The mission of Susan G. Komen® is to save lives by meeting the most critical needs in our communities and investing in breakthrough research to prevent and cure breast cancer

INFLAMMATORY BREAST CANCER INNOVATOR GRANTS

Generously Supported by the Milburn Foundation and the Inflammatory Breast Cancer Research Foundation

2016-2017 Request for Applications

Susan G. Komen
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INFLAMMATORY BREAST CANCER RESEARCH GRANTS

Susan G. Komen, the Milburn Foundation, and the Inflammatory Breast Cancer Research Foundation have entered into a groundbreaking partnership to provide a unique funding opportunity addressing key needs in this understudied form of breast cancer.

Susan G. Komen envisions a world without breast cancer. In order to reach this goal, we must develop treatments for all forms of breast cancer, including those that are rare and difficult to diagnose or treat such as inflammatory breast cancer.

Inflammatory breast cancer (IBC) is a rare, but aggressive type of locally advanced breast cancer. Although sometimes a lump in the breast can be felt with other types of breast cancer, it is less common with IBC. With other breast cancers, warning signs may not occur for years. However, with IBC, signs tend to appear much faster.

Because of the frequent lack of a breast lump and symptoms such as redness and swelling, IBC may first be mistaken for an infection. IBC is often diagnosed after symptoms do not improve with a course of antibiotics.

Because IBC is both aggressive and difficult to diagnose, most patients with IBC have advanced-stage disease by the time they begin treatment.

Additional IBC research is required to increase our understanding of how IBC can be better diagnosed and how biology drives its progression, thereby leading to improved prognosis and more effective treatment for those with this aggressive disease. These grants are intended to spur ideas that will impact not only IBC, but also Triple Negative Breast Cancer (TNBC), as a greater portion of IBC cases are also triple negative. Therefore, the goal is that by improving our understanding of IBC, we can simultaneously increase the understanding of how to target and treat TNBC.

A major goal of this partnership is to promote innovative ideas to expand the knowledge of IBC and develop innovative new treatments. An additional goal is to attract new investigators from diverse disciplines to apply their expertise to the IBC field. Therefore, in addition to established IBC investigators, we encourage investigators from all fields to submit proposals for innovative IBC research, regardless of prior research experience.

These Inflammatory Breast Cancer Research Grants are intended to stimulate the exploration of new ideas and novel approaches to the field of IBC research that have significant potential to rapidly improve our understanding of IBC and TNBC. This program will consist of two stages. In the first stage, one year of funding will be awarded to allow investigators to establish the foundation of a robust and innovative IBC research project. In the second stage, awardees will have the opportunity to compete for additional funding to build upon their original project. Such projects may include, but are not limited to, methods that will:

- Develop novel diagnostic methods for rapidly identifying and diagnosing IBC
- Refine genetic/genomic profiling of IBC
- Discover new targeted therapies for IBC
- Explore and further define the causes of IBC
- Discover additional risk factors for IBC

ABOUT THE PARTNERS

Susan G. Komen

At Susan G. Komen®, we are committed to saving lives by meeting the most critical needs in our communities and investing in breakthrough research to prevent and cure breast cancer. Our Research Program is an essential driving force for achieving this mission.

Komen has sustained a strong commitment to **supporting research** that will identify and deliver cures for breast cancer. This commitment has resulted in important progress that has contributed to many significant advances in breast cancer over the past 30 years. Since its founding in 1982, Komen has funded more than $920 million in research, provided $2.9 billion in funding to screening, education, treatment, and psychosocial support programs, and has served millions of people in more than 30 countries worldwide.

Our research focus has evolved over the years. In the beginning we focused on understanding the basic biology of breast cancer. As we learn more about the factors that make cancer cells grow and spread, we are able to invest more in the translation of this knowledge into treatment, early detection and prevention, ***with the goal of supporting work that has significant potential to lead to new treatments and technologies that will reduce the number of breast cancer deaths by 50 percent within the next decade.***

Milburn Foundation

The Milburn Foundation is a private charitable organization that supports progressive research to cure breast cancer and Triple Negative Inflammatory Breast Cancer (TNIBC) by working with partners in innovative ways.

The Milburn Foundation joins forces with companies of all sizes, public charities and direct donors who share our goals. Together, we design programs that build momentum behind funding critical research. The Milburn Foundation specifically targets innovative work that might not otherwise receive grants or donations. Matching gift campaigns are a key way the Milburn Foundation builds momentum with our partners. We are always looking for new ways to fight breast cancer through research, partnership and innovation.

http://www.themilburnfoundation.org/

Inflammatory Breast Cancer Research Foundation

The Inflammatory Breast Cancer Research Foundation (ICBRF) was founded to address a lack of research and education for inflammatory breast cancer (IBC). IBCRF's goal is to improve the lives of those touched by IBC, an advanced and accelerated form of breast cancer usually not detected by mammograms or ultrasounds. We do this by tenaciously fostering innovative research, creatively educating stakeholders of all kinds and tirelessly advocating for both current patients and survivors.

http://www.ibcresearch.org/

KEY DATES

Application System Opens:	October 10, 2016
Application Due:	November 28, 2016, by 1 p.m., Eastern Standard Time
Award Notification:	On or around April 15, 2017

ELIGIBILITY

Principal Investigators and Primary Institutions must conform to the following eligibility criteria to be considered for funding. Eligibility requirements must be met at the time of application submission, November 28, 2016.

Principal Investigators:

- Must have a doctoral degree, including M.D., Ph.D., Dr.PH, D.O., or equivalent.
- May be tenure track or non-tenure track faculty or a Postdoctoral Fellow (note: Postdoctoral Fellows must designate a Lead Mentor. The Lead Mentor must have a full time faculty appointment at the same institution).
- Are not required to be currently conducting IBC research.
- Are not required to be U.S. citizens or residents.
- Must ensure that all past and current Komen-funded Grants are up to date and in compliance with all Komen requirements; e.g., progress report submissions, IRB approvals, etc.

Institution

- Must be a non-profit institution or organization anywhere in the world.
- May not be a governmental agency (i.e. NIH, NCI etc.) within any country.
- Must agree to adhere to Komen's Policies and Procedures for Research and Training Grants, available at http://ww5.komen.org/ResearchGrants/FundingOpportunities.html.

FUNDING INFORMATION AND GRANT TERM

Applicants/PIs may request funding of up to $60,000 per year for one year. During this time, the PI is expected to establish the foundation for a robust and innovative IBC research project that also has the potential to impact triple negative breast cancer. Following the completion of this initial term, PIs will be invited to compete for a larger award to expand upon this project. Budgets should reflect the costs appropriate to support the Research Project. Funds can be used to supplement an existing IBC project, including a clinical trial, if no budgetary overlap can be demonstrated. This can include the addition of critical staff (e.g. Postdoctoral Fellows or Graduate Students).

Applicant/PIs must follow the following budget guidelines:

- Personnel costs ARE allowed on the project and may include Postdoctoral Fellows, Research Technicians, and Graduate Students.
- Equipment costs ARE limited to no more than 25% of total direct costs.
- Advocate Involvement: Reasonable compensation of Patient Advocate(s), including travel expenses, is allowed when they perform services that would otherwise be a contracted expense.
- Travel costs ARE allowed for purposes specifically related to the proposed Research Project for the PI and Key Personnel conducting the research (e.g. Postdoctoral Fellow or Graduate Student).
- Publication costs and meeting-related poster printing costs ARE allowed for purposes specifically related to the proposed Research Project.

APPLICATION: REQUIREMENTS

Applications may not exceed 10 pages, including research proposal, references, letters of collaboration or any figures and tables. The Applicant/PI biosketch and budget justifications are not included in this page number limit. Pages that exceed the 10 page limit will be removed from the Application.

The Applicant/PI biosketch must be no more than 5 pages and in NIH format. A template is available for download on the proposalCENTRAL website.

Budget Justifications must be included. A template is available for download to assist with describing proposed expenditures for the grant term. Separate budget justifications for all contractual/consortium agreements must also be submitted if applicable.

Patient Advocate Involvement

Susan G. Komen has a strong commitment to including breast cancer Patient Advocates to provide the patient perspective in the design and implementation of both research projects and Career Development Plans. As part of this ongoing effort**, Komen requires that one or more Patient Advocate(s) be included and named as Key Personnel on all grants at the date of Application submission, November 28, 2016.**

Utilizing Patient Advocates as a part of their projects will enable Komen applicants to become more aware of how their research is important to patients, to emphasize the urgent need to find cures, and to learn from patients' perspectives. **Patient Advocates involved in the proposed research project must be designated as a Key Person.**

There are many ways to engage advocates in your research project. The following are several examples:

- Patient Advocate Mentors can be involved early in the development of the project to provide input about its relevance and impact to patients.
- Patient Advocate Mentors may be invited to attend grantee lab meetings or give presentations to provide the patient point of view and a different perspective to the project.
- They can be included in clinical trial development, provide input on potential barriers to accrual, and help develop patient education materials.
- Patient Advocate Mentors can assist in communicating the importance of the results of the research project to the public using lay language that will be better understood by the general public.

Komen Advocates in Science have developed a detailed guide with suggestions for the inclusion of advocates in research which can be found in proposalCENTRAL.

Who can serve as a Patient Advocate? In summary, those who:

- Have been diagnosed with breast cancer or have a strong personal connection to breast cancer (i.e., family member or caregiver), and who are able to represent a collective breast cancer patient/survivor Have a basic understanding of the science of breast cancer.
- Is actively involved in the breast cancer research advocacy community.
- Have a basic understanding of the science of breast cancer and the peer review research process.

A guide for how to become a Patient Advocate and the attributes appropriate for that role can be found in proposalCENTRAL.

For assistance in identifying trained advocates for your application or to discuss including advocates in the proposed research project, contact advocatesinscience@komen.org.

Optional: Use of Komen Tissue Bank

The Susan G. Komen Tissue Bank at the Indiana University Simon Cancer Center (KTB) is the only repository in the world for normal breast tissue and matched serum, plasma and DNA. It is a goal of the KTB to acquire biomolecules and tissue specimens from the entire continuum of breast development from puberty to menopause. The KTB collects the following types of samples: fresh frozen tissue; formalin-fixed paraffin-embedded (FFPE) tissue; blood products including whole blood, plasma, serum; and DNA from lymphocytes. These samples are available to investigators to conduct research which will provide insight into breast oncogenesis. Additionally, the KTB has created a virtual tissue bank which will be populated with data derived from research completed with KTB samples; other researchers from around the world will be able to access this data.

The KTB invites researchers to take advantage of the available normal breast tissue to understand the biology of breast cancer. Komen is encouraging the use of this unique resource by inviting Applicants/PIs to include plans for utilizing tissues from the KTB in their grant application. For more information, visit http://komentissuebank.iu.edu.

APPLICATION: REVIEW PROCESS

Each Application will be reviewed by a panel of three scientists with appropriate expertise and a Patient Advocate, along with additional experts as necessary to conduct a thorough review of the proposed project. Scientists, advocate, biostatistician, and special reviewers (as needed) assess the strengths and weaknesses of each application based on the defined review criteria, described below.

Applications that are deemed most meritorious will proceed to discussion and final scoring by the Peer Review committee, facilitated by the Chairperson. Applications that are non-competitive will be triaged and will not be discussed or receive a final score. The Scientific Advisory Board (SAB) reviews the results of peer review and issues a recommendation for funding. It is important to note that the SAB does not conduct a re-review of individual grant applications, but rather focuses on the most highly ranked applications and their alignment with Komen's strategic objectives. Please see Appendix B: Notification Process for full details about accepting a Komen Grant.

APPLICATION: REVIEW CRITERIA

The Application will be reviewed using the following criteria:

Research Question and Significance	• Does the proposal directly address inflammatory breast cancer and/or inflammatory breast cancer that is triple negative? • Does the proposed research question represent a novel approach, a challenge to current paradigms, or add in a significant and measureable way to what is currently known about inflammatory breast cancer? • If the Applicant/PI has not adequately explained the relevance of the research question, what is the major flaw?
Scientific Approach, Merit, and Feasibility	• Do the proposed study hypothesis(es), specific aims, and scientific approach comprehensively address the overarching research question(s)? • Are the specific outcomes/deliverables of the proposed research plan adequately described? • Are potential problems and alternative strategies adequately addressed? Are benchmarks for success appropriate? • If the project is in the earlier stages of discovery, will the strategy establish feasibility and are particularly risky aspects well managed? • Does the proposed research utilize valid laboratory/preclinical models? • If the study includes a clinical trial, are you convinced of the feasibility/appropriateness of the patient accrual goals, target population, clinical protocols, or potential clinical benefit?

Scientific and Patient Impact	• Does the proposed research question have significant potential to advance our understanding of inflammatory breast cancer and triple negative breast cancer, and thus reduce the current number of breast cancer deaths by 50 percent in the next decade? • Is (Are) the research question(s) important to the breast cancer patient and survivor community? • Are Patient Advocates effectively utilized in the research proposal and was the role of the Patient Advocate clearly described in the application? How could the Applicant/PI more effectively include Patient Advocates in their research? • Does the Applicant/PI demonstrate significant potential to impact the IBC field, as evidenced by prior funding, publications, and other accomplishments? If the Applicant/PI is new to the IBC field, do they convey a commitment to IBC research? * Quality of life or survivorship projects will not be accepted unless they directly address reductions in mortality.
Resources and Timeline	• Are the institutional support, equipment, and other resources (including any needed Critical and Unique Materials needed) necessary for the successful conduct of the proposed research (such as drugs, animal models, biological specimens, patient populations, etc.) clearly available to the investigators? If not currently available, has the Applicant/PI demonstrated that they can obtain the material or have access to these materials at the start of the project, if funded? • Does the Research Timeline provide a reasonable expectation of progress throughout the project?
Statistical Plan	• Is there a rationale for the selection of statistical tests? Is it discussed which statistical procedure will be used for each analysis? • Is the sample size justified? Are the power calculations discussed in the application? • Are randomization methods of the experimental groups included? • Are blinding procedures for both the people conducting the experiments and those analyzing the data described? If impossible to blind those involved in the experiment, is there a discussion of the reasons? • Are the exclusion criteria established? Is there an analysis plan to assess dropouts and deaths?