



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.

POSTDOCTORAL FELLOWSHIP RESEARCH GRANTS

BASIC RESEARCH — TRANSLATIONAL RESEARCH — CLINICAL RESEARCH

2009-2010 REQUEST FOR APPLICATIONS

KOMEN RESEARCH PROGRAM

Komen's Research Program plays a critical role in energizing science to find the cures by funding discoveries, individuals, and the resources essential to ending breast cancer. This program supports research and trainings through many different types of grants and awards, each designed to meet specific objectives and to optimize results. The 2009-2010 Research Program and portfolio of Requests for Applications (RFA) continues Komen's strategic focus on reducing breast cancer incidence and/or mortality. This RFA provides specific details about Postdoctoral Fellowship Research (PDF) grants and what investigators need to know to apply for a grant under this program.

POSTDOCTORAL FELLOWSHIP RESEARCH GRANTS

The Postdoctoral Fellowship (PDF) Grants seek to (a) attract scientists into careers addressing important research questions about breast cancer, (b) expand the skills and expertise of breast cancer researchers in training, and (c) position trainees for independent careers conducting breast cancer research that will directly affect breast cancer patients.

KEY DATES

RFA Released	September 1, 2009
Pre-Application Due	October 1, 2009, by 8 p.m., e.t.
Full Application Due	November 17, 2009, by 8 p.m., e.t.
Application Review	December 7, 2009 to February 5, 2010
Award Notification	April 2010
Anticipated Funding Start	May 2010

TRAINING GOALS BY RESEARCH AREAS

Komen is committed to training across the research continuum and therefore has developed 3 types of PDF training awards. These include:

- (1) **Basic Research PDF grants** seek to expand skills and expertise in basic sciences and methods that substantially advances progress in breast cancer research that will lead to future reductions in breast cancer incidence and/or mortality.
- (2) **Translational Research PDF grants** seek to expand skills and expertise in the application of laboratory, clinical and applied disciplines to research that translates laboratory, clinical, and/or population discoveries into important new clinical tools and applications leading to reductions of breast cancer incidence and/or mortality within the next decade.
- (3) **Clinical Research PDF grants (New!!)** seek to (a) attract outstanding physicians who wish to pursue a career path that blends patient care with high impact, clinical and/or translational breast cancer research, (b) expand the research skills and expertise of physicians who have completed their residency or subspecialty medical/surgical training, (c) position trainees for independent careers as physician scientists with the knowledge and expertise to conduct and manage an active research program that will significantly impact breast cancer patients, and (d) support high quality research concepts that, if successful, could provide the basis for reducing breast cancer incidence and mortality within the next decade.

ELIGIBILITY

Applicants and institutions must conform to the following eligibility criteria to be considered for funding under the PDF program. Eligibility requirements must be met by the time of full application submission.

Applicants - Mentors

(The individual identified as the Principal Investigator(s) on the application must be the Mentor(s))

- Must hold a full-time faculty appointment with an accredited institution
- Must not be the Principal Investigator (PI)/mentor on more than one Komen Postbaccalaureate Training or Postdoctoral Fellowship (PDF) grant awarded in the same year/annual funding cycle
- Must currently conduct breast cancer research
- 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

Fellow

- Must have a doctoral degree, including MD, PhD, DrPH, DO, or equivalent.
- By the start date of the fellowship award, must be no more than;
 - 3 years post-completion of his/her most recent clinical M.D. fellowship, or
 - 5 years post-completion of his/her most recent MD residency or PhD
- May not hold any current faculty appointments
- May not currently be or have been a fellow on a Komen PDF grant
- Must conduct the proposed research and training at the applicant/mentor institution
- Must ensure that all past and current Komen-funded grants or awards are up to date and in compliance with Komen requirements (e.g., progress report submissions, IRB approvals, etc.)
- Are not required to be U.S. citizens or residents

Specifically for Clinical Fellowships:

- Must be a physician (MD, DO, or international equivalent with explanation). Candidates from breast-related subspecialists are encouraged to apply, including those with backgrounds in medical oncology, surgical oncology, radiation oncology and/or radiology.
- Must have completed all formal medical/surgical training by the start of the clinical fellowship
- Must be able to commit at least 60% of full-time effort to research during each year of the award period

Institutions

- Must be a nonprofit institution or organization in the United States or abroad.
- Must agree with Komen's Policies and Procedures for Research and Training Grants for funding, including for example, regulatory assurances, ownership of equipment, intellectual property, liability and insurance, and reporting requirements.

DESIGNATED RECIPIENTS

Grants are awarded to the Mentor(s) as the PI(s). Grants may be awarded to a single PI/Mentor or up to a total of two Co-PI's/Mentors. Komen is particularly interested in providing training support for minority scientists. A portion of available funds will be designated for applications supporting minority fellows. Awards will be made to the Mentor/Fellow pair, therefore changes in Fellow will not be permitted prior to award or within the first 12 months of the award period.

FUNDING INFORMATION

Applicants may request either two or three years of funding. Applications under the PDF program may request up to \$60,000 per year (direct costs only) for each of the initial 2 years, with \$60,000 (direct costs only) for the optional 3rd year, based on an assessment of first-year progress.

FULL APPLICATION REVIEW PROCESS

Full applications proceed through a two-phase review process, including an online review by assigned reviewers and review committee discussion in either a conference call or face-to-face meeting. Each application is initially assigned to a review committee and then assigned to individual reviewers within that committee. Applications are reviewed by three reviewers, including two scientists (including laboratory, clinical, and public health investigators), and one advocate. Scientist reviewers are selected for their professional credentials and expertise in the specific areas of science under consideration for funding. Advocate reviewers are selected for their commitment to ending breast cancer and their interest in research and scientific peer review. Scientist and advocate reviewers assess the strengths and weaknesses of each application based on the defined review criteria for that RFA. Scientist reviewers assign review scores for all review criteria and advocate reviewers assign a score only for the impact criterion.

Based on initial criteria scores from assigned reviewers, applications with large score discrepancies across reviewers are identified for assigned reviewers. Reviewers also receive feedback about the distribution of their scores compared to the committee. Reviewers may then adjust scores based on review critiques and re-review of assigned applications. Approximately 60 to 70 percent of applications are then triaged out of review discussion based on individual criteria score distributions within each review committee. Applications with persisting large score discrepancies are moved back into discussion to ensure appropriate resolution of disparate assessments. All reviewers are given an opportunity to retrieve triaged applications back into discussion or recommend that an application be moved out of discussion. Triage ensures that all applications with a reasonable opportunity for funding receive a thorough discussion by the full review committee.

Following review committee discussion of each application, committee members assign a single, overall application score. These overall scores are normalized across committees and are used by Komen's Scientific Advisory Board (SAB) to make final funding recommendations that ensure strategic balance across Komen's research portfolio and reflect organizational priorities. SAB recommendations are then forwarded to Komen's Board of Directors who determines the final slate of applications for funding. After Board approval, applicants are notified by email when notifications of intent to fund and applicant review summaries are posted to their Komen Grants Access account. All applicant review summaries include un-edited reviewer critiques and mean scores for each review criteria. Applicant review summaries for applications that proceeded to review committee discussion also include a summary of the review discussion and the final normalized overall score.



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.

SCIENTIFIC PEER REVIEW CRITERIA

Evaluations for funding consideration are based on each of the following review criterion. These criteria are listed in Komen's order of importance. However, the first two criteria, Scientific Merit and Training 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.

PDF APPLICATIONS WILL BE EVALUATED ON THE FOLLOWING CRITERIA	
Scientific Merit	Does the proposed research answer the 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 the study hypothesis?
Training Impact	Assuming the fellow acquires the proposed knowledge and skills, will the fellowship position him/her as an independent investigator likely to make significant contributions in breast cancer research, particularly high impact research that directly affects individuals? How evident and clearly defined is the fellow's commitment to a career in breast cancer research? How well does the proposed research align with and further the fellow's specific career goals? How well do the training components align with and further the fellow's specific career goals?
Mentor	Does the mentor have experience with mentoring and sufficient time to actively engage in the training of the fellow? Is the mentor committed to the specific training and career development of this fellow?
Fellow	Does the fellow demonstrate the expertise and commitment to capitalize on the training experience and pursue a productive career in breast cancer research?
Training Experience	Does the proposed research project and training program promote research independence for the fellow? Does the training environment provide rich opportunities for expanding the fellow's knowledge and skills in research, particularly research leading to the translation of discoveries to clinical tools and applications? Does the environment promote training opportunities such as coursework, presentations, journal clubs, seminars, collaborative interactions, and attendance at scientific meetings? How will the environment contribute to the fellow establishing future leadership for a defined area of research?

SUBMISSION PROCESS

The application process includes two distinct steps: (1) Submission of a pre-application, followed by (2) submission of a full grant 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 Komen Grants Help Desk support, which provides both email and telephone assistance with the application process.

Komen Grants Access

Komen's research application process is managed through Komen's online Grants Access system. All applications **must** be submitted electronically through this online system, which can be accessed at www.KomenGrantsAccess.org. First-time users must register and create a username and password. This username and password allows users to enter Grants Access to develop, modify, and submit pre-applications and applications. Once users have registered in Komen's Grants Access system, they do not need to reregister in order to apply for other Komen funding opportunities.

Komen Grants Help Desk Support

All inquiries regarding application submission should be directed to the Komen help desk at helpdesk@komengrantsaccess.org or 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 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 allow Komen to anticipate the number of applications that will be received, to identify review committee and to begin the process of recruiting and assigning reviewers and screening for conflicts of interest. Lists of collaborators and/or key personnel are used to complete an initial screen for conflicts of interest.

- **Register/Log in to Grants Access:** Applicants must go to www.KomenGrantsAccess.org and register as a new user or log in using their existing username and password. Select “Start a New Application” to begin entering pre-application information.
- **Enter Required Information:** Three 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 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 Applicant Signing Official and Alternate Submitter(s):** Applicants must provide an Applicant Signing Official (ASO) who is authorized to sign on behalf of the organization access to their application on Komen Grants Access. **The ASO is the only individual who can provide final approval and submit the full application, however the PI may submit the pre-application..** The PI also may provide permission to an individual in his/her organization to enter 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 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 submit a full application. To submit a pre-application, the applicant should click on the Final Review and Submit tab to view a checklist of all items to be included in the pre-application. Once they are 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 specified deadline, the pre-application will not be submitted and the applicant will no longer be eligible to submit an application under this RFA. No changes or modifications can be made to the PI name, institution, the first topic code or translational code once the pre-application has been submitted. The first topic code must accurately describe the primary focus of research submitted in the full application.
- **Retain E-mail Confirmation:** Once the pre-application has been submitted, the PI will receive an e-mail confirming successful submission and providing a tracking ID number for use in referencing the application. **The PI should retain this confirmation for his/her records.**

INFORMATION REQUIRED FOR THE PRE-APPLICATION

Permanent Information: PI name, institution, translational code 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
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 	<p>PI: Name, degrees, institution, and contact and demographic information</p>
	<ul style="list-style-type: none"> • Enter a check next to each eligibility requirement 	<p>Eligibility: The PI must certify compliance with eligibility requirements for the PI/Mentor and Fellow.</p>
	<ul style="list-style-type: none"> • Enter in text boxes 	<p>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</p>
Tab 2: Application Summary Information	<ul style="list-style-type: none"> • Enter in text boxes 	<p>Title: Working title of application</p>
	<ul style="list-style-type: none"> • Enter in text boxes • 5,700-character limit (approximately 1 page) 	<p>Scientific Abstract and Specific Aims (Project Description): Provide a description of the research to be proposed in the application including the study hypothesis and specific aims. Structure this description as described below.</p> <p>Project Summary</p> <ul style="list-style-type: none"> • Background, rationale, and significance • Study objective/hypothesis • Specific aims
	<ul style="list-style-type: none"> • Enter in text boxes • 5,700-character limit (approximately 1 page) 	<p>Impact Statement: Provide a description of the training impact the fellow will gain as a result of the research to be proposed in the application.</p> <p>Training Impact: Describe the fellow's commitment to a career in breast cancer research and specific career goals. Describe how the proposed research and training components align with and further these goals. Describe how the proposed research and training will position the fellow as an independent investigator likely to make significant contributions in breast cancer research, particularly high impact research that directly affects individuals.</p>
	<ul style="list-style-type: none"> • Select from dropdown lists • First topic code and translational code may not be changed after submission 	<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 Common Scientific Outline (CSO) codes that best characterize the focus of the research described in your application for funding.</p> <p>Translational Codes: 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>Tab3: 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 Summary and Templates tab • Do NOT password-protect PDF files! 	<p>Biographical Sketch: Biographical sketches must be included for the PI/Mentor and Fellow as well as other supporting scientists, technicians, or graduate students involved in the proposed research. Include information about education/training, previous employment, experience, honors, publications, and patents.</p> <p>Principal Investigator (PI)/Co-Principal Investigator (Co-PI)/Mentor: The individual(s) designated by the applicant organization to direct the research project to be supported by the grant. The PI(s)/Mentor(s) are responsible and accountable to the applicant organization officials and Komen for the proper conduct of the research project.</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/grantee organization or another participating organization.</p>
	<ul style="list-style-type: none"> • Enter in text boxes • You must specify the % effort and corresponding year for each collaborator, coinvestigator, subawardee, graduate students, mentors or other personnel associated with or working on your grant. 	<p>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 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/grantee organization or another participating organization. Note that mentor committees are encouraged but not required. Members of a mentor committee should be listed as collaborators.</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 gets a fair review.</p>
<p>Tab 7: Final Review & Submit</p>	<ul style="list-style-type: none"> • Verify that all required information is included • Approve and submit application before the deadline • PI will receive e-mail verification of successful submission 	<p>Submission: The PI or Alternate Submitter may submit the pre-application. The PI 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 to access a list of all current applications. Select “View/Edit” next to the application title to modify the application.

- **Enter Required Information:** Six sections of information are required in the full application, each corresponding to the tabs at the top of all application pages in Grants Access. These application sections are:

- (1) Contacts & Eligibility;
- (2) Application Summary Information;
- (3) Collaborators, Conflicts of Interest (COI), & Biosketches;
- (4) Abstracts and Project Proposal;
- (5) Budget; and
- (6) Supporting & Regulatory Documents.

The specific information to be provided in each section is detailed in each of the tables below. The Summary & 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 by Komen. Templates are available for download in the Summary & Templates tab. Applications will be rejected if they are not in English, are not uploaded properly (non-password protected PDF and predefined fields, where appropriate), or do not meet the page limit requirements. Komen recommends the following formatting guidelines:

- (1) Font size—12 point in Times New Roman
- (2) Line spacing—single space (not ‘at least’ or ‘exactly’ line spacing)
- (3) Margins—no smaller than 0.5 inch on all sides
- (4) Page size—no larger than 8.5 by 11 inches
- (5) Page numbers—included 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 summary of each application section and current status is presented in the Summary & 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 PI or Alternate Submitter. Sections noted as Pending ASO Approval have been marked final by the PI 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 so that they can approve and submit the application.

- **ASO Approval and Submission:** The ASO will receive an auto-generated e-mail from Grants Access indicating that all application sections have been marked final by the PI. 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. 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/PI and ASO will receive an e-mail confirming successful submission of the application. **The PI should retain this confirmation for his/her records.**

INFORMATION REQUIRED FOR THE FULL APPLICATION		
Tab 1	Data Entry and Format Requirements	Information Requirements
Contacts and 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 PI to assist him/her with the application process</p> <p>Application Signing Official (ASO): The official from the applicant organization authorized to sign on behalf of the organization</p> <p>Grants Contract Official: The official from the applicant organization authorized to negotiate the terms and conditions of any grant contract administered by Komen</p> <p>Financial Official: The official from the grantee organization authorized to sign financial reports, supervise financial administration of a grant, and receive check payments from Komen upon award of the grant</p> <p>Media Contact: The official from the grantee organization authorized to provide or request press release information pertaining to an awarded grant application</p> <p>Technology Transfer Official: The official from the grantee organization who answers questions relating to copyrights, patents, or disclosures resulting from an awarded research project</p>
	<ul style="list-style-type: none"> • Enter in a check next to each eligibility requirement 	<p>Applicant and Fellow Eligibility: The PI/Mentor must certify compliance with all individual eligibility requirements. Eligibility requirements related to faculty appointments and years since completion of academic degrees and/or training programs must be substantiated by supporting documents uploaded in the Supporting & Regulatory Documents Tab.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab 2	Data Entry and Format Requirements	Information Requirements
<p>Application Summary Information</p>	<ul style="list-style-type: none"> • Select from question choices or dropdown lists 	<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 Codes: 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.</p>



INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab 3	Data Entry and Format Requirements	Information Requirements
<p>Collaborators, COI, and Biosketches</p>	<ul style="list-style-type: none"> • Upload biosketches as PDF files • 4-page limit per individual's biographical sketch • Templates provided under Summary and Templates tab • Do NOT password-protect PDF files! 	<p>Biographical Sketches: Biographical sketches must be included for the PI/Mentor and Fellow as well as other supporting scientists, technicians, 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)/Co-Principal Investigator (Co-PI)/Mentor: The individual designated by the applicant(s) organization to direct the research project to be supported by the grant. The PI/Co-PI is/are responsible and accountable to the applicant organization officials and Komen for the proper conduct of the research project.</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/grantee organization or another participating organization.</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 collaborator, coinvestigator, subawardee, graduate students, mentors or other personnel associated with or working on your grant. 	<p>Collaborators & COI's: List 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/grantee organization or another participating organization. Note that mentor committees are encouraged but not required. Members of a mentor committee should be listed as collaborators.</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 gets a fair review.</p>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab 4	Data Entry and Format Requirements	Information Requirements
<p>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>
	<ul style="list-style-type: none"> • Enter in text box • 5,700-character limit (approximately 1 page) 	<p>Impact Statement: Describe the fellow's commitment to a career in breast cancer research and specific career goals. Describe how the proposed research and training components align with and further these goals. Describe how the proposed research and training will position the fellow as an independent investigator likely to make significant contributions in breast cancer research, particularly high impact research that directly affects individuals.</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, Specific Aims & Research Outcomes</p> <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 and task.</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>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab 4	Data Entry and Format Requirements	Information Requirements
Project Proposal	<p>All research proposal sections must be included in the application and must be presented in the order listed below.</p>	
	<ul style="list-style-type: none"> • Upload as a PDF file • 5-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>Hypothesis and Objective: State the hypothesis to be tested and the objective of the proposed research, 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>Training Experience: Explain how the proposed research project and training program will promote research independence for the fellow and leadership for a defined area of research. Describe the specific ways in which the training environment provides rich opportunities for expanding the fellow’s knowledge and skills in research, particularly research leading to the translation of discoveries to clinical tools and applications.</p> <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 5	Data Entry and Format Requirements	Information Requirements
<p>Budget</p>	<ul style="list-style-type: none"> • Enter budget information in data entry fields. • No personnel on the grant may have a base salary above \$186,600 per year. • Equipment cannot exceed 30 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>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. (include only those receiving fringe benefits).</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 personnel expenses, such as consultant fees, payments made to student assistants, hourly staff or other employee/staff that do not receive fringe benefits, etc.</p> <p>Supplies: Costs for any supplies needed for the execution of the project that will be funded through the award (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 award (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 award.</p> <p>Travel: Any travel to be funded through the award (i.e., scientific meetings, grantee meetings, etc.).</p> <p>Other expenses: Expenses that will be funded through the award not captured in any of the other budget line items.</p> <p>Consortium/contractual cost: Costs associated with subcontractor or consortium (awards 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.).</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>

INFORMATION REQUIRED FOR THE FULL APPLICATION *continued*

Tab 6	Data Entry and Format Requirements	Information Requirements
<p>Supporting & Regulatory Documents</p>	<ul style="list-style-type: none"> • Enter reference contact information. • Auto-generated email is sent to reference with encrypted link to upload letter. 	<p>Letters of Recommendation: Confidential letters of recommendation are required from the mentor and at least one, but no more than two, other individuals who can critically appraise the qualifications of the Fellow. Additionally, the mentor letter must indicate the mentor’s history studying breast cancer.</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> <p>Documentation of Eligibility: Eligibility requirements related to faculty appointments and years since completion of academic degrees and/or training programs must be substantiated by supporting documentation. Documentation may include for example, official transcripts, signed institutional letters, and/or signed Mentor letters.</p> <p>Eligibility requirements must be met by the time of full applications submission.</p> <p>Clinical Protocols: Applications proposing research involving clinical trials must include a copy of the proposed clinical protocol.</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>Existing and Pending Grant Support: Provide the following information for all current and/or pending research grants held by the PI/Mentor and Fellow:</p> <ul style="list-style-type: none"> • Title • Supporting agency • Name and address of funding agency’s grants officer • Performance period • Amount of funding • Percentage of applicant’s time • Brief description of the project’s goals • List of the 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 7	Data Entry and Format Requirements	Information Requirements
<p>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>