



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

2010-2011 REQUEST FOR APPLICATIONS

Susan G. Komen for the Cure
5005 LBJ Freeway, Suite 250
Dallas, Texas 75244
Toll-free: 1-866-921-9678
Email: helpdesk@komengrantsaccess.org
Website: www.komen.org



KOMEN RESEARCH PROGRAM

Komen's Research Program plays a critical role in energizing science to find the cures by funding the discoveries, individuals, and resources essential to ending breast cancer. The Program supports research and training through many different types of grants and awards, each designed to meet specific objectives and to optimize outcomes. The 2010-2011 Research Program and its portfolio of Requests for Applications (RFA) continues Komen's strategic focus on reducing breast cancer incidence and/or mortality within the decade.

This RFA provides specific details about Promise Grants (PG) and what investigators need to know to apply.

KEY DATES

RFA Released	June 3, 2010
Pre-Application Due	August 10, 2010, by 8 p.m., EDT
Pre-Application Decision Date	October 5, 2010
Full Application Due	December 7, 2010, by 8 p.m., EDT
Application Review	December 7, 2010 to February 15, 2011
Board Approval	March 2011
Award Notification	March 2011
Anticipated Funding Start	April 2011

RESEARCH FOCUS

Promise Grants are organized around a critical issue or question that is being addressed by a set of closely-related clinical and laboratory projects designed to achieve significant results not attainable by investigators working independently. These grants differ significantly from Komen's Investigator-Initiated Research (IIR) Grants. While the IIR Grants support one or two principal investigators to test a single hypothesis through one or more related research studies, utilizing either laboratory, clinical or public health approaches, Promise Grants are intended support two or three principal investigators and an investigative team that brings together and integrates laboratory, clinical and/or public health disciplines to conduct several related projects, the results of which converge to answer critical questions.

Research projects supported by Promise Grants must provide an integrated approach to solving a critical challenge that will lead to the rapid translation of scientific discoveries into new or enhanced clinical tools and applications with the greatest potential to significantly reduce breast cancer incidence and/or mortality within the next decade. Projects must be designed to yield converging evidence that answers an important over-arching problem in breast cancer (e.g., resistance to currently available targeted therapies or novel therapies for triple negative breast cancer). Relevant research applications may include components that focus on breast cancer biology; genetics; epidemiology; prevention; detection; risk assessment; biomarkers of risk, disease burden, and/or treatment response or resistance; novel therapeutics; lifestyle interventions with the potential to affect disease outcomes (e.g., incidence and/or mortality); and novel approaches that enhance understanding of the breast cancer disease process.

Special Interest Issue: Population Disparities in Breast Cancer Outcomes

Integrated programs of research projects addressing critical challenges in population disparities in breast cancer outcomes are of special interest and may receive funding priority. Programs of research addressing disparities in breast cancer outcomes must have significant potential to lead to reductions in disparities in breast cancer incidence and/or mortality within the decade. Of particular interest are studies of the biologic determinants of disparities in breast cancer outcomes; models of clinical care that address the causes of disparities in care and outcomes across population groups; and public health interventions that specifically address the provision of health care services in community settings and associated factors in breast cancer care and outcomes.

Other important research issues such as symptom management, quality of life, end of life care, psychosocial aspects of breast cancer, and basic research without a disease endpoint such as incidence and/or mortality will not be considered for funding this year, but may be the focus of other Requests for Applications issued at another time.

Applications addressing topics other than those described above will be administratively withdrawn from consideration, and will not be reviewed or scored.

ELIGIBILITY

Applicants and institutions must conform to the following eligibility criteria to be considered for funding through a Promise Grant. Eligibility requirements must be met at the time of full application submission.

Applicants

- 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

- Must be a nonprofit institution or organization anywhere in the world
- May include involvement of an industry partner, however industry partners may not be reimbursed for any fee or profit
- 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 www.KomenGrantsAccess.org

DESIGNATED RECIPIENTS

Grants will be awarded to at least two, but no more than three, Co-Principal Investigators (Co-PIs) and the application must clearly indicate the individuals serving as Co-PIs. At least one Co-PI must be a basic/translational scientist and one Co-PI must be a clinical investigator with experience conducting clinical trials.

Under rare circumstances exceptions may be granted, but a request for PI specialty exception must be submitted prior to the pre-application deadline. Exception requests should be submitted to Dr. Marianne H. Alciati at malciati@komen.org or 1-972-701-2050.

Cross-institutional involvement is encouraged and may include both academic and industry partners.

FUNDING INFORMATION

Applicants may request five years of funding of up to \$6.5 million over the timeframe of the Grant (combined direct and indirect costs).

Budgets are not required to be balanced across each year of the Grant, but rather should reflect the appropriate costs incurred within that year of research. It is anticipated that these costs may vary during the project based on investigator involvement and clinical trial implementation.

Partial Grants may be made 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.

PROJECT AND RESEARCH REQUIREMENTS

Research Integration — Applicants must propose an integrated program of research projects that addresses an overarching area of importance. The project should provide converging evidence that will lead to rapid translation and advances that have the potential to reduce breast cancer incidence and/or mortality within the next decade.

Cross-Disciplinary and Multi-Institutional Teams — Research projects must involve a cross-disciplinary team of laboratory and clinical researchers, biostatisticians and advocates. Cross-institution collaboration is strongly encouraged.

At Least Two Co-Principal Investigators — At least one Co-PI must be a basic/translational scientist and one Co-PI must be a clinical investigator with experience conducting clinical trials. Under rare circumstances exceptions may be granted, but a request for PI specialty exception must be submitted prior to the pre-application deadline. Exception requests should be submitted to Dr. Marianne H. Alciati at malciati@komen.org or 1-972-701-2050.

Clinical Testing and Human Subjects Involvement — Clinical testing of a promising agent, strategy or intervention must be initiated during the term of the Grant. Continuation of animal studies in the same or different non-human species will not be supported. Applicants must address the efficiency and speed with which all necessary IRB approvals will be obtained.

Advocate Involvement — Advocate involvement must be meaningful and appropriate to the proposed program of research and their involvement must be clearly described in the pre-application and full application. Advocates should be listed as collaborators in the 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 program of research, contact advocatesinscience@komen.org.

Promise Grantee Annual Meeting — Komen may convene an annual meeting of Promise Grant investigators and/or may request a project presentation to share research progress and findings with the Scientific Advisory Board and explore potential collaborations. Costs associated with these meetings should be included in the application budget. It is expected that research findings will be shared as quickly as possible.

NEW! KOMEN REVIEW PROCESS

Komen has instituted a new, multi-step approach to application submission and review that includes:

- 1) Submission of pre-applications which are scientifically peer-reviewed to identify those Applicants to be invited to submit full applications; and
- 2) By invitation only submission of full applications, which are scientifically peer-reviewed to order applications for funding based on review criteria.

Pre-application peer review is replacing responsiveness review. This is a substantial modification that significantly changes the components and importance of the pre-application.

The study proposed in the full application may not differ in any substantial way from the study proposed in the pre-application. Non-substantial changes may include minor rewording of the hypothesis or specific aims or minor modification of the scientific approach. Scientific reviewers will evaluate any changes between a pre-application and full application and eliminate from consideration full applications reflecting substantive changes from the pre-application.

PRE-APPLICATION PEER REVIEW PROCESS

Pre-applications must describe the study hypothesis and specific aims, scientific approach, clinical impact, and research significance of the proposed study.

Each application is assigned to a review committee and then assigned to individual reviewers within that committee. The applications will be reviewed by three scientists with appropriate expertise and by a highly qualified advocate reviewer who has participated in Komen's Advocates in Science program. Scientist and advocate reviewers assess the strengths and weaknesses of each application based on the defined review criteria described below.

Approximately 20-25% of the submitted pre-applications will be identified as the most meritorious and aligned with Komen's research objectives. Upon approval by Komen's Scientific Advisory Board, Applicants will be invited to submit full applications for further peer review and funding consideration. Applicants are strongly encouraged to carefully complete a pre-application that clearly addresses each element of the review criteria.

Applicants are notified by email whether they are invited to submit full applications. Un-edited reviewer comments will thereafter be posted to Applicants' Komen Grants Access accounts.



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 \$1.3 billion to fulfill our promise, becoming the largest source of nonprofit funds dedicated to the fight against breast cancer in the world.

Pre-application Scientific Peer Review Criteria

Scientist reviewers will evaluate and score the scientific approach and feasibility, clinical impact, and research significance while advocate reviewers will evaluate and score clinical impact, as described below.

Scientific Approach and Feasibility	Will the proposed specific aims answer the study hypothesis? Will the scientific approach effectively test and answer each specific aim? Does the organizational structure of the research team promote research feasibility? How likely is it that the proposed specific aims and research goals will be met according to the project timeline and scope provided?
Clinical Impact	Is the answer to the study hypothesis important to our ability to reduce breast cancer incidence and/or mortality? Will the proposed research lead to substantial advances and/or contribute large leaps of understanding or knowledge that will contribute to reductions in breast cancer incidence and/or mortality within the decade? Is the proposed integration of advocates appropriate for the research plan and will this involvement facilitate the translation of the research findings into clinical practice?
Research Significance	Does the study address an important question that is not likely to be addressed without Komen funding? Does the proposed study offer a unique opportunity to explore an important issue and/or employ a novel approach to reducing breast cancer incidence and/or mortality? Will the study outcomes advance our knowledge of breast cancer in an important way and/or contribute to changes in the focus of future research questions or the way we conduct research on this issue?

FULL APPLICATION REVIEW PROCESS

Full applications proceed through a two-step review process. The first step includes a review and rating process by the assigned reviewers who will assess the strengths and weaknesses of each application based on the defined review criteria described below. During the second step, the review committee discusses all full applications during a face-to-face meeting. Following review committee discussion of each application, all committee members assign a single, overall application score. These overall scores are averaged and then used by Komen's Scientific Advisory Board (SAB) to make final funding recommendations across all research mechanisms. Applications are recommended for funding in the order of the overall average score.

SAB recommendations are then forwarded to Komen's Board of Directors which determines the final slate of applications for funding. After Board approval, Applicants are notified by email when notifications of intent to fund and review summaries are posted to their Komen Grants Access account. All review summaries include un-edited reviewer critiques for each review criterion, a summary of the review discussion, and the average overall score.



Full Application Scientific Peer Review Criteria

Evaluations for funding consideration are based on each of the following review criteria. **These criteria are listed in order of importance to Komen.** The first two criteria, Scientific Merit and Clinical Impact, are substantially more important and will be given greater emphasis in the review of the merits of each application. Applicants should read the criteria questions carefully and ensure that their application addresses all aspects of each criterion.

<p>Scientific Merit</p>	<p>Does the proposed research answer each study hypothesis? Does the research use valid research and statistical methods? Does the research anticipate and remedy potential experimental problems to ensure effective resolution of study hypotheses? Will the research as proposed yield evidence of biologic efficacy or demonstrate effects in breast or other relevant tissue? Will the project result in the initiation of clinical testing of a promising agent, strategy or intervention within the duration of the Grant?</p>
<p>Clinical Impact</p>	<p>How likely is it that the proposed research will introduce new clinical applications or sufficiently enhance existing applications to result in reductions in breast cancer incidence and/or mortality within the next decade? Can these research findings be translated rapidly into clinical practice? Once translated, will these research findings lead to rapid reductions in breast cancer and/or mortality? Is the proposed integration of advocates appropriate for the research plan and will this involvement facilitate the translation of the research findings into clinical practice?</p>
<p>Research Integration</p>	<p>Are the individual research projects effectively integrated to efficiently yield answers to important clinical questions? How well do the individual research projects leverage the unique opportunities of an integrated research program and cross-disciplinary team? How effectively does the proposed program of research leverage unique expertise, resources, care settings, relationships, and organizational commitments across researcher disciplines and institutions or industry?</p>
<p>Feasibility</p>	<p>How likely is it that the proposed research goals and milestones will be achieved within the scope of the funded project?</p>
<p>Expertise</p>	<p>Do the PI's and their research teams have the expertise to effectively implement all aspects of the proposed research? Do the PIs have adequate experience conducting clinical trials and the laboratory experiments proposed? Are advocates integrally and appropriately involved in the design and execution of the proposed research?</p>

SUBMISSION PROCESS

The application process includes two distinct steps:

- (1) Submission of a pre-application, and, if invited
- (2) Submission of a full application with supporting documentation.

Applicants should be aware of three important resources for submitting their application, Komen Grants Access, the online system used for managing the application process, the User Guide, which provides information for navigating the system, and the Komen Grants Help Desk, which provides both email and telephone assistance with the application process.

Komen Grants Access

Komen's research application process is managed online through Komen Grants Access. All applications must be submitted electronically through this online system at www.KomenGrantsAccess.org.

First-time users must register and create a username and password. This username and password allows users to enter Komen Grants Access to develop, modify, and submit pre-applications and full applications. Once users have registered in the Komen Grants Access system, they do not need to re-register in order to apply for other Komen funding opportunities.

Application System User Guide

The user guide may be accessed via a link in the upper right corner of Komen Grants Access. The purpose of the user guide is to provide general information and instructions regarding the use of the Komen Grants Access Application System. The user guide does not provide information on specific requirements of grant mechanisms; this information can be found in the RFA.

Komen Grants Help Desk

All inquiries regarding application submission should be directed to the Komen Grants Help Desk at helpdesk@komengrantsaccess.org or 1-866-921-9678. The Help Desk hours of operation are Monday through Friday, 9 a.m. to 5 p.m., Eastern Time. One day prior to and on the submission deadline, the Help Desk hours are extended to 9 a.m. to 8 p.m., Eastern Time.



STEP 1: SUBMISSION OF PRE-APPLICATIONS

Pre-applications are scientifically peer-reviewed to identify applications that are deemed the most meritorious and aligned with Komen's research objectives. Upon approval by Komen's Scientific Advisory Board, Applicants will be invited to submit full applications for further peer review and funding consideration.

All information in the application must be written in English.

Register/Log in to Grants Access

Applicants should go to www.KomenGrantsAccess.org and click the "Applicant" button. Returning Komen Grants Access users can sign in using their existing username and password. New users must register on the site.

Once logged in on the "My Applications" page, click on "Start a New Application" to begin entering pre-application information.

My Applications: Start New Applications

All currently open research funding opportunities will appear on this page. Select a funding opportunity to begin the application submission process. Three sections of information are required in the pre-application – application identification, application classification, and submitter role. Each section corresponds to a tab at the top of the user interface on Komen Grants Access. Applicants will be able to view these tabs after they have entered and saved the initial application information entered on the "Start a New Applications" page. Applicants and Alternate Submitters (described below) may edit or add application information by accessing these tabs and can save sections as draft or final at the bottom of each page.

Invite Application Signing Official and Alternate Submitter(s)

Access to the application must be provided to an Application Signing Official (ASO) who is authorized to sign on behalf of the organization. The ASO is the only individual who can provide final approval and submit the application. The Applicant also may provide permission to an Alternate Submitter, an individual in his/her organization who may enter Komen Grants Access to assist in preparing the application. To provide access to these individuals, Applicants should click the "Contacts and Eligibility" tab and enter the required information. An e-mail invitation will be automatically sent to each individual with instructions for registering or logging into Komen Grants Access. This information must be provided at the time of pre-application submission.

INFORMATION REQUIRED FOR THE PRE-APPLICATION

Permanent Information: No changes/modifications can be made to the PI name, institution, translational code and the first of the two selected topic codes cannot be changed once the pre-application has been submitted, and this information will remain the same for the full application. It is therefore imperative that this information is accurate. All other fields can be changed during the full application process.

Tab	Data Entry and Format Requirements	Information Requirements
Tab 1: Contacts and Eligibility	<ul style="list-style-type: none"> • Enter in text boxes • PI name may not be changed after submission • PI institution may not be changed after submission 	PI: Name, degrees, institution, and contact information
	<ul style="list-style-type: none"> • Enter a check next to each eligibility requirement 	Eligibility: The Applicant must certify compliance with PI eligibility requirements.
	<ul style="list-style-type: none"> • Search for individuals already in the system or invite them to create an account. 	Co-PI and Alternate Submitter: At least one Co-PI is required; Alternate Submitter is optional.
	<ul style="list-style-type: none"> • Enter in text boxes 	Application Signing Official (ASO): Enter name, institution, and contact information. The ASO is the official from the applicant organization authorized to sign on behalf of the organization
	<ul style="list-style-type: none"> • Enter in text boxes Optional 	Post Award Contacts: Enter name, phone and email address of grants contract official, financial official, media contact, and technology transfer official.

INFORMATION REQUIRED FOR THE PRE-APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
Tab 2: Application Summary Information	<ul style="list-style-type: none"> • Enter in text boxes • 160 character limit • Do not enter in all capital letters 	<p>Title: Working title of application</p>
	<ul style="list-style-type: none"> • Enter in text boxes • 17,100-character limit (approximately 3 pages) 	<p>Scientific Approach: Provide a description of the research to be proposed in the application. This description is an important part of the pre-application review and should clearly describe the research to be proposed and how the project (a) addresses the RFA objectives; (b) aligns with the annual research focus; and (c) incorporates each of the project requirements as appropriate</p> <p>Research Feasibility: Provide a description of the research project feasibility structured in two areas as follows:</p> <ol style="list-style-type: none"> 1) Project Timeline: Provide the projected timeline for progress over each year of the research project. Include research goals and milestones related to the initiation and execution of key steps within the project plan. 2) Description of the Research Team and Organizational Structure: Describe briefly the research team proposed and how the members are integrated. Describe the organizational structure in relation to support of the research proposed.



INFORMATION REQUIRED FOR THE PRE-APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 2: Application Summary Information</p>	<ul style="list-style-type: none"> • Enter in text boxes • 11,400-character limit (approximately 2 pages) 	<p>Clinical Impact and Research Significance Statements:</p> <p>Clinical Impact Statement: Provide a description of the clinical impact in terms of incidence and/or mortality reduction of the research to be proposed in the application. Explain how the proposed research will lead to substantial advances that will significantly accelerate progress in finding and applying cures that will reduce breast cancer incidence and/or mortality within the next decade.</p> <p>Structure the Clinical Impact Statement according to the “Clinical Issue and Research Outcome” and “Steps and Timeline to Clinical Impact” sections as described below:</p> <p>Clinical Issue and Research Outcome: Describe both the clinical issue in breast cancer addressed by the proposed research and the targeted population (for example, triple negative breast cancer) and how the overall outcome of the proposed research (for example, a new drug) will contribute to reductions in incidence and/or mortality.</p> <p>Steps and Timeline to Clinical Impact: Describe the projected succession of steps and timeline of the research outcome(s) to achieve clinical impact. Include 1) the steps and timeline to be addressed during the period of proposed research; and 2) the subsequent steps and timeline to be addressed in future projects along the path to clinical impact.</p> <p>Research Significance: Describe the unique opportunity to explore the issue or employ a novel approach, and how the research will advance our knowledge or contribute to changes in the focus and/or conduct of future research studies.</p>
	<ul style="list-style-type: none"> • Enter in text boxes 	<p>Project Information: Enter proposed project start date, end date, and requested duration of the Grant term.</p>
	<ul style="list-style-type: none"> • Select from dropdown lists • First topic code and translational code may not be changed after submission 	<p>Application Classification</p> <p>Translational Codes: Select the translational research code that best characterizes the translational focus of the research described in your application</p> <p>Topic Codes: Select up to two topic codes that best characterize the focus of the research described in your application</p> <p>CSO Research Classification: Select up to two Common Scientific Outline (CSO) codes that best characterize the focus of the research described in the application</p>

INFORMATION REQUIRED FOR THE PRE-APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 3: Collaborators, COI & Biosketches</p>	<ul style="list-style-type: none"> • Upload under the “My Profile” tab • Enter in text boxes • 17,100-character limit (approximately 3 pages) 	<p>Investigators and Submitters: Verify that the biosketch of PI is uploaded. If the biosketch does not appear on this screen as a .pdf icon, it must be uploaded under the “My Profile” tab.</p>
	<ul style="list-style-type: none"> • Enter in text boxes • Upload biographical sketches as PDF files • 4-page limit per individual’s biographical sketch • Templates provided under Submission Status and Templates tab • Do NOT password-protect PDF files! 	<p>Percent Effort for Investigators and Collaborators</p> <p>Add Investigator or Collaborator: Enter information for proposed PI, named investigators and key personnel including level of effort.</p> <p>Biographical Sketch: Upload biographical sketch for collaborators ONLY. Include information about education/training, previous employment, experience, honors, publications, and patents.</p> <p>Role for Application: Select role via the drop-down box.</p> <p>Co-Principal Investigator (Co-PI’s): The individuals designated by the applicant organization to direct the research project to be supported by the Grant. The Co-PI’s are responsible and accountable to the ASO and Komen for the proper conduct of the research project. A Co-PI may be employed by, or be affiliated with, the Applicant organization or another organization participating in the project under a consortium agreement. Co-PI(s) must devote a sufficient percentage of time to the project adequate to fulfill their role as key personnel for the Grant.</p> <p>Co-Investigators: An individual working under the leadership of the PI in the scientific development or execution of the project. Investigators must devote a specified percentage of time to the project, typically less than that of the PI and are considered key personnel. The Investigator may be employed by, or be affiliated with, the Applicant organization or another participating organization.</p> <p>Co-PIs and Co-Investigators are considered key personnel on the proposed project.</p> <p>Collaborators: An individual working with the PI/Co-PI(s) in the scientific development and/or execution of the research project. Collaborators do not devote a specified percentage of time to the project and are not considered key personnel. A collaborator may be employed by, or be affiliated with, the Applicant’s organization or another participating organization.</p> <p>Other allowable roles: Consultant, Mentor, Fellow, Graduate Student, Other Student, Other</p>
	<ul style="list-style-type: none"> • Enter in text boxes 	<p>Conflicts of Interest (COI): A conflict of interest is a situation in which a reviewer or individual involved in a funding decision about your application, a family member, a friend, or other associate is in an actual or apparent position to gain or lose personally, professionally, or financially from a decision by Komen to fund or not fund your application.</p> <p>You are required to identify all individuals associated with your application. This information is used to make sure that no one involved in the evaluation of your application has a conflict of interest with anyone involved in your application. This is a critical step in ensuring that your application gets a fair review.</p>

INFORMATION REQUIRED FOR THE PRE-APPLICATION <i>continued</i>		
Tab	Data Entry and Format Requirements	Information Requirements
Tab 4: Hypothesis & Specific Aims	<ul style="list-style-type: none"> • Enter in text boxes • Text formatting (e.g., bold, <i>italics</i>, <u>underlining</u>) is NOT retained in text box entries • 2850 character limit for hypothesis and each aim 	<p>HYPOTHESIS: State the hypothesis of the proposed research.</p> <p>SPECIFIC AIMS: Concisely state the specific aims of the study.</p>
Tab 8: Final Review & Submit	<p>Verify that all required information is included</p> <ul style="list-style-type: none"> • Approve and submit application before the deadline 	<p>Submission: Once all sections of the pre-application are marked final, the Applicant or Alternate Submitter must submit the pre-application before the deadline to be eligible to proceed through the review process.</p> <p>To submit a pre-application, the Applicant must click on the “Final Review and Submit” tab to view a checklist of all items to be included in the pre-application. Once certain that all required information has been entered or uploaded, the Applicant must enter their login password and click on the “Submit Pre-application” button then “Continue” to submit their pre-application.</p> <p>If an Applicant fails to follow these steps by the deadline, the pre-application will not be submitted and no extension of time will be granted.</p>

E-mail Confirmation

Once the pre-application has been submitted, the Applicant will receive an e-mail confirming successful submission and providing a tracking ID number for use in referencing the application. The Applicant should retain this confirmation for his/her records.

Pre-Application Peer Review and Notification

Once the pre-application deadline has passed, the pre-application review process will be conducted. At the conclusion of the review, if the pre-application is determined to be most meritorious and aligned with Komen’s research objectives, the Applicant will receive notification and gain access to all full application components. If the application is determined to be non-competitive, the Applicant will receive notification that the application has been removed from further consideration.

STEP 2: SUBMISSION OF FULL APPLICATIONS

Log in to Grants Access

Applicants should go to www.KomenGrantsAccess.org and click the “Applicant” button to log in.

Access the Application

Applicants should click on “My Applications” on the top navigation bar access a list of all current applications. Select “View/Edit” next to the application title to develop the full application.

Enter Required Information

Seven sections of information are required in the full application, each corresponding to the tabs at the top of all application pages in Komen Grants Access. These application sections are:

1. Contacts & Eligibility;
2. Application Summary Information;
3. Collaborators, Conflicts of Interest (COI) & Biosketches;
4. Hypothesis & Specific Aims
5. Abstracts & Project Proposal;
6. Budget;
7. Supporting & Regulatory Documents; and
8. Final Review & Submit

The specific information to be provided in each section is detailed in each of the tables below. The “Submission Status & Templates” tab presents summary information about the status of each section of the application and templates for use in completing the application.

After Applicants have completed all information in a section, they must mark the section as final by clicking the “Finalize” button at the bottom of the page. The “Final Review & Submit” tab is accessed only by the ASO after all application sections have been marked final to allow the ASO to certify institutional eligibility requirements and submit the application. Only the ASO can submit an application; thus it is important that Applicants allow sufficient time for ASO review, certification, and final submission.

Verify Format Requirements

Uploaded documentation must follow the formats specified below. Templates are available for download in the “Submission Status & Templates” tab. Applications will be rejected if they are not written in English, are not formatted properly (e.g., documents containing password protection will be rejected) or exceed the page limit requirements. Komen recommends the following formatting guidelines:

- Font size—12 point in Times New Roman
- Line spacing—single space (not ‘at least’ or ‘exactly’ line spacing)
- Margins—no smaller than 0.5 inch on all sides
- Page size—no larger than 8.5 by 11 inches
- Page numbers—included as a header or footer in the main body of the PDF document

The recommended formatting guidelines are provided to ensure readability. Any application that is determined to be unreadable or overly burdensome for reviewers may be administratively rejected and will not be considered for further review or funding. It is strongly suggested that Applicants keep this in mind when formatting documents.

Review Application Checklist

A checklist summarizing each application section and current status is presented in the “Submission Status & Templates” tab. Each section will be noted as Draft, Pending ASO Approval, or ASO Approved & Submitted.

- **Draft** sections either require additional information or have not been finalized by the Applicant or Alternate Submitter.
- **Pending ASO Approval** sections have been marked final by the Applicant but have not been approved and submitted by the ASO. Once all sections of the application have been marked final and their status is Pending ASO Approval, an e-mail notification will automatically be sent to the ASO assigned to the application. The ASO must review each section of the application and verify compliance with each organizational eligibility requirement. If the ASO finds that changes are required to any part of the application, he or she may reset any section to draft.
- **ASO Approved & Submitted** sections have been fully reviewed, approved, and submitted by the ASO. Once all sections are approved and eligibility verified, the ASO must provide password approval for the entire application and click the “Final Approval and Submit” button at the bottom of the Final Review & Submit page.

INFORMATION REQUIRED FOR THE FULL APPLICATION		
Tab	Data Entry and Format Requirements	Information Requirements
Tab 1: Contacts and Eligibility	<ul style="list-style-type: none"> • Enter in text boxes • Enter in a check next to each eligibility requirement 	<p>Principal Investigator: Contact information may be updated; however, the PI and organization cannot be changed.</p> <p>Applicant Eligibility: The Applicant must certify compliance with all individual eligibility requirements.</p> <p>Co-Principal Investigator: At least one co-PI is required. Additional Co-PIs can be identified on Tab 3: Collaborators, COIs & Biosketches.</p> <p>Alternate Submitter: An individual designated by the Applicant to assist him/her with the application process</p> <p>Application Signing Official (ASO): The official from the Applicant’s organization authorized to sign on behalf of the organization</p> <p>Post Award Contacts (optional): Enter name, phone and email address of grants contract official, financial official, media contact, and technology transfer official.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
Tab 2: Application Summary Information	<ul style="list-style-type: none"> • Select from question choices or dropdown lists • Please do not enter the application title in all capital letters. 	<p>Application Identification</p> <p>Application Type: Select “new application”.</p> <p>Application Title: Can be revised.</p> <p>Pre-Application Scientific Approach: Read only.</p> <p>Pre-Application Impact Statement: Read only.</p>
	<ul style="list-style-type: none"> • Enter in text boxes 	<p>Project Information</p> <p>Enter proposed project start date, end date, and requested duration of the Grant term.</p>
	<ul style="list-style-type: none"> • The first topic code cannot be revised. 	<p>Application Classification</p> <p>Translational Code: Select the translational research code that best characterizes the translational focus of the research described in your application for funding.</p> <p>Topic Codes: Select up to two topic codes that best characterize the focus of the research described in your application for funding.</p> <p>CSO Research Classification: Select up to two CSO codes that best characterize the focus of the research described in your application for funding.</p> <p>Answer questions about use of the following as described within your application for funding: Animal Subjects; Biological/ Anatomical Substances; Human Subjects.</p> <p>Clinical Trials: If you are conducting a clinical trial, answer a question about the type of clinical trial described in your application for research funding. Note that applications proposing research involving clinical trials must include a copy of the proposed clinical protocol. The protocol must be uploaded under Tab 7, “Supporting and Regulatory Documents.”</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 3: Collaborators, COI, and Biosketches</p>	<ul style="list-style-type: none"> • Upload under the “My Profile” tab • Enter in text boxes • Upload biographical sketches as PDF files • 4-page limit per individual’s biographical sketch • Templates provided under Submission Status and Templates tab • Do NOT password-protect PDF files! 	<p>Investigators and Submitters: Verify that the biosketch of PI is uploaded. If the biosketch does not appear on this screen as a .pdf icon, the biosketch must be uploaded under the “My Profile” tab.</p> <p>Percent Effort for Investigators and Collaborators Add Investigator or Collaborator: Enter information for proposed PI, named investigators and key personnel including level of effort.</p> <p>Biographical Sketch: Upload biographical sketch for collaborators ONLY. Include information about education/training, previous employment, experience, honors, publications, and patents.</p> <p>Role for Application: Select role via the drop-down box.</p> <p>Co-Principal Investigator (Co-PI’s): The individuals designated by the applicant organization to direct the research project to be supported by the Grant. The Co-PI’s are responsible and accountable to the ASO and Komen for the proper conduct of the research project. A Co-PI may be employed by, or be affiliated with, the Applicant organization or another organization participating in the project under a consortium agreement. Co-PI(s) must devote a sufficient percentage of time to the project adequate to fulfill their role as key personnel for the Grant.</p> <p>Co-Investigators: An individual working under the leadership of the PI in the scientific development or execution of the project. Investigators must devote a specified percentage of time to the project, typically less than that of the PI and are considered key personnel. The Investigator may be employed by, or be affiliated with, the Applicant organization or another participating organization.</p> <p>Co-PIs and Co-Investigators are considered key personnel on the proposed project.</p> <p>Collaborators: An individual working with the PI/Co-PI(s) in the scientific development and/or execution of the research project. Collaborators do not devote a specified percentage of time to the project and are not considered key personnel. A collaborator may be employed by, or be affiliated with, the Applicant’s organization or another participating organization.</p> <p>Other allowable roles: Consultant, Mentor, Fellow, Graduate Student, Other Student, Other</p>
	<ul style="list-style-type: none"> • Enter in text boxes 	<p>Conflicts of Interest (COI): A conflict of interest is a situation in which a reviewer or individual involved in a funding decision about your application, a family member, a friend, or other associate is in an actual or apparent position to gain or lose personally, professionally, or financially from a decision by Komen to fund or not fund your application.</p> <p>You are required to identify all individuals associated with your application. This information is used to make sure that no one involved in the evaluation of your application has a conflict of interest with anyone involved in your application. This is a critical step in ensuring that your application gets a fair review.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
Tab 4: Hypothesis & Specific Aims	<ul style="list-style-type: none"> • Enter in text boxes • Text formatting (e.g., bold, <i>italics</i>, <u>underlining</u>) is NOT retained in text box entries • 2,850-character limit (approximately 1/2 page), each 	<p>Hypothesis: State the hypothesis of the proposed research.</p> <p>Specific Aims & Tasks: Concisely state the specific aims of the study. For each specific aim describe the work to be accomplished as tasks indicating measurable milestones. Select the completion year and quarter for each aim.</p> <p>Products And Outcomes: Identify tangible outcomes, products, and deliverables expected for each specific aim. Examples of products include novel therapies, biomarkers, risk assessment tools and/or algorithms, new technologies, etc.</p>
Tab 5: Abstracts & Project Proposal	<ul style="list-style-type: none"> • Enter in text box • 5,700-character limit (approximately 1 page) • Plain text only. 	<p>Scientific Abstract: Provide a concise description of the proposed research written for scientific audiences. The scientific abstract must include descriptions of (1) the scientific rationale supporting the proposed research; (2) the specific hypothesis or hypotheses to be tested and the expected results; (3) the research aims and design; and (4) how the project uniquely advances our understanding of breast cancer and leads to reductions in incidence and/or mortality.</p>
	<ul style="list-style-type: none"> • Enter in text box • 5,700-character limit (approximately 1 page) Plain text only 	<p>General Public/Lay Abstract: Provide a concise description of the proposed research written to be understandable by nonscientist audiences. The public abstract must include descriptions of (1) the study hypothesis and how it will be tested; (2) how the project uniquely advances our understanding of breast cancer and leads to reductions in incidence and/or mortality; and (3) the importance of the research to patients with breast cancer.</p> <p>Jargon should not be used, and complex terminology relevant to the research should be explained or defined. The public abstract should not be a duplicate of the scientific abstract.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 5: Abstracts & Project Proposal</p>	<ul style="list-style-type: none"> • Auto-populates from pre-application • Revisions may be entered in text boxes • 11,400-character limit (approximately 2 pages) 	<p>Clinical Impact and Research Significance Statements:</p> <p>Clinical Impact Statement - Provide a description of the clinical impact in terms of incidence and/or mortality reduction of the research to be proposed in the application. Explain how the proposed research will lead to substantial advances that will significantly accelerate progress in finding and applying cures that will reduce breast cancer incidence and/or mortality within the next decade.</p> <p>Structure the Clinical Impact Statement according to the “Clinical Issue and Research Outcome” and “Steps and Timeline to Clinical Impact” sections as described below:</p> <p>Clinical Issue and Research Outcome: Describe both the clinical issue in breast cancer addressed by the proposed research and the targeted population (for example, triple negative breast cancer) and how the overall outcome of the proposed research (for example, a new drug) will contribute to reductions in incidence and/or mortality.</p> <p>Steps and Timeline to Clinical Impact: Describe the projected succession of steps and timeline of the research outcome(s) to achieve clinical impact. Include 1) the steps and timeline to be addressed during the period of proposed research; and 2) the subsequent steps and timeline to be addressed in future projects along the path to clinical impact.</p> <p>Research Significance: Describe the unique opportunity to explore the issue or employ a novel approach, and how the research will advance our knowledge or contribute to changes in the focus and/or conduct of future research studies.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
Tab 5: Abstracts & Project Proposal	All research proposal sections must be included in the application and must be presented in the order listed below.	
	<ul style="list-style-type: none"> • Upload as a PDF file • 20-page limit, including figures, graphs, tables, and diagrams • Do NOT password-protect PDF files! 	Background: Present the ideas and reasoning behind the proposed work, citing relevant references
		Hypothesis and Objective: State the hypothesis to be tested and the objective of the proposed research, including any supporting rationale.
		Study Design: Provide details about the experimental design, methods, and analysis for the proposed research. If the methods are new or unusual, describe them in sufficient detail for evaluation of feasibility and merit. Address potential problems and present alternative methods and approaches. Describe the statistical plan. Include a detailed plan for the recruitment of human subjects or the acquisition of samples as appropriate.
<ul style="list-style-type: none"> • Upload as a separate PDF file • Do NOT password-protect PDF files! 	Research Integration: Describe how the proposed individual research projects provide an integrated approach to efficiently yield answer to important clinical questions. Discuss how the proposed individual's research projects leverage the unique opportunities of an integrated research program. Provide evidence that the proposed program of research effectively leverages unique expertise (including advocate expertise), resources, care settings, relationships, and organizational commitments across researcher disciplines and institutions.	
<ul style="list-style-type: none"> • Upload as a separate PDF file • Do NOT password-protect PDF files! 		References: List references cited in the project proposal. Do NOT include references in the same PDF as your project proposal. This could affect the number of pages in the proposal and may disqualify your application during automated compliance checks of page limits.

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 6: Budget</p>	<ul style="list-style-type: none"> • Enter budget information in data entry fields. • Personnel on the project are limited to a base salary at or below \$199,700 per year. • Equipment cannot exceed 30% of direct costs. • Indirect costs cannot exceed 25% of direct costs. • Budget justifications are required for <ul style="list-style-type: none"> - Salaries & Wages - Supplies - Equipment - Patient care costs - Travel - Other expenses 	<p>Budget and Justifications: Budget information and justifications must include each of the following:</p> <p>Salaries and wages: The salaries of the PI and key personnel on the project. <u>Percent effort must be provided for the PI, and all key personnel even if they are not being compensated.</u> Percent effort for each should be included in the Salaries and Wages section under Budget Justification. If a collaborating investigator is considered key personnel, they should be included in the personnel costs and the associated budget justification.</p> <p>Fringe benefits: Employee compensation other than wages and salaries, such as health insurance, life insurance, and pension plans.</p> <p>Other personnel costs: All other costs associated with personnel on the project and to be paid by the Grant.</p> <p>Supplies: Costs for any supplies needed for the execution of the project that will be funded through the Grant (i.e., lab supplies, etc.).</p> <p>Equipment: Costs for any equipment needed for the execution of the project that will be funded through the Grant (i.e., cryostats, centrifuges, etc.)</p> <p>Patient care costs: Costs associated with the care of any patients (i.e., human subjects) proposed and to be supported by the Grant.</p> <p>Travel: Any travel to be funded through the Grant (i.e., scientific meetings, grantee meetings, etc.) for individuals named on the Grant only.</p> <p>Other expenses: Expenses that will be funded through the Grant not captured in any of the other budget line items. Note that society membership dues are not permitted expenses.</p> <p>Consortium/contractual costs: Costs associated with subcontractor or consortia (grants made to other organizations or institutions). Costs should be presented using the same budget categories listed above (Personnel, Salaries and Wages, Fringe Benefits, Supplies, etc.) Indirect costs paid to subcontractors or consortia may not exceed 25% of the direct costs paid, and these indirect costs must be applied against the 25% permitted to be allocated against the entire Grant.</p> <p>Indirect cost allocation: (cannot exceed 25% of direct costs) Indirect costs are all expenses not directly related to the conduct of the project.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 7: Supporting & Regulatory Documents</p>	<ul style="list-style-type: none"> • Upload letters of resource support, eligibility documentation and clinical protocols as PDF files. • Do NOT password-protect PDF files! 	<p>Letters of Resource Support: Provide letters of resource support confirming the laboratory space, equipment, and other resources available to the investigator for this project.</p>
	<ul style="list-style-type: none"> • Upload existing and pending support as PDF files. • Templates provided under Summary and Templates tab. • Do NOT password-protect PDF files! 	<p>Clinical Protocols: Applications proposing research involving clinical trials must include a copy of the proposed clinical protocol.</p> <p>Existing and Pending Grant Support: Provide the following information for all current and/or pending research grants held by the Applicant:</p> <ul style="list-style-type: none"> • Title • Supporting agency • Name and address of funding agency's grants officer • Grant term • Amount of funding • Percentage of Applicant's time • Brief description of the project's goals • Specific Aims
	<ul style="list-style-type: none"> • Upload regulatory assurances as PDF files, if available. • Regulatory Assurances are NOT required to submit an application. • Do NOT password-protect PDF files! 	<p>Regulatory Assurances</p> <ul style="list-style-type: none"> • Disclosure of human subjects/animal use • Disclosure of human biological/anatomical materials use • Disclosure of recombinant DNA or biohazardous materials use <p>Submission of final IRB, IACUC and/or HIPAA approvals is not required until after the grant has been awarded.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 8: Final Review & Submit</p>	<ul style="list-style-type: none"> • Verify that all required information is included. • Enter a check next to each institutional eligibility requirement. • Approve and submit application before the deadline. • PI and ASO will receive e-mail verification of successful submission. 	<p>Full Applications: An ASO must certify compliance with institutional eligibility requirements and approve and submit the full application.</p> <p>The ASO must provide password approval for the entire application and click the “Final Approval and Submit.” If the ASO fails to click the Final Approval and Submit button by the specified deadline, the application will not be submitted and will not be considered for funding under this RFA.</p>

Retain E-mail Confirmation

Once the application has been submitted by the ASO, the Applicant and ASO will receive an e-mail confirming successful submission of the application. The Applicant should retain this confirmation for his/her records.

Full Application Peer Review and Notification

Once the application deadline has passed, the review process will be conducted. At the conclusion of the review, Komen’s Scientific Advisory Board (SAB) reviews the results and makes final funding recommendations across all research mechanisms. Applications are recommended for funding in the order of the overall average score.

SAB recommendations are then forwarded to Komen’s Board of Directors which determines the final slate of applications for funding. After Board approval, Applicants are notified by email when notifications of intent to fund and review summaries are posted to their Komen Grants Access account. All review summaries include un-edited reviewer critiques for each review criterion, a summary of the review discussion, and the average overall score.

APPENDIX A: ADVOCATE INVOLVEMENT IN PROMISE GRANTS

Advocate involvement is a required element of the proposed program of research to be supported by a Komen Promise Grant. Advocate involvement must be meaningful and appropriate for the research projects and **must be clearly described in the pre-application and full application**. Advocates could be involved in many facets of the research project, including identification of the research question, project design, oversight, recruitment, and evaluation, in addition to other areas. 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. These are not intended to be viewed as required elements, but instead serve as examples of the contributions that advocates can make. 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®), and their role in the project should be independent of their employment.
- Advocates should not be employees of any of the organizations applying for the Grant.
- 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

- Reviewing the proposed design of the 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 through messaging and community outreach, such as:
 - Creating patient education materials to explain the research project and clinical trial, the importance of the research to breast cancer, and how the trial might be an option for patients
 - Working with community organizations to inform and engage breast cancer patients in the trial
- 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.
- Creating an educational approach 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, web conferences, and written materials they can use on their web sites and in their newsletters.

- 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.
- Speaking in the community about the results of your 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 if appropriate



ADVOCATES IN SCIENCE



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.