



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.

INVESTIGATOR-INITIATED RESEARCH GRANTS

2010-2011 REQUEST FOR APPLICATIONS

Annual Research Focus Areas

- Prevention/Early Detection
- Novel Therapeutics and Resistance
- Biology of Breast Cancer
- Disparities in Breast Cancer Outcomes

Susan G. Komen for the Cure
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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 the Investigator-Initiated Research (IIR) Grants and what investigators need to know to apply.

INVESTIGATOR-INITIATED RESEARCH GRANTS

IIR Grants seek to stimulate exploration of important issues and novel approaches that will lead to reductions in breast cancer incidence and/or mortality within the next decade.

KEY DATES

RFA Released	May 10, 2010
Pre-Application Due	June 25, 2010, by 8 p.m., EDT
Pre-Application Decision Date	September 7, 2010
Full Application Due	November 2, 2010, by 8 p.m., EDT
Application Review	November 2, 2010 - January 14, 2011
Board Approval	January 2011
Award Notification	February 2011
Anticipated Funding Start	April 2011

NEW! ANNUAL RESEARCH FOCUS

Komen is introducing a new approach to its IIR RFA in an effort to align supported research projects with Komen's annual strategic objectives and to provide consistency for the research community. For the next few years, the IIR RFA will focus on four standing topic areas – prevention/early detection; novel therapeutics and resistance; the biology of breast cancer; and disparities -- within which very specific research issues will be identified for that year's RFA. Therefore, the recurring topic areas will remain constant from year to year, but the specific research issues will change each year. Only applications addressing the specific research issues for that year will be accepted; however, it is expected that a broad range of laboratory and clinical investigations will be proposed within each specific annual research issue. All proposed research must have significant potential to lead to reductions in breast cancer incidence and/or mortality within the decade.

The IIR specific research issues for 2010-2011 are:

Prevention/Early Detection — Research seeking to a) identify and/or implement interventions to prevent breast cancer in asymptomatic women or prevent second primary breast cancers; b) identify early stage breast cancer or pre-malignant lesions; and c) identify women at high risk for developing breast cancer.

FY11 Annual Research Issue:

1. Molecular Predictors of High Risk and Early Disease

Novel Therapeutics and Resistance — Research seeking to a) identify, validate, and/or test new treatments or treatment combinations for disease initially resistant to therapy, b) discover, validate and/or test biomarkers of treatment resistance and/or response following resistance to initial therapy, c) identify and/or elucidate mechanisms and/or predictors of acquired resistance, and/or d) explore new approaches for overcoming mechanisms of treatment resistance.

FY11 Annual Research Issue:

1. Targeted Therapies for Hormone Receptor Positive Breast Cancer with Resistance to Endocrine Therapies

Biology of Breast Cancer – Research seeking to understand molecular and/or cellular processes involved in the initiation and progression of breast cancer and their specific implications for prevention and treatment of breast cancer.

FY11 Annual Research Issues:

1. Biological Underpinnings and Therapeutic Implications of Micrometastases; or
2. Epigenetic Alterations

Disparities in Breast Cancer Outcomes – Research seeking to a) understand the biologic, behavioral, social and systems causes of disparities in breast cancer outcomes across population groups, and b) identify, validate and test health services and public health interventions that address the causes of disparities in care and outcomes across population groups.

FY11 Annual Research Issues:

1. All Issues Relevant to Disparities as Defined Above

Applications addressing topics other than those described above as annual research issues 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 an IIR 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 not simultaneously apply for a Komen Career Catalyst Research Grant or be the Principal Investigator (PI) on a Career Catalyst Research Grant currently in the first or second year of funding
- 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.
- Are not required to be U.S. citizens or residents

INSTITUTIONS

- Must be a nonprofit institution or organization anywhere in the world
- 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 a single Principal Investigator (PI) or two Co-Principal Investigators (Co-PI's).

FUNDING INFORMATION

Applicants may request either two or three years of funding as follows:

- Up to \$400,000 in total over two years (combined direct and indirect costs); or
- Up to \$600,000 in total over three years (combined direct and indirect costs)

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.

Pre-application Scientific Peer Review Criteria

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

Scientific Approach	Will the proposed specific aims answer the study hypothesis? Will the scientific approach effectively test and answer each specific aim?
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 to large leaps of understanding or knowledge that will contribute to reductions in breast cancer incidence and/or mortality within the decade?
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 breast cancer research? Will the study outcomes advance our knowledge of breast cancer 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, average criterion scores, 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.

Scientific Merit	Will the proposed research answer the study hypothesis? Will the scientific approach effectively test and answer each specific aim? Does the research use valid research and statistical methods? Does the research anticipate and remedy potential experimental problems to ensure effective resolution of the study hypothesis?
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 to large leaps of understanding or knowledge that will contribute to reductions in breast cancer incidence and/or mortality within the decade?
Research Significance	Does the study address an important question(s) 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 breast cancer research? Will the study outcomes advance our knowledge of breast cancer and/or contribute to changes in the focus of future research questions or the way we conduct research on this issue?
Feasibility	How likely is it that the proposed research goals and milestones will be achieved within the scope of the funded project?
Expertise	Does the PI/Co-PI and his/her research team have the expertise to effectively implement all aspects of the proposed research?

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 two important resources for submitting their application, Komen Grants Access, the online system used for managing the application process, 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.

A User Guide is available after signing into the application system to help Applicants navigate through the application process.

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.



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.

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.

- Register/Log in to Grants Access: Applicants should go to www.KomenGrantsAccess.org and register as a new user or log in using their existing username and password. They should click on "Start a New Application" to begin entering pre-application information.
- Enter Required Information: All information must be written in English. Four sections of information are required in the pre-application; 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 Application" 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.
- Final Review and Submit Pre-Application: 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. 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 click on the "Final Approval and Submit" button to submit their pre-application. If an Applicant fails to click the "Final Approval and Submit" button by the deadline, the pre-application will not be submitted and no extension of time will be granted.
- Peer Review and Notification: Once the pre-application has been submitted, 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.
- Retain 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.

INFORMATION REQUIRED FOR THE PRE-APPLICATION

Permanent Information: No changes/modifications can be made to the PI name, institution, translational code or the first of the two selected topic codes 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 & 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, 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"> • Enter in text boxes 	Application Signing Official (ASO): Enter name, institution, and contact information. The ASO is the official from the Applicant's organization authorized to sign on behalf of the organization
Tab 2: Application Summary Information	<ul style="list-style-type: none"> • Enter in text boxes 	Title: Working title of application
	<ul style="list-style-type: none"> • Enter in text boxes • 11,400-character limit (approximately 2 pages) 	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, and (b) aligns with the annual research focus.

INFORMATION REQUIRED FOR THE PRE-APPLICATION *continued*

Permanent Information: PI name, institution, and the first of the two selected topic codes cannot be changed after submission. All other fields can be changed during the full application process.

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 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. Address key steps such as preclinical cell line development and/or testing, animal validation, human tissue validation, Phase I, II, and III clinical trials, as well as key milestones such as IND, IDE, and NDA submissions.</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"> • Select from question choices or dropdown lists • The first topic code and translational code cannot be revised 	<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 Codes: Select up to two CSO codes that best characterize the focus of the research described in your application for funding.</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>

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 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>Biographical Sketch: Include a biographical sketch for the proposed PI, named investigators and key personnel. Include information about education/training, previous employment, experience, honors, publications, and patents.</p> <p>Co-Principal Investigator (Co-PI): 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 Applicant organization officials 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-PIs and Investigators are considered key personnel on the proposed project.</p>
	<ul style="list-style-type: none"> • Enter in text boxes • You must specify the % effort and corresponding year for each investigator (including the PI and Co-PI; if applicable) collaborator, coinvestigator, subawardee, postdoctoral fellows, graduate students, mentors or other personnel associated with or working on your proposed project 	<p>Investigators, Collaborators & COI's: List collaborators and/or persons identified as conflicts of interest and their institutions</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>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>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 *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 4: Hypothesis & Specific Aims</p>	<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 	<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 indicating measurable milestones.</p>
<p>Tab 8: Final Review & Submit</p>	<ul style="list-style-type: none"> • Verify that all required information is included • Approve and submit application before the deadline • Applicant will receive e-mail verification of successful submission 	<p>Submission: The Applicant or Alternate Submitter may submit the pre-application. The Applicant or Alternate Submitter must click on the “Final Approval and Submit” button to submit their pre-application. If an Applicant fails to click the Final Approval and Submit button by the specified deadline, the pre-application will not be submitted and the Applicant will no longer be eligible to submit an application under this RFA.</p>

STEP 2: SUBMISSION OF FULL APPLICATIONS

- **Access the Application:** Applicants should click on “My Applications” on the top navigation bar in Komen Grants Access to access a list of all current applications. Select “View/Edit” next to the application title to modify the application.
- **Enter Required Information:** Eight 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 and Specific Aims
 - (5) Abstracts and Project Proposal;
 - (6) Budget;
 - (7) Supporting & Regulatory Documents; and
 - (8) Final Review and 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., document 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.
- **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.

INFORMATION REQUIRED FOR THE FULL APPLICATION		
<p>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 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 change from the pre-application.</p>		
Tab 1	Data Entry and Format Requirements	Information Requirements
Contacts & Eligibility	<ul style="list-style-type: none"> • Enter in text boxes 	<p>Contact Information: E-mail and phone information is required for each of the following institutional personnel:</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>
	<ul style="list-style-type: none"> • Enter in a check next to each eligibility requirement 	<p>Applicant Eligibility: The Applicant must certify compliance with all individual eligibility requirements.</p>

INFORMATION REQUIRED FOR THE FULL 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 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. Address key steps such as preclinical cell line development and/or testing, animal validation, human tissue validation, Phase I, II, and III clinical trials, as well as key milestones such as IND, IDE, and NDA submissions.</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
	<ul style="list-style-type: none"> • Select from question choices or dropdown lists • The first topic code and translational code cannot be revised 	<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 Codes: Select up to two CSO codes that best characterize the focus of the research described in your application for funding.</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>Animal Subjects: Answer questions about use of animal subjects in the research described in your application for funding.</p> <p>Biological/Anatomical Substances: Answer questions about the use of biological and/or anatomical substances in the research described in your application for funding.</p> <p>Human Subjects: Answer questions about the use of human subjects in the research described in your application for funding.</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, & Biosketches</p>	<ul style="list-style-type: none"> • Upload biosketches 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>Biographical Sketches: Biographical sketches must be included for the PI and all supporting scientists, technicians, fellows, or graduate students involved in the proposed research. Provide education/training information, previous employment, experience, honors, and publications relevant to this research.</p> <p>Principal Investigator (PI): The individual(s) designated by the Applicant's organization to direct the research project to be supported by the grant. The PI is responsible and accountable to the Applicant organization officials and Komen for the proper conduct of the research project.</p> <p>Co-Principal Investigator (Co-PI): An individual who shares the responsibilities for the conduct of the research with the PI, including the scientific development, execution and overall management of the research project. A Co-PI may be employed by, or be affiliated with, the Applicant's 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 project.</p>
	<ul style="list-style-type: none"> • Enter in text boxes and identify relationship to application • You must specify the % effort and corresponding year for each investigator (including PI), collaborator, coinvestigator, subawardee, postdoctoral fellows, graduate students, mentors or other personnel associated with or working on your project. 	<p>Investigators, Collaborators & COI's: List investigators (including PI and any Co-PI's), collaborators and/or persons identified as conflicts of interest</p> <p>Collaborators: An individual working with the PI in the scientific development and/or execution of the research project. Collaborators 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>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's organization or another participating organization.</p> <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 <u>required</u> 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 receives a fair review.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab	Data Entry and Format Requirements	Information Requirements
<p>Tab 4: Hypothesis & Specific Aims</p>	<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 	<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 indicating measurable milestones. Select the completion year and quarter for each aim.</p> <p>Research 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>
<p>Tab 5: Abstracts & Project Proposal</p>	<ul style="list-style-type: none"> • Enter in text box • 5,700-character limit (approximately 1 page) 	<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) 	<p>Public 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
Tab 5: 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 • 10-page limit, including figures, graphs, tables, and diagrams • Do NOT password-protect PDF files! 	<p>Background: Present the ideas and reasoning behind the proposed work, citing relevant literature. Preliminary data are permitted, but are not required.</p>
		<p>Objective and Hypothesis: Present the objective(s) of the proposed research and the hypothesis to be tested, including any supporting rationale.</p>
		<p>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.</p>
<ul style="list-style-type: none"> • Upload as a separate PDF file • Do NOT password-protect PDF files! 	<p>References: List references cited in the project proposal.</p> <p>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.</p>	

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 percent of direct costs. • Indirect costs cannot exceed 25 percent 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>Personnel costs: All costs associated with personnel on the project and to be paid by the Grant.</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>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 related to the research project 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 due are not permitted expenses.</p> <p>Consortium/contractual cost: Costs associated with subcontractors 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 percent of the direct costs paid, and these indirect costs must be applied against the 25 percent permitted to be allocated against the entire Grant.</p> <p>Subtotal direct costs: Total of all direct costs which include: personnel, fringe benefits, supplies, equipment, patient care costs, travel, expenses and consortium/contractual costs.</p> <p>Indirect cost allocation: (cannot exceed 25 percent of direct costs) Indirect costs are all expenses not directly related to the conduct of the project, including indirect cost allocations for subcontracts or consortia.</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 and clinical trial 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 provide under Submission Status and Templates tab. • Do NOT password-protect PDF files! 	<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. • Applicant 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>