foundation as the funding

agency, the date of approval, and is signed by the IACUC Chair or equivalent institution official. Prior IACUC certification for another project cannot be substituted, but can be officially amended to include the proposed project.

LETTER OF INTENT SUBMISSION INSTRUCTIONS

Letters of Intent (LOIs) must be submitted through email to grants@grayfoundation.org before **12:00 pm (noon) United States Eastern Time on December 17, 2018**. Only one LOI per investigator will be accepted. A limited number of applicants whose LOIs are deemed most meritorious will be invited to submit Full Proposals and be considered for the available grants. A decision regarding the LOI will be provided to the applicants by January 15, 2019.

The materials to be submitted:

- Signature form
- LOI submission form (detailed instructions on the form)
- Researchers' Biosketches
- Letter of Institutional Commitment (The letter must be written by the department head, dean, or other senior member of the institution. The letter must include a statement that the institution understands and agrees to the indirect cost policy of the Gray Foundation.)

Note: no budget is required at the LOI phase

Submit all the materials above to grants@grayfoundation.org.

IMPORTANT: A receipt confirmation email will be sent to the applicants within one (1) business day of LOI submission. If you do not receive this email after sending your application, you should immediately contact the Gray Foundation (see contact information below). **It is the responsibility of the applicant to ensure the Letter of Intent was completed correctly, all required information is present, and that the Letter of Intent was received by the Gray Foundation.**

Changes to the LOI: Any change to the submitted LOI past the submission deadline must be sent to the Gray Foundation as soon as possible. Changes in material aspects of the LOI (investigators, aims, milestones, etc) may be allowed or declined in the Gray Foundation's discretion.

INQUIRIES

Inquiries about the program guidelines, eligibility requirements, application materials, and application status can be directed to the Gray Foundation at grants@grayfoundation.org.

(INVITED) FULL PROPOSAL SUBMISSION INSTRUCTIONS

Only invited applicants may submit Full Proposals. Completed Full Proposals should be emailed to the Gray Foundation by **12:00 p.m. (noon) United States Eastern Time on March 1, 2019**, at grants@grayfoundation.org.

The materials to be submitted:

- Signature form
- Full Proposal form (Detailed instructions on the form)
- Budget
- Budget justification
- Researchers' Biosketches
- Letter of Institutional Commitment (The letter must be written by the department head, dean, or other senior member of the institution. The letter must include a statement that the institution understands and agrees to the indirect cost policy of the Gray Foundation.)
- Project milestones and deliverables (form)
- Appendices (if applicable), i.e., Institutional Approval Letters for Research involving human and/or animal subjects

Submit all the materials above to grants@grayfoundation.org.

IMPORTANT: A receipt confirmation email will be sent to the applicants within one (1) business day of the Full Proposal submission. If you do not receive this email after sending your application, you should immediately contact the Gray Foundation (see contact information below). **It is the responsibility of the applicant to ensure the Full Proposal was completed correctly, all required information is present, and that the material was received by the Gray Foundation.**

Changes to the application: any change to the submitted application past the submission deadline must be sent to the Gray Foundation as soon as possible. Changes in material aspects of the Full Proposal (research, budget, milestones, etc) may be allowed or declined in the Gray Foundation's discretion.

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