

KOMEN RESEARCH PROGRAMS

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

CAREER CATALYST RESEARCH GRANTS
– BASIC/TRANSLATIONAL and CLINICAL RESEARCH

2015-2016 REQUEST FOR APPLICATIONS

Susan G. Komen
5005 LBJ Freeway, Suite 250
Dallas, Texas 75244
Research Programs Help Desk: 1-866-921-9678
Questions: www.komen.org/researchhelpdesk
Website: www.komen.org

TABLE OF CONTENTS

KEY DATES

Application System Opens:	May 6, 2015
Pre-Application Due:	June 17, 2015, by 1 p.m., Eastern Standard Time
Pre-Application Decision:	September 16, 2015
Full Application Due:	November 9, 2015, by 1 p.m., Eastern Standard Time
Award Notification:	On or around April 15, 2016

KOMEN RESEARCH PROGRAM

At Susan G. Komen®, we are committed to ***ending*** breast cancer forever by ***empowering people, energizing science*** to find the cures, and ***ensuring quality care*** for all people, everywhere. Our Research Program is an essential driving force for achieving this mission.

Komen has sustained a strong commitment to **supporting research** that will identify and deliver cures for breast cancer. This commitment has resulted in important progress that has contributed to many significant advances in breast cancer over the past 30 years. Since its founding in 1982, Komen has funded more than $847 million in research, provided $1.8 billion in funding to screening, education, treatment, and psychosocial support programs, and has served millions of people in more than 60 countries worldwide.

Our research focus has evolved over the years. In the beginning we focused on understanding the basic biology of breast cancer. As we learn more about the factors that make cancer cells grow and spread, we are able to invest more in the translation of this knowledge into treatment, early detection and prevention, ***with the goal of supporting work that has significant potential to lead to reductions in breast cancer incidence and mortality within the decade.***

CAREER CATALYST RESEARCH GRANTS – BASIC/TRANSLATIONAL and CLINICAL

Career Catalyst Research (CCR) Grants are intended to foster promising breast cancer researchers who are in the early stages of their faculty careers by providing support for up to three years of "protected time" for research career development under the guidance of a Mentor Committee. It is expected that awardees will launch independent research careers and successfully compete for subsequent research project funding in breast cancer following the successful completion of a CCR Grant, thereby playing key roles in reducing breast cancer incidence and mortality, with the ultimate goal of ending breast cancer forever.

Applications proposing research that does not directly relate to breast cancer and clearly identify the significant potential to lead to reductions in breast cancer incidence and/or mortality within the next decade will be administratively withdrawn from consideration and will not be reviewed or scored.

CCR Grants will have 2 Research Focus Areas: Basic/Translational and Clinical.

1. Basic/Translational:

CCR-Basic and Translational Research Grants provide support for hypothesis-driven research projects that have significant potential to advance our understanding of breast cancer, lead to reductions in breast cancer incidence and/or mortality, and move us toward the goal of a world without breast cancer. Studies focusing on quality of life or survivorship issues are not appropriate for this research focus area. This award mechanism is appropriate for early faculty members with either a Ph.D or M.D. who are proposing research projects that are laboratory- or field-based and do not meet Komen's definition of clinical research. A project involving clinical trial samples for a study in conjunction with a clinician that does not involve the Applicant having direct patient interaction would also be appropriate for the Basic/Translational Focus area.

Appropriate research projects include, but are not limited to, the following areas:

- Breast cancer biology;
- Novel approaches that enhance understanding of the breast cancer disease process;
- Etiology;
- Genetics;
- Molecular/genetic epidemiology;
- Prevention;
- Detection;
- Risk assessment;
- Biomarkers of risk, disease burden, and/or treatment response or resistance;
- Novel therapeutics;
- Metastasis;
- Research seeking to understand the biologic, behavioral, and social causes of disparities in breast cancer outcomes across population

2. Clinical:

CCR-Clinical Research Grants provide support for hypothesis-driven clinical research projects that have significant potential to advance our understanding of breast cancer, lead to reductions in breast cancer incidence and/or mortality, and move us toward the goal of a world without breast cancer.

Komen defines **clinical** research as hypothesis driven, patient-oriented research for which an **investigator directly interacts with human subjects/patients. Such studies may be conducted** in conjunction with laboratory-based research, as appropriate. This includes studies such as therapeutic interventions or clinical trials. *Clinical trials are research studies that involve people and explore whether a *medical strategy, treatment, or device* is safe and effective for humans. A clinical trial may also be *observational, where individuals are only observed and the outcomes measured by researchers*.

***Note:** Clinical trials require that all subjects provide informed consent. If a project is not consenting patients, but rather using patient samples collected previously, then it is not considered a clinical trial.

Applications that relate to mitigating post-treatment effects (i.e., Quality of Life applications) could be seen as contributing to the reduction of mortality, such as those projects focused on cardiotoxicity, etc. In addition, some applications may deal with encouraging segments of the population to be screened, and thus overcome barriers to early detection – again, this is seen as directly related to Komen's mission to reduce mortality.

Appropriate research projects include, but are not limited to, the following areas:

- Novel approaches that enhance understanding of the breast cancer disease process;
- Etiology;
- Prevention;
- Detection;
- Biomarkers of risk, disease burden, and/or treatment response or resistance;
- Novel therapeutics;
- Metastasis;
- Lifestyle interventions with the potential to impact disease outcomes (e.g., incidence and/or mortality);
- Research seeking to understand the biologic, behavioral, and social causes of disparities in breast cancer outcomes across population groups or identify, validate and test health services and public health interventions that address the causes of disparities in care and outcomes; and
- Studies focusing on quality of life or survivorship issues that directly impact incidence and mortality.

ELIGIBLE APPLICANTS/DESIGNATED RECIPIENTS

Applicants/PIs, Mentors, and Institutions must conform to the following eligibility criteria to apply for a CCR Grant. **Eligibility requirements must be met at the time of Full Application submission (November 9, 2015).**

Grants will be awarded to a single Principal Investigator (PI). ***Co-Principal Investigators (Co-PIs) are not allowed.***

Applicant/PI

- Must have a doctoral degree, including MD, PhD, DrPH, DO, or equivalent
- Must currently hold a faculty appointment or have a formal offer letter from the Institution that confirms position and start date at the time of Full Application submission (**November 9, 2015**), verified by the Letter of Institutional Support
- Must not have held any faculty appointment, including non-tenure and tenure track appointments combined, for more than a total of 6 years at the time of Full Application submission (**November 9, 2015**), verified by the Letter of Institutional Support
- May only submit ONE application to each focus area (Basic/Translational or Clinical) per funding cycle, but may accept only ONE grant if awarded
- Must not simultaneously hold a Komen Postdoctoral Fellowship (PDF) Grant. If a PDF grant is currently held, the PDF grant term must expire before the start of the CCR, if funded
- If the Applicant is the recipient of a previous Komen CCR grant, the awarded CCR must end within 3 months of receiving Notification of Intent to Fund for the FY16 cycle or the funding will be withdrawn
- Must not currently be a Principal Investigator on an existing R01 research grant or Komen IIR grant.
- Must conduct the proposed research and training at the Lead Mentor's institution, which may be located anywhere in the world
- Must have adequate space and facilities to conduct the proposed research and protected time for research, as verified by the Letter of Institutional Support
- 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. at the time of Full Application submission (**November 9, 2015)**
- Is not required to be a U.S. citizen or resident
- Must be able to commit at least 75% of full-time effort to research including, but not limited to, the Komen grant during each year of the grant period, verified by the Letter of Institutional Support - Note: Level of effort committed to the proposed project does not determine salary level; salary levels are determined by the applicant's institutional policies

Institution

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

FUNDING INFORMATION AND GRANT TERM

Applicants/PIs may request funding of up to $150,000 per year (combined direct and indirect costs) for up to three years ($450,000).

Budgets are not required to be submitted with the Pre-Applications. However, applicants should take note of the following budget guidelines:

- Personnel on the project are limited to a base salary at or below $250,000 per year; salary support for the Lead Mentor or members of the Mentor Committee is NOT allowed
- Level of effort committed to the proposed project does not determine salary level; salary levels are determined by the applicant's institutional policies
- Reasonable compensation of advocates is allowed when advocates perform services that would otherwise be a contracted expense. Compensation may be in the form of salary, per-hour compensation, or honoraria; additionally, grant funds can be used for advocate participation in scientific conferences that would enhance their knowledge and skills related to the research project
- Research Technicians may be included as salaried personnel on the project
- Reasonable travel costs ARE allowed for purposes specifically related to the proposed Research Project
- Publication costs and meeting-related poster printing costs ARE allowed for purposes specifically related to the proposed Research Project
- Reasonable coursework and training expenses (i.e. laboratory management course, trans-disciplinary training etc.) related to the career and professional development of the Applicant/PI ARE allowed; tuition towards a degree-granting program is NOT allowed
- Equipment costs are limited to no more than 25% of total direct costs
- Indirect costs cannot exceed 25% of total direct costs (including any indirect costs paid through subcontracts or consortia)
- Graduate Students and Postdoctoral Fellow tuition costs are NOT allowed; stipends and salaries to Graduate Students and Postdoctoral Fellows are permitted
- Visa costs are NOT allowed
- Professional membership dues or subscription dues are NOT allowed

APPLICATION REQUIREMENTS

Required: Lead Mentor

At least one Mentor must be at the same institution as the PI and serve as the onsite representative for the entire Mentor Committee, designated as the Lead Mentor in application materials. A letter from the Lead Mentor describing their role and commitment to advancing the career independence of the Applicant/PI is required.
The Lead Mentor:

- Must hold a full-time faculty appointment with an accredited institution (at the same institution as the Applicant/PI)
- Must currently conduct breast cancer research, or alternately, at least one member of the Mentor Committee must have breast cancer research experience
- Is not required to include % effort but must clearly delineate their mentoring role in the Letter of Support from Lead Mentor
- Is not required to be a U.S. Citizen or resident

Required: Mentor Committee

The Applicant/PI must propose a Mentor Committee and designate one Lead Mentor. The primary purpose of the Mentor Committee is to provide the research, scientific, clinical, management, and leadership guidance necessary to foster the Applicant/PI's career advancement and assist in the successful development of the proposed research project. Letters of support from all other members of the Mentor Committee are required only at the time of Full Application submission. **Biosketches are required from all members of the Mentor Committee for submission of a Pre-Application**. Members of the Mentor Committee are not required to currently conduct breast cancer research but should provide expertise, leadership or support to the Applicant/PI and proposed research project. Members of the Mentor Committee are not required to include % effort.

Required: Research Plan

The Applicant/PI must propose a research plan that describes the research question and its significant potential to advance our understanding of breast cancer, lead to reductions in breast cancer incidence and/or mortality within the next decade, and move us toward the goal of a world without breast cancer. A clear and concise outline of the hypothesis(es), specific aims, and the scientific approach that will be taken to address each specific aim must be included, along with a statement of the importance of the research to breast cancer patients and the potential impact of the research project, if successful.

Required: Career Development Plan

The Applicant/PI must submit a Career Development Plan (CDP) illustrating the Applicant/PI's career goals; how the Applicant/PI intends to develop the skills and experience necessary to achieve career advancement during the Grant term; and how the Applicant/PI will sustain research independence beyond the Grant term. The Career Development Plan should include items such as coursework conducive to the Applicant/PI's career development and opportunities for interaction with other groups and scientists such as presentations, journal clubs, seminars, lab meetings, collaborative interactions, and attendance at scientific meetings. Training in career skills, e.g., grant-writing and laboratory management are strongly encouraged. The applicant could also address their long term goals, i.e., anticipated timeline for publications, future grant applications and career milestones.

Susan G. Komen has funded over $135 million in research grants for early career/young investigators.

Required: Advocate Mentor

Susan G. Komen® has a strong commitment to including breast cancer Patient Advocates to provide the patient perspective in the design and implementation of both research projects and Career Development Plans. As part of this ongoing effort**, Komen requires that one or more Patient Advocate(s) be included and named as Key Personnel on all Career Catalyst Research grants at Full Application (due on November 9, 2015)**. While applicants are strongly encouraged to include a Patient Advocate at **Pre-Application (due on June 16, 2015)**, naming a Patient Advocate as a Key Person is not a requirement for Pre-Application submission. A Patient Advocate will be required for Full Application if an Applicant is selected to submit a Full Application.

Utilizing Patient Advocates as a part of their CCR project will enable Komen applicants to become more aware of how their research is important to patients, to emphasize the urgent need to find cures, and to learn from patients' perspectives. This is an important aspect of Komen's commitment to training early investigators for an impactful career in breast cancer research. **Patient Advocates involved in the proposed research project must be designated as a Key Person and member of the Mentor Committee.**

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

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

Komen will hold a webinar hosted by members of Komen Advocates in Science on **Involving Patient Advocates in Research** before the Full Application due date. All applicants who have submitted a Pre-Application in proposalCENTRAL will receive an invitation to join.

Who can serve as an advocate? Read more here.

- Advocates should be individuals who have a strong personal connection to breast cancer
- Advocates should have a basic understanding of the science of breast cancer
- The advocate role should focus on providing a broad patient perspective, and not on clinical or research-related input.
- Advocates may be employed by your institution, as long as their role will not present a conflict of interest or present any likelihood of bias in their ability to represent the patient perspective.
- More than one advocate may be involved in your project.

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

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

Patient Advocates bring the patient voice to research

Optional: Use of Komen Tissue Bank

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

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

PRE-APPLICATION REVIEW PROCESS AND REVIEW CRITERIA

Susan G. Komen® utilizes a multi-step approach to application and review that first requires submission of a Pre-Application, which are administratively reviewed for eligibility, submission of required application materials, adherence to formatting requirements, and responsiveness to the research focus specified in this RFA. Applications that do not meet eligibility, submission, formatting, or responsiveness requirements will be administratively withdrawn and WILL NOT undergo scientific review.

Each qualified Pre-Application is reviewed by a panel of three scientists with appropriate expertise and a patient advocate. Scientist and advocate reviewers assess the strengths and weaknesses of each application based on the defined review criteria described below.

Only Applicants/PIs with Pre-Applications deemed most meritorious and aligned with Komen's research mission will be invited to submit Full Applications. It is anticipated that Full Applications will be invited from approximately 20-25% of pre-application submitters.

Applicants/PIs will be notified of Pre-Application review decisions via email. Once notifications are sent, Applicants/PIs will be granted access to reviewer comments. Applicants/PIs invited to submit a Full Application will then be granted access to the Full Application site.

Through our research grants, we have supported more than 450 clinical trials

Pre-Application: Review Criteria

The Pre-Application will be reviewed using the following criteria:

Career Development Potential	• Does the Applicant/PI present a clear, convincing, and feasible plan for developing the necessary research, scientific, clinical, management, and leadership skills to achieve career advancement during the grant term? • Does the Applicant/PI demonstrate the potential and commitment to effectively leverage his/her Grant to obtain independent funding for continued breast cancer research? • Does (do) the Mentor(s) demonstrate significant and personalized commitment to mentoring the Applicant? • Does (do) the Mentor(s) have the research, mentorship, leadership and other relevant experience necessary to effectively mentor the Applicant/PI to help the Applicant/PI attain their stated career goals? • Is the application well written with attention to grantsmanship, detail, clear presentation of information, and careful adherence to application requirements?
Research Question and Significance	• Does the proposed research question represent a novel approach, a challenge to current paradigms, or add in a significant and measureable way to what is currently known about breast cancer?
Scientific Approach and Feasibility	• Does the proposed study hypothesis(es) comprehensively address the overarching research question(s)? • Are the specific outcomes/deliverables of the proposed research plan considered feasible with the proposed resources including institution, mentors and collaborators?
Scientific and Patient Impact	• Does the proposed research question have significant potential to advance our understanding of breast cancer and lead to reductions in breast cancer incidence and/or mortality within the next decade? • Is (Are) the research question(s) important to the breast cancer patient and survivor community?

PRE-APPLICATION SUBMISSION INSTRUCTIONS

Administrative Requirements

Applicants/PIs must follow the Pre-Application submission instructions, including page limitations, submission of required application materials, and format guidelines such as the prescribed font and margin size. All application materials must be in English and must be submitted online in the proposalCENTRAL system. No paper applications or applications sent by email will be accepted.

Failure to adhere to these instructions will result in applications being administratively withdrawn from consideration prior to peer review, without appeal.

Pre-Application Submission Deadline

Pre-Applications must be completed by 1pm, EST (U.S.) on **Wednesday, June 17, 2015**, using the proposalCENTRAL website at https://proposalcentral.altum.com.

Applicants are strongly encouraged to complete, review and submit their applications with sufficient time to allow for technical difficulties, varying time zones, human error, loss of power/internet, sickness, travel, etc. Applicants may review their submissions for accuracy until the application submission deadline.

Extensions to the Pre-Application submission deadline will not be granted to allow for lateness, corrections, or submissions of missing information, with the rare exception made for severe extenuating circumstances at the sole discretion of Komen.

Getting started in proposalCENTRAL

If you are a new user of proposalCENTRAL, follow the "REGISTER" link and complete the registration process. After you register, complete your Professional Profile (green tab second from the left) before starting an application.

If you are already registered with proposalCENTRAL, access the site and log in with your username and password. If you have forgotten your password, click on the "Forgot your password?" link. Provide your e-mail address in the space provided; your username and password will be sent to you by e-mail.

To start a Pre-Application, select the "Grant Opportunities" tab (gray tab furthest to the right). A list of applications will be displayed. Find "**Susan G. Komen CCR Basic/Translational and Clinical**" and click the "Apply Now" link (second to last column) to create your Pre-Application.

Complete all fields in the application and all templates that are provided. Upload all requested documents in portable document format (PDF). Uploaded documents must be converted to PDF prior to submission in the proposalCENTRAL system and should not be password protected or they may not convert properly. See the proposalCENTRAL FAQ section, https://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp, for more information.

If you have difficulties registering, logging in, or creating your application, contact proposalCENTRAL Customer Support immediately:

Phone: (800) 875-2562 or (703) 964-5840
E-mail: pcsupport@altum.com

Pre-Application Sections

The following information is required to submit a complete Pre-Application. Numbers correspond to the application sections found on the left side of the proposalCENTRAL website.

1. **TITLE PAGE**
   Enter the title of the research project directly into the proposalCENTRAL system. The title is limited to no more than 81 characters in length (including spaces). Do not use abbreviations or all capital letters. A project title must be entered and saved before additional sections may be accessed.

   Research Focus Area
   Please select the appropriate focus area for the research proposed from the dropdown menu:
   - CCR Basic/Translational
   - CCR Clinical

   Please refer to page 3 and 4 for definitions of Basic/Translational and Clinical research focus areas.

2. DOWNLOAD TEMPLATES & INSTRUCTIONS

The Request for Application (RFA) Guidelines and Application Instructions document, the Policies and Procedures, and all templates can be downloaded from this page.

You must download and complete the following templates: Pre-Application Narrative Template, Biosketch Template, Cited Publication Template, and Pre-Application Submission Checklist. See Section 7 for instructions on how to complete each template.

Click the "Download" link to save each of the templates to your computer.

Use your word processing software (e.g., MS Word, WordPerfect) to complete the Pre-Application Narrative Template, Cited Publication Template, Biosketch Template, and Pre-Application Submission Checklist on your computer and then convert templates to PDF format. You do not need to be connected to the internet or the proposalCENTRAL system while working on the templates.

Upload the completed template files to your online application.

See page 17 for instructions on how to complete and upload the templates.

3. ENABLE OTHER USERS TO ACCESS THIS PROPOSAL.

Optional.

4. APPLICANT/PRINCIPAL INVESTIGATOR (PI)

Enter contact information **for the Applicant/PI** directly into the proposalCENTRAL system. When entering contact information, do not use personal addresses.

5. INSTITUTION & CONTACTS

Enter information regarding the lead institution, signing official, and financial officer directly into the proposalCENTRAL system.

6. KEY PERSONNEL

Do not list the PI as Key Personnel in this section.

Key personnel include the Lead Mentor, Committee Members, major Collaborators, and Patient Advocate Mentor(s) who are integral to the execution of the research plan.

Komen defines Key Personnel as an individual who contributes to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the Grant. Typically, these individuals devote a defined percentage of effort to the project, and have doctoral or other professional degrees. Collaborators/Consultants at the postdoctoral or graduate student level may be considered Key Personnel if their involvement meets this definition.

Each Key Person must have a level of effort listed in proposalCENTRAL (0-100%). Patient Advocates, the Lead Mentor, and members of the Mentor Committee may list 0% effort. Other Key Personnel must list greater than 0% effort. Salary support is not required for Key Personnel. Please note: Salary support is not allowed for the Lead Mentor or members of the Mentor Committee.

Add new contacts by entering the e-mail address of the Key Person you wish to add. Click 'Add'. Add Key Personnel information for the person selected. Select the appropriate Role from the dropdown. Enter the percent effort proposed for this Key Person on this project. When entering contact information, do not use personal addresses for the Key Person.

NON-KEY PERSONNEL

Non-Key Personnel may include Graduate Students, Postdoctoral Fellows (except for Postdoctoral Fellows submitting a PDF grant), Research Technicians, and/or Collaborators who can easily be replaced without affecting the functionality of the grant or significantly impacting the execution of the proposed project (ex. a biostatistician or research technician who manages a mouse colony). A Non-Key Person may have 0% effort. If a Non-Key Person draws a salary from the grant budget, a level of effort must be listed.

Add new contacts by entering the e-mail address of the Key Person you wish to add. Click 'Add'. Add Non-Key Personnel information for the person selected. Select the Non-Key Personnel Role from the dropdown. Enter the percent effort proposed for this Non-Key Person on this project. When entering contact information, do not use personal addresses for the Non-Key Person.

Please see Appendix A for a detailed list of definitions and allowed Personnel for each grant mechanism.

7. ATTACH NARRATIVE AND SUPPORTING DOCUMENTS

Pre-Application Narrative Template

Download the template from proposalCENTRAL and fill in the following sections. The Pre-Application Narrative (Sections A-E) is limited to 3 pages in total. Page lengths for each section of the narrative are recommended below. .

Document Format

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

- Must be in Portable Document Format (.pdf)
- Font Size: 12 point or larger. Figure Legends may be 9 point or larger.
- Font Type: Times New Roman. Biosketches using the provided NIH template may use Arial.
- Spacing: No more than six lines of type within a vertical inch (2.54 cm).
- Page Size: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- Margins: At least 0.5 inch (1.27 cm) in all directions.
- Headers or Footers may only be used for page numbers on Supporting Documents, but margins must remain at least 0.5 inches with the header or footer. Formatting of the header and footer on the Pre-Application template must not be altered and **MUST BE INCLUDED**.
- Recommended lengths for each narrative section of the application are provided. The complete Pre-Application narrative (Sections A-E of the Template) must not exceed 3 pages in length.

Guidelines for Images

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

The following elements are required components of the Pre-Application: Pre-Application Narrative and Supporting Documents

Pre-Application Narrative (3 page limit):

Applicants may exceed the recommended page length for a given section as described below provided that the total narrative is no more than 3 pages, including figures and tables. References and biosketches are not included in this page number limit.

Section A: Title (81 Character limit):
Applicants/PIs should enter the title of their proposal exactly as it is entered in proposalCENTRAL.

Section B: Research Question and Significance (0.5 page recommended):
Describe the research question and how it represents a novel approach, a challenge to current paradigms, or adds in a significant and measureable way to what is currently known about breast cancer.

Section C: Hypothesis(es) and Specific Aims (0.5 page recommended):
Clearly and concisely outline the hypothesis(es), specific aims, and the scientific approach that will be taken to address each specific aim. Clearly and concisely address the following:

- Describe how the proposed study hypothesis(es) comprehensively addresses the overarching research question(s).
- Describe how the proposed specific aims fully answer the study hypothesis(es).

Section D: Scientific and Patient Impact (1 page recommended):
Address the following questions using non-scientific language appropriate for a lay audience:

- Describe your project and your project's impact as you would explain to a non-scientist, such as your sister, neighbor, friend, etc. in 3-5 sentences. Include how the research question(s) as outlined in Section B has significant potential to lead to a reduction in breast cancer incidence and/or mortality within the next decade.
- Describe the research question and its significance in having the potential to advance our understanding of breast cancer and lead to reductions in breast cancer incidence and/or mortality within the next decade. "Within the next decade" is **not** a required timeframe but instead conveys the interest of Komen in supporting research that has the potential to *quickly* translate to clinical application and move us toward the goal of a world without breast cancer
- Have you consulted breast cancer survivors/advocates in the development of the research project or Career Development Plan? If so, please describe how a patient advocate will be involved in your project.

Section E: Career Development Plan (1 Page recommended):
Describe your career goals and how you intend to develop the skills and experience necessary to achieve career advancement during and after the Grant term. The Plan should address the following:

- Present a clear, convincing, and feasible plan for developing the necessary research, scientific, clinical, management, and leadership skills to establish and maintain an independent program of research excellence and productivity. The description should include items such as any classes, seminars, and opportunities for interaction with other groups and scientists such as presentations, journal clubs, seminars, lab meetings, mentor meetings, collaborative interactions, and attendance at scientific meetings. Training in career skills, e.g. grant-writing and presentation skills are strongly encouraged.
- Explain how the Mentor Committee members will be utilized to guide the Applicant/PI toward research excellence and independence.

Pre-Application Supporting Documents

The following documentation is required to support the Pre-Application Narrative:

1. Cited publications
2. Statement of Commitment from Applicant/PI
3. Biosketches for Key Personnel
4. Letter of Support from Lead Mentor
5. Letter of Institutional Support
6. Letter of Support from Patient Advocate(s) (if named on Pre Application)
7. Pre-Application Submission Checklist

Please note: any additional documents that are uploaded to the application and are not listed above will be deleted from the application file and will not undergo review.

1. Cited Publications

No more than 10 references to relevant publications may be listed. References must be numbered and follow the formatting example on the Cited Publications template and below. References are not included in the Pre-Application Narrative 3-page limit.

Example (Journal Article):

1. Warrell RP Jr, Frankel SR, Miller WH Jr, Scheinberg DA, Itri LM, Hittelman WN. Differentiation therapy of acute promyelocytic 584 leukemia with tretinoin (all-trans-retinoic acid). N Engl J Med 324:1385–93, 1991.

2. Statement of Commitment from Applicant/PI

A signed Statement of Commitment must be submitted by the Applicant/PI, on Institution Letterhead, describing how the Applicant/PI demonstrates the potential, expertise, and commitment to capitalize on the CCR Grant and how it will further the Applicant/PI's career development. In this statement, describe how the Applicant/PI's prior training and research experience are appropriate for this grant.

3. Biosketches

Required for the following Key Personnel:

- Applicant/PI
- Lead Mentor
- Mentor Committee Members
- Patient Advocate(s) (if applicable)

Biosketches should not be included for other Key personnel, Non-Key personnel, Collaborators, Research Technicians, etc.

Please submit each biosketch as a separate and named document. A single PDF for all biosketches will not be accepted.

Biosketches must be no more than 5 pages each and in NIH format. A template is available for download on the proposalCENTRAL website. Advocate biosketches may be submitted in any format.

Biosketches are not included in the Pre-Application Narrative 3-page limit.

4. Letter of Support from Lead Mentor

A signed Letter of Support must be submitted by the Lead Mentor, on Institution Letterhead, describing their role and commitment to advancing the career independence of the Applicant/PI. For the Pre-Application, only the required letter from the Lead Mentor should be submitted; however, all members of the Mentor Committee must provide a letter of support only at the time of Full Application submission. The letter from the Lead Mentor should address the following:

- Explain the Lead Mentor's commitment to mentoring the Applicant/PI and plan to support the career development of the Applicant/PI during the grant term.
- Describe the research, mentorship, leadership and other relevant experience the Mentor possesses to effectively mentor the Applicant/PI and help the Applicant/PI attain their stated career goals.
- The Mentor's experience mentoring postdoctoral or junior faculty level researchers, including evidence of successful mentoring outcomes as demonstrated by examples of previously mentored postdoctoral trainees and/or young investigators and their current titles/positions.
- The potential and commitment of the Applicant/PI to capitalize on the training to be provided through the Komen CCR.

5. Letter of Support from Patient Advocate Mentor(s) (required if Advocate is included at Pre-Application)

A signed Letter of Support must be submitted by the named Patient Advocate describing their role and commitment to the proposed project.

- Describe the Patient Advocate Mentor(s)'s relevant experience and qualifications as a breast cancer patient advocate.
- Explain the active role that the Patient Advocate Mentor will have on the project.
- If applicable, describe any previous experience the Patient Advocate Mentor may have with research or research proposals.
- Describe the potential and commitment of the Applicant/PI to further their training in breast cancer research.

6. Letter of Institutional Support

A Letter of Institutional Support must be submitted and signed by the department chair, on Institution Letterhead. If the department chair is also the Lead Mentor for the application, this letter must be submitted by the Dean. This letter may not be provided by the Lead Mentor.

The Letter must include all of the following information:

- Confirmation of the date and specific title of Applicant/PI's current faculty appointment.
- The total number of years the Applicant/PI has held a non-tenure or tenure track faculty appointment at the current institution and all previous institutions, if applicable. If the Applicant/PI has held a non-tenure or tenure track faculty position at institutions and/or departments other than their current appointment, the current institution should confirm these previous appointments as faculty and their duration in the Letter.
- The Applicant/PI's own available research space (for bench scientists) and start up package (if applicable).
- Amount of protected time and proposed level of committed to research effort (The Applicant must be able to commit at least 75% of full-time effort to research including, but not limited to, the Komen grant during each year of the grant period, verified by the Letter of Institutional Support, see page 6) and the additional institutional support the Applicant/PI is receiving to successfully conduct the proposed research and implement the proposed Career Development Plan.

Applications that submit Letters that do not include all the required information stated above will be administratively withdrawn and WILL NOT undergo scientific review.

7. Pre-Application Submission Checklist

   Download the Submission Checklist from proposalCENTRAL and indicate all tasks that have been completed and reviewed. Sign the Pre-Application Submission Checklist, indicating that all instructions have been followed and that all Key Personnel listed on the Pre-Application have agreed to participate in the proposed study before uploading the checklist into proposalCENTRAL.

Failure to complete ALL sections of the Checklist or to provide a signature indicates that the Application has not been verified by the Applicant and will result in Administrative Withdrawal of the Application without appeal.

Uploading the attachments into your application

Once you have converted your attachments to PDF files, the next step is to upload the files to your online application.

- Make certain that the converted PDF files are closed on your computer.
- Open your application and go to the section for attaching files.
- Enter "your last name_ description of the file" in the "Describe Attachment" field, e.g. "Smith_PI Biosketch" or "Smith_Proposal Narrative".
- Select the appropriate type of attachment from the drop-down list. NOTE: After selecting attachment type, the screen will show the file types (e.g., PDF, .doc) that are allowed for that type of attachment. Only PDF attachments are permitted for this application submission.
- Click on the "Browse" button to select the file from your computer.
- The "Choose File" dialog box opens for you to search for the template file on your computer's hard disk or local area network.
- Select the file and click "Open."
- The file location and name will display in the window adjacent to the "Browse" button.
- Click on the "Upload Attachment" button. You will get a confirmation message on your screen that the file was uploaded successfully. You will also see that your file is now listed in the "Uploaded Attachment" section of the screen. Two links are available in each row of an uploaded attachment: DEL and SHOW. "DEL" allows you to delete the file, if necessary, and "SHOW" opens the uploaded file. Open and review your uploaded file.

8. **VALIDATE.** Validate the application on proposalCENTRAL. This is an essential step. An application that has not been validated cannot be submitted. "Validate" checks for required data and required attachments. You will not be able to submit if all the required data and attachments have not been provided.

9. **SUBMIT.** After successfully passing the validate check and printing your documents, click the "**Submit"** link. An e-mail will be sent to you confirming your submission.

Once your application is submitted you may view it by accessing the "Submitted" link under the Manage Proposals tab. The status column will show "Submitted" and the date submitted. You may need to refresh your browser screen after submitting the application to see the updated status.

FULL APPLICATION SUBMISSION

Only Applicants/PIs with Pre-Applications deemed most meritorious and aligned with Komen's research mission will be invited to submit Full Applications. Instructions on how to submit a Full Application will be provided on the Pre-Application decision date listed above under 'KEY DATES'. **Full Applications are due on November 9, 2015**.

Please note, additional requirements will apply for Full Applications:

1. The Principal Investigator will be required to include an ORCID identifier. **ORCID** (**Open Researcher and Contributor ID**) is a non-proprietary alphanumeric code to uniquely identify scientific and other academic authors. You can register for an ORCID at any time: http://orcid.org/.

2. A Patient Advocate Mentor must be included in the Full Application as a Key Person and member of the Mentor Committee and the Patient Advocate Involvement Plan section completed in the Full Application Proposal Narrative. Failure to include a Patient Advocate will result in administrative withdrawal. For assistance in identifying trained advocates or to discuss including advocates in the proposed research project, contact advocatesinscience@komen.org.

QUESTIONS?

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

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

Today, there are more than 3 million breast cancer survivors in the U.S.

Appendix A: Application Definitions of Personnel

Applicants should designate personnel on their proposed grant as follows: *(Please note: roles may be limited by grant mechanism as listed. Only roles applicable to a specific grant mechanism will be listed in the application drop-down menu in proposalCENTRAL.)*

I. Principal Investigator (PI)/Applicant:

The individual designated by the Applicant's organization to direct the research project and/or Training Program (GTDR only) to be supported by the grant. The PI is responsible and accountable to the Applicant organization officials and Susan G. Komen® for the proper conduct of the research project.

ROLE	Role limited to applicable grant mechanism:
Principal Investigator (PI)/Applicant	Required: All Grants (only 1 PI per application)

II. Key Personnel:

Komen defines Key Personnel as an individual who contributes to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the Grant. Typically, these individuals devote a defined percentage of effort to the project, and have doctoral or other professional degrees. Collaborators/Consultants at the postdoctoral or graduate student level may be considered Key Personnel if their involvement meets this definition. **Each Key Person must have a level of effort listed in proposalCENTRAL (0-100%).** Patient Advocates, the Lead Mentor, and members of the Mentoring Committee may list 0% effort. Other Key Personnel must list greater than 0% effort. Level of effort committed to the proposed project does not determine salary level. Salary levels are determined by the applicants institutional policies. Salary support is not required for Key Personnel. Please note: Salary support is not allowed for the Lead Mentor or members of the Mentoring Committee. For Postdoctoral Fellowships, salary/stipend support is allowed ONLY for the Applicant/PI.

KEY PERSONNEL ROLE	Role limited to applicable grant mechanism:		
	CCR	**PDF**	**GTDR**
Advocate Mentor/Patient Advocate	Optional at Pre-App; Required at Full App	Optional at Pre-App; Required at Full App	Optional
Collaborator (Key)	Optional	Optional	Optional
Co-Mentor	*Not allowed*	Optional (1 per grant)	*Not allowed*
Committee Member	Required	Optional	*Not allowed*
Co-PI	*Not allowed*	*Not allowed*	Optional (1 per grant)
Lead Mentor	Required (1 per grant)	Required (1 per grant)	*Not allowed*

Advocate Mentors/Patient Advocates (Optional for all grants at Pre-Application):

Komen has a strong commitment to including breast cancer patient advocates to provide patient perspective in the design and implementation of both research projects and Career Development Plans. Patient Advocates can be involved early in the development of the project to provide input and ensure that the proposed work has impact for patients. During pre-application submission, they can assist by reviewing the scientific and patient impact section to help communicate the importance of the project to breast cancer patients. Advocates must be included on Mentoring Committees and invited to project presentations to provide the patient point of view and a different perspective to the project. They can be included in clinical trial development, providing input on potential barriers to accrual and help develop patient education materials. Patient Advocates can also help communicate the importance of the results of the project to the public using lay language that everyone can understand. If a Patient Advocate is involved in the proposed research project, they are required to be listed as a Key Person and member of the Mentor Committee.

An identified Patient Advocate Mentor(s) will be required for CCR application at Full Application and are strongly encouraged for all applications at all stages. Postdoctoral Fellowship Full Applications will not be required to name a Patient Advocate but will be required to submit a Patient Advocate Involvement Plan. Awarded PDFs will be assigned an Advocate if one is not named on the application.

Collaborators (Key Person):

An individual that is working with the PI, who benefits or strengthens the proposed research as a result of their expertise in the research area, provides an essential resource or equipment contribution, or offers the skills needed to efficiently execute the proposed research supported by the grant. Collaborators who are considered Key Personnel must contribute to the scientific development or execution of a project in a substantive, measurable way (ex. a researcher provides 13 unique cell lines that are critical to the completion of the project.) A collaborator may be employed by, or be affiliated with, the Applicant's organization or another participating organization.

Co-Mentor (PDF):

An individual designated to assist the Lead Mentor to provide the research, scientific, clinical, management, and leadership guidance necessary to foster the Applicant/PI's career advancement and research project development. Only 1 Co-Mentor is allowed per application. The Co-Mentor may provide needed expertise to the proposed project.

Co-PI (GTDR):

An individual designated to assist the PI in directing the training program and/or research project to be supported by the grant. The Co-PI may provide additional mentoring, expertise and/or experience relevant and necessary for the success of a multidisciplinary training program. The Co-PI is also responsible and accountable to the Applicant organization officials and Komen for the proper conduct of the research project. Only a single Co-PI can be named on GTDR grants. PDF and CCR grants may NOT include a Co-PI.

Lead Mentor (PDF):

An individual designated to provide the research, scientific, clinical, management, and leadership guidance necessary to foster the Applicant/PI's career advancement and the successful development of the proposed research project. Only 1 Lead Mentor is allowed per application. The Lead Mentor must be at the same institution as the PI. The Lead Mentor should be active in the field of breast cancer, or alternatively the Co-Mentor must have breast cancer research experience, and should be committed both to the research training of the Applicant/PI and to the direct supervision of the Applicant/PI's research. A Mentor may only be designated as a Lead Mentor on ONE Komen Postdoctoral Fellowship Grant Application submitted in this cycle.

Lead Mentor (CCR):

An individual designated to provide the research, scientific, clinical, management, and leadership guidance necessary to foster the Applicant/PI's career advancement and assist in the development of the proposed research project. The Lead Mentor must currently conduct breast cancer research, or alternatively at least one member of the Mentor Committee must have breast cancer research experience. Only 1 Lead Mentor is allowed per application. The Lead Mentor must be at the same institution as the PI and serve as the onsite representative for the entire Mentor Committee.

Mentor: Committee Member (CCR and PDF):

An individual designated to assist in providing research, scientific, clinical, management, and leadership guidance necessary to foster the Applicant/PI's career advancement and assist in the development and patient impact of the proposed research project.

III. Non-Key Personnel

Non-Key Personnel may include graduate students, postdoctoral fellows (except for postdoctoral fellows submitting a PDF grant), research technicians, and/or collaborators who can easily be replaced without impacting the functionality of the grant or significantly impacting the execution of the proposed project (ex. a biostatistician or research technician who manages a mouse colony). A Non-Key Person may have 0% effort. If a Non-Key Person draws a salary from the grant budget, a level of effort must be listed. For GTDR grants, Non-Key Personnel may ONLY include designated Mentors for the Training Program.

NON-KEY PERSONNEL ROLE	Role limited to applicable grant mechanism:		
	CCR	**PDF**	**GTDR**
Collaborator (Non-Key)	Optional	Optional	*Not Allowed*
Graduate Student	Optional	*Not Allowed*	*Not Allowed*
Mentor (GTDR)	*Not Allowed*	*Not Allowed*	Optional
Postdoctoral Fellow	Optional	*Not Allowed*	*Not Allowed*
Research Technician	Optional	*Not Allowed*	*Not Allowed*

Collaborators:

An individual working with the PI in the scientific development and/or execution of the research project. Collaborators should be listed as Key Personnel if their contribution is essential to the grant and if their role cannot be fulfilled by another Collaborator or individual. Collaborators may be listed as Non-Key Personnel if they do not meet the definition of Key Personnel, but will still be responsible for proposed work on the research project (ex. a biostatistician or technician who maintains a mouse colony). A collaborator may be employed by, or be affiliated with, the Applicant's organization or another participating organization.

Graduate Student:

Komen does not utilize this category for Key Personnel. Graduate students may be listed as a Non-Key Person for CCR Grants. Graduate students participating in Komen's Graduate Training in Disparities Research Program may not be listed as Non-Key Personnel (please see Non-Key Personnel definition above). For GTDR grants, Non-Key Personnel can only include designated Mentors.

Mentor (GTDR):

An individual designated to assist in providing mentoring, teaching, research, scientific, clinical, and/or leadership guidance necessary to foster the Applicant/PI's development and management of their training program in breast cancer disparities and assist in the development of the proposed research project. Mentors should have a strong track record in breast cancer disparities research and successful mentoring of graduate-level students. Multiple Mentors may be involved in the program with each focusing on specific aspects of the training. For GTDR applications, the only Non-Key Personnel permitted are Mentors.

Postdoctoral Fellow:

Komen does not utilize this category. For Postdoctoral Fellowship Grant applications, the Fellow should always be listed as the Applicant/PI. Postdoctoral Fellows (CCR) may be listed as a Collaborator (either Key or Non-Key), if their role fits Komen's definition of either Key or Non-Key Personnel (see definitions above).

Research Technician:

Research technicians aid scientists in their experiments by monitoring and recording their findings and managing day to day activities of the lab. Research technicians are not considered Key Personnel and should be included as Non-Key Personnel. A Research Technician may be employed by, or be affiliated with, the Applicant's laboratory, organization or another participating organization.