



Because breast cancer is everywhere, **SO ARE WE.**

At Susan G. Komen for the Cure®, we are committed to ENDING breast cancer forever by ENERGIZING SCIENCE to find the cures and ensuring QUALITY CARE for all people, everywhere.

PROMISE GRANTS

2011-2012 REQUEST FOR APPLICATIONS

Research Focus Area:

The Causes of and/or Approaches to the Problem of Late Recurrence

Susan G. Komen for the Cure
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Dallas, Texas 75244
Research Programs Help Desk: 1-866-921-9678
Email: helpdesk@komengrantsaccess.org
Website: www.komen.org



KEY DATES

Application System Opens	June 22, 2011
Pre-Application Due	August 1, 2011, by 8 p.m., ET
Pre-Application Decision	October, 3, 2011
Full Application Due	December 15, 2011, by 8 p.m., ET
Award Notification	March 31, 2012

KOMEN RESEARCH PROGRAM

Susan G. Komen for the Cure's Research Programs play a critical role in energizing science to find the cures by funding the discoveries, individuals, and resources essential to ending breast cancer. The Programs support research and training through many different types of grants and awards, each designed to meet specific objectives and optimize outcomes. The 2011-2012 Request for Applications (RFAs) continues Komen's strategic focus on reducing breast cancer incidence and mortality within the decade.

PROMISE GRANTS

Promise Grants are intended to support collaborative, multi-disciplinary research programs that integrate a set of highly synergistic clinical and/or laboratory based research projects to address a critical issue or question in breast cancer research. Programs funded through this grant mechanism are expected to achieve results that would not otherwise be attainable by investigators working independently and should have significant potential to reduce breast cancer incidence and/or mortality within the decade.

Promise Grant funding will support two or three highly collaborative principal investigators and a multi-disciplinary investigative team. The investigative team should utilize their combined laboratory, clinical and/or public health expertise to effectively address the proposed research question(s). Promise Grant teams are expected to include breast cancer consumer advocates as active and integrated members of the research program to maximize the potential for translation of the research findings into outcomes that will impact patient care. While initiation of a clinical trial during the grant term is not required, it is encouraged. However, research programs must include testing of human samples and/or specimens at some point during the grant term.

2011-2012 Promise Grant Research Focus:

The Causes of and/or Approaches to the Problem of Late Recurrence

Applications for FY12 Promise Grants must focus on the causes of and/or approaches to the problem of late recurrence, which is defined as breast cancer recurrence that occurs more than 5 years after the original diagnosis.

The proposed research must have significant potential to prevent the development of late recurrence of breast cancer. Of particular interest are studies directed towards understanding the underlying biology, developing models, identifying predictors, and developing therapeutic approaches and/or novel imaging techniques relevant to the prevention of late recurrence. The inclusion of bioinformatics and computational approaches is encouraged, as noted below.

Examples of research programs may include, but are not limited to:

- Tumor dormancy
- Immune mediators of tumor suppression and growth
- Prediction of patients at greatest risk of late recurrence
- Strategies to prevent late recurrence

Applications addressing topics other than those that fall within the annual research focus will be administratively withdrawn from consideration, and will not be reviewed or scored.

Bioinformatics and Computational Approaches

In the past few decades, technology has empowered us with the ability to collect and integrate data on a large scale. From molecular interactions to population studies, this ability to handle complex data has revolutionized our understanding of disease processes. With the recent developments of the field of cancer systems biology, breast cancer research must keep pace with the vast amount of data generated from high-throughput studies and computational methods. Therefore, special consideration will be given to those applications that integrate bioinformatics or other computational approaches within the research proposals.

FUNDING INFORMATION AND GRANT TERM

Applicants may request three to five years of funding in combined direct and indirect costs over the timeframe of the Grant as follows:

- 3 years up to \$4,500,000
- 4 years up to \$6,000,000
- 5 years up to \$7,500,000

Budgets are not required to be equivalent across each year of the Grant, but rather should reflect the costs appropriate to support the research program each year.

Note the following guidelines:

- Personnel on the project are limited to a base salary at or below \$250,000 per year
- Expenses incurred by advocates during the grant term should be reimbursed. Reasonable compensation of advocates is permitted when advocates perform services that would otherwise be a contracted expense. Compensation may be in the form of salary, per-hour compensation, or honoraria. Additionally, grant funds can be used for advocate participation in scientific conferences that would enhance their knowledge and skills related to the research
- Equipment costs are limited to no more than 30% of direct costs
- Indirect costs cannot exceed 25% of direct costs (including any indirect costs paid through subcontracts or consortia)
- Professional membership dues are not allowable expenses

Partial Grant funding may be awarded based on review recommendations. In the event that multiple applications are submitted from a single institution, the total number of Grants being made to a single institution may be considered in making final funding decisions.



Susan G. Komen for the Cure®

Nancy G. Brinker promised her dying sister, Susan G. Komen, she would do everything in her power to end breast cancer forever. In 1982, that promise became Susan G. Komen for the Cure and launched the global breast cancer movement. Today, Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all and energize science to find the cures. Thanks to events like the Komen Race for the Cure®, we have invested more than \$1.9 billion to fulfill our promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world.

DESIGNATED RECIPIENTS

Principal Investigators

Promise Grants will be awarded to a team of two or three principal investigators (PIs.) Cross-institutional involvement is encouraged and may include both academic and industry partners.

At least one PI must be a basic/translational investigator and one PI must be a clinical investigator with experience conducting clinical trials. Under rare circumstances exceptions may be granted, but a request for a PI specialty exception must be submitted prior to the pre-application deadline. Exception requests should be submitted via email to the Research Program Help Desk.

Primary Institution

Grant Agreements will be executed between Susan G. Komen for the Cure and one PI's institution. The primary institution will serve as the administrator of the Grant funds and will hold responsibility for the disbursement of the funds to other participating institutions, management of the budget, and submission of all required documents and reports. Although the primary institution will be the main point of contact for the purposes of the Grant, it is expected that all named PIs will share equal authority and responsibility for leading and directing the research program, both intellectually and logistically. It is expected that the primary institution will enter into subcontracts with any other participating institutions, and assurances that these contractual agreements have been executed will be required prior to funding.

ELIGIBILITY

Principal investigators and institutions must conform to the following eligibility criteria to apply for a Promise Grant. Eligibility requirements must be met at the time of full application submission.

Principal Investigators

- Must have a doctoral degree, including MD, PhD, DrPH, DO, or equivalent
- Must currently hold a faculty appointment
- Must ensure that all past and current Komen-funded grants or awards are up to date and in compliance with all Komen requirements; e.g., progress report submissions, IRB approvals, etc.
- Are not required to be U.S. citizens or residents

Institutions

- Primary institution must be a nonprofit institution or organization anywhere in the world
- Other participating institutions may be nonprofit institutions or industry partners, however industry partners may not be reimbursed for any fee or profit
- All institutions and industry partners must agree to adhere to Komen's Policies and Procedures for Research and Training Grants including, for example, regulatory assurances, ownership of equipment, intellectual property, liability and insurance and reporting requirements. Copies of these Policies and Procedures are available at <http://ww5.komen.org/ResearchGrants/FundingOpportunities.html>

RESEARCH PROGRAM REQUIREMENTS

Research Integration

Applicants must propose an integrated program of research projects that addresses an over-arching issue of importance within the research focus area indicated in this RFA. The results should provide converging evidence that will lead to rapid translation and advances that have significant potential to reduce breast cancer incidence and/or mortality within the next decade.

Cross-Disciplinary or Multi-Institutional Teams

Research programs must involve a cross-disciplinary team of laboratory and clinical researchers, biostatisticians, and patient advocates. Although cross-institution collaboration is not required, it is strongly encouraged.

Clinical Testing and Human Subjects Involvement

While initiation of a clinical trial during the grant term is not required, it is encouraged. However, all proposed research programs must include testing of human samples and/or specimens. Proposals that include initiation of a clinical trial during the grant term MUST include a clinical protocol at the time of full application, though IRB approval is not required at that time. All full applications must also include certification of the ability to obtain the necessary types and quantities of human specimens.

Patient Advocate Involvement

Breast cancer patient advocates provide the patient perspective when research projects are being designed and implemented. As such, patient advocates must be meaningfully and actively involved in the proposed research program. They should be included on advisory boards, steering committees, or any other decision-making entities, and should also be involved in other aspects of the research program such as planning and oversight, research subject recruitment, program evaluation, and/or dissemination of information to the public. Interactions with the research team members should be well-integrated and ongoing, not limited to attending seminars or meetings.

Since the plan for advocate involvement is rated by the review Committee, the plan must be clearly described in both the pre-application and full application. Advocates should also be listed as collaborators in the key personnel list for the application.

A guide, presented by Susan G. Komen for the Cure® Advocates in Science, is attached as Appendix A, and provides suggestions for the inclusion of advocates. For assistance in identifying trained advocates or to discuss including advocates in the proposed research program, contact advocatesinscience@komen.org.



Susan G. Komen for the Cure has been dedicated to funding breast cancer research since inception in 1982. At the local level in the U.S., Komen works through a grassroots network of 120 Affiliates who serve as the face and voice of the Komen organization in 48 states across the country. All of the Affiliates actively participate in generating the funds that are used to sponsor the Komen research grants. Twenty five percent of all the money raised locally is pooled at the national level and invested in Research and Training Grants. In 2011, Susan G. Komen for the Cure is funding 82 research grants, totaling \$55 million. Of that, over \$32 million came directly from the Komen Affiliate Network. More than just numbers, these statistics emphasize that local Komen Affiliates — and through them communities all over the country — are committed to supporting the scientific community at large by raising money and breast cancer awareness.

REVIEW PROCESS

Susan G. Komen for the Cure® utilizes a multi-step approach to application and review that requires submission of a pre-application and submission of a full application upon invitation only. Pre-applications are first administratively reviewed for eligibility, adherence to formatting requirements, and responsiveness to the research focus specified in this RFA. Each qualified application is then reviewed by a panel of three scientists with appropriate expertise and a patient advocate. Scientist and advocate reviewers assess the strengths and weaknesses of each application based on the defined review criteria described below.

Only applicants with pre-applications deemed most meritorious and aligned with Komen's research mission will be invited to submit full applications. It is anticipated that full applications will be invited from approximately 20-25% of pre-application submitters.

Applicants will be notified of pre-application review decisions via email. Once notifications are sent, applicants will be granted access to un-edited reviewer comments.

Pre-application Scientific Peer Review Criteria

Reviewers will evaluate and score pre-applications based on the following criteria:

Research Significance and Clinical Impact	<ul style="list-style-type: none">• Will the overarching research question(s), if successfully answered, have significant potential to lead to a reduction in breast cancer incidence and mortality within the next decade?• If successfully completed, will the research advance our knowledge of breast cancer in an important way and/or contribute to the way that we conduct breast cancer research?
Scientific Approach and Feasibility	<ul style="list-style-type: none">• Will the proposed study hypothesis(es) comprehensively address the overarching research question(s)?• Will the proposed specific aims fully answer the study hypothesis(es)?• Will the scientific approach effectively address each specific aim?• Does the research team, as described, contain all of the key expertise that is necessary to successfully address the overarching research question(s), and do they have the significant potential for successful research collaboration?• Are the proposed research projects well integrated into a coherent and synergistic research program?
Advocate Plan	<ul style="list-style-type: none">• Are advocates an integral part of research team, and will they play an active role in the proposed research program?• Is the involvement of advocates likely to facilitate the translation of the research findings into outcomes that will impact patient care?

PRE-APPLICATION SUBMISSION INSTRUCTIONS

Applications must be submitted online through proposalCENTRAL at <https://proposalcentral.altum.com/>. Details regarding pre-application formatting, content and supporting documents are provided below. Applicants are encouraged to draft application content using Word or other word-processing software prior to the opening of the application system. Pre-Application Narratives must be converted to PDF prior to submission.

Pre-Application Narrative

Below is a description of the narrative content that must be included in the application, including the recommended page length for each section. Applicants may exceed the recommended page length for a given section provided that the total narrative is no more than 7 pages, including figures and tables. References and biosketches are not included in this page number limit.

Research Issue and Clinical Impact and Significance (1 page recommended):

Describe both the research issue that will be addressed in the application and the clinical impact and significance of this issue in terms of incidence and/or mortality reduction. Applicants should address the following points:

- How the proposed research addresses the specific research focus as described in this RFA.
- How the overarching research question(s), if successfully answered, lead to a reduction in breast cancer incidence and mortality within the next decade.
- How the outcomes from the proposed research plan will advance our knowledge of breast cancer and/or contribute to changes in the way that research is conducted on this issue.

Hypothesis, Specific Aims and Approach (3 pages recommended):

Clearly and concisely outline the hypothesis(es), specific aims, and the approach that will be taken to address each specific aim. In this section, address the following:

- How the proposed study hypothesis(es) addresses the overarching research question(s).
- How the proposed specific aims will answer the study hypothesis(es).
- How the scientific approach addresses each specific aim.
- How the proposed research projects integrate into a coherent and synergistic research program.
- How advocates will be integrated into the planning and operations of the team.
- And what specific role advocates will play in facilitating the translation of the research findings into outcomes that will impact patient care.

Research and Advocate Team (1 page recommended):

Describe the structure and expertise of the research and advocate team, paying particular attention to the following:

- The key expertise needed to successfully address the proposed specific aims, and how the key research personnel named on the grant application will meet this need.
- The key expertise needed to successfully implement the advocate plan, and how the advocates named on the grant application will meet this need.

Project and Time to Clinical Impact Timeline (2 pages recommended):

Provide the projected timeline for progress over each year of the proposed research program. Include the following:

- Research goals and milestones that are related to the initiation and execution of key steps within the application.
- Projected succession of key steps over each year of the proposed research program to achieve clinical impact.
- Any subsequent steps towards clinical impact that will be necessary after project completion.

Pre-Application Supporting Documents

The following documentation is required to support the pre-application:

Biosketches

Required for all key research personnel. Biosketches must be no more than 4 pages each and in NIH format. A template will be available for download on the application website. Applicants are not required to submit a biosketch for advocates, but advocates should be listed as key personnel.

Biosketches are not included in the overall 7-page limit.

References

No more than 10. References are not included in the overall 7-page limit.

Document Format

Please follow the formatting requirements below. Applications not adhering to these format requirements may be administratively withdrawn prior to review.

- Must be in PDF file format.
- Font Size: 12 point or larger.
- Font Type: Times New Roman.
- Spacing: No more than six lines of type within a vertical inch (2.54 cm).
- Page Size: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- Margins: At least 0.5 inch (1.27 cm) in all directions.
- Print Area: 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- Use of headers and footers is not permitted.
- Recommended lengths for each narrative section of the application are provided. The complete application narrative must not exceed 7 pages in length.

Guidelines for Images

- Reduce the file size of documents with images by “inserting” the image (as opposed to “cutting” and “pasting”).
- Insert only PNG, GIF or JPG graphic files as images in your Word document. Other graphical file formats are either very large or difficult to manipulate in the document.
- Do not insert Quick Time or TIFF objects into your document.
- Anchor the images you embed in your document. Once you have anchored the “inserted” image, you can format text to wrap around the image.
- Do not edit your images in Word. Use a graphics program.
- Do not embed your images in tables, text boxes, and other form elements.
- Do not add annotations over the images in Word. Add annotations to the images in a graphics program.

FULL APPLICATION SUBMISSION

Only applicants with pre-applications deemed most meritorious and aligned with Komen’s research mission will be invited to submit full applications. Instructions on how to submit a full application will be provided on the pre-application decision date listed above.

QUESTIONS?

Contact information for all inquiries regarding application submission is provided below.

Type of Inquiry	Contact
All programmatic inquiries (including questions related to eligibility, program requirements, Komen policies and procedures, etc.)	Research Programs Help Desk Email: helpdesk@komengrantsaccess.org Phone: 1-866-921-9678 (Toll-free within the United States and Canada)
All technical inquiries related to the online application system, proposalCENTRAL (including questions related to system access, navigation, document uploads, etc.)	Altum/proposalCENTRAL Email: pcsupport@altum.com Phone: 1-800-875-2562 (Toll-free within the United States and Canada), or 1-703-964-5840 (International)

APPENDIX A: ADVOCATE INVOLVEMENT IN PROMISE GRANTS

Breast cancer patient advocate involvement is a required element of the proposed research program to be supported by a Komen Promise Grant. Advocates provide the patient perspective when research projects are being designed and implemented. As such, advocates must be meaningfully and actively involved in aspects of the proposed research program, such as in planning and oversight, research subject recruitment, program evaluation, and/or dissemination of information to the public and should also be included on advisory boards, steering committees, or any other decision-making entities. Interactions with the research team members should be well-integrated and ongoing, not limited to attending seminars and semi-annual meetings.

The following guide, presented by Susan G. Komen for the Cure® Advocates in Science, provides suggestions for the inclusion of advocates. For assistance in identifying trained advocates or for questions about how to include advocates in your proposed program of research, please contact advocatesinscience@komen.org.

Who can serve as an advocate?

- Advocates should be individuals who have been diagnosed with breast cancer or have a strong personal connection to breast cancer.
- Advocates should be involved with a breast cancer advocacy organization (not limited to Susan G. Komen for the Cure®). Since the role of the advocates is to provide the patient perspective, advocates should not be employed as health care professionals, though they can be employed by an institution in the grant application.
- Regardless of their professional credentials, advocates should have a high level of training (such as having participated in the Komen Advocates in Science training programs or similar training) and familiarity with current issues in breast cancer research.

Ideas for advocate involvement

- Creating educational activities for local, regional, and national groups and organizations to inform them of the research you are conducting and its importance to breast cancer patients through community events, seminars, or web conferences.
- Creating patient education materials to explain the research project and/or clinical trial, the importance of the research to breast cancer, and how the trial might be an option for patients.
- Reviewing the proposed design of a clinical trial and providing guidance from the point of view of a breast cancer patient with regard to eligibility, frequency of invasive testing, etc.
- Developing the approach for patient accrual to the clinical trial through messaging and community outreach, such as:
 - Speaking as part of the research team at scientific meetings and conferences to present the impact of the work to the breast cancer patient.
 - Preparing and delivering a poster presentation for scientific meetings and conferences, for instance, on the approach to patient accrual.
 - Developing an educational approach for patients to explain how the results could be an option for their treatment.

- Monitoring patient accrual and suggesting modifications to the approach if needed.
- Monitoring the patient experience, such as through development of a questionnaire or personal interview, and providing assistance and support when necessary.
- Reviewing the language contained in Informed Consent forms, questionnaires, and other documents related to patient involvement for readability and sensitivity.
- Assisting in the development of the lay abstract.
- Speaking in the community about the results of the research. This is best done as a team with a researcher and an advocate making the presentation.
- Being included as an author on a publication as appropriate.



Advocates in Science (AIS) is a diverse and dedicated community of volunteer advocates fostering excellence in research advocacy and greater advocate involvement in all aspects of breast cancer research. Breast cancer survivors and others affected by breast cancer provide unique and valuable perspectives on the cancer experience, issues that will most influence those affected by breast cancer, and the urgency of finding cures and ending breast cancer forever. AIS involves advocates in a variety of scientific activities, including specific training for participating in grant review, as well as ongoing education to enhance their advocacy skills and expand their scientific knowledge.