



## 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.

# POSTDOCTORAL FELLOWSHIP GRANTS – BASIC/ TRANSLATIONAL and CLINICAL RESEARCH

## 2015-2016 REQUEST FOR APPLICATIONS

Susan G. Komen

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## 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 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 cause cancer cells to 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.**

## POSTDOCTORAL FELLOWSHIP GRANTS – BASIC/TRANSLATIONAL and CLINICAL

Postdoctoral Fellowship (PDF) Grants are intended to attract and support promising scientists and clinician/scientists who are embarking on careers dedicated to breast cancer research. By providing funding to outstanding postdoctoral/postgraduate fellows under the guidance of a mentor, Komen seeks to ensure that a diverse pool of highly trained scientists will emerge as the next generation of leaders in the field of breast cancer research. These leaders will play 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.

### PDF Grants will have 2 Research Focus Areas: Basic/Translational and Clinical

#### 1. Basic/Translational:

**PDF-Basic and Translational Research Grants** provide support for 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 fellows with either a Ph.D or an 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 groups

## 2. Clinical:

**PDF-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;
- Risk assessment;
- 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 issue that impact incidence and mortality.

## ELIGIBLE APPLICANTS/DESIGNATED RECIPIENTS

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

Grants are awarded to the Fellow (designated as the Applicant/Principal Investigator (PI) on the application), Lead Mentor and Co-Mentor, if applicable.

RESTRICTIONS: Changes to the Fellow/Lead Mentor are not permitted after the Pre-Application has been submitted or during the Grant term. A mentor may participate as Lead Mentor on ONE Postdoctoral Fellowship application per grant cycle, but may serve on multiple Mentor Committees or serve as a Co-Mentor on multiple PDF applications.

### Applicant/PI (Fellow)

- Must have a doctoral degree, including MD, PhD, DrPH, DO, or equivalent by the date of Full Application submission, **November 9, 2015**:
  - For physician applicants with an MD, DO, MD/PhD or equivalent: if a clinical fellowship has been completed, the Applicant/PI must be no more than 3 years post-completion of his/her most recent clinical fellowship as verified by the Letter of Support from the Mentor. If no clinical fellowship has been completed, the Applicant/PI must be no more than 5 years post-completion of his/her most recent medical residency as verified by the Letter of Support from the Mentor
  - For applicants with a PhD or equivalent: Applicant/PI must be no more than 5 years post-completion of his/her PhD, as determined by date of degree confirmation and verified by the Letter of Support from Mentor
- May not hold any appointment designated as faculty
- May not currently be, or have formerly been, a fellow on a Komen Postdoctoral Fellowship (PDF) Grant.
- Is not required to be a U.S. citizen or resident
- 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 conduct the proposed research and training at the Lead Mentor's institution, which may be located anywhere in the world
- 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 Support from Mentor \*Note: effort dedicated to the proposed grant does not determine salary level. Salary effort is 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 \$60,000 per year (direct costs only) for a minimum of two years (\$120,000) and maximum of three years (\$180,000).

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

- Applicant/PI salary may be supplemented by Mentor's funding
- 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
- Equipment costs are limited to no more than 25% of total direct costs
- 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.
- Salary support for the Lead Mentor, Co-Mentor or Member of Mentor Committee is NOT allowed
- Indirect costs are NOT allowed
- Visa costs are NOT allowed
- Professional membership dues or subscription dues are NOT allowed



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

## APPLICATION REQUIREMENTS

### **Required: Mentor**

The Applicant/PI (the Fellow) must propose ONE Lead Mentor and may propose ONE Co-Mentor. The primary purpose of the Lead Mentor and Co-Mentor (if applicable) is 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. The Lead Mentor or Co-Mentor should be active in the field of breast cancer and the Mentor(s) should be committed both to the research training of the Applicant/PI and

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to the direct supervision of the Applicant/PI's research. A letter from the Lead Mentor and Co-Mentor (if applicable) describing their role and commitment to advancing the career development of the Applicant/PI, is required to support the Pre-Application.

### Lead Mentor

- Must hold a full-time faculty appointment with an accredited institution
- The Lead Mentor must be at the same institution as the Applicant/PI
- Must currently conduct breast cancer research, or the Co-Mentor 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
- Can be a Lead Mentor on only ONE Komen Postdoctoral Fellowship Grant application submitted in this cycle
- 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. at the time of Full Application submission, **November 9, 2015**
- Is not required to be a U.S. citizen or resident

### Co-Mentor (if applicable)

- Must hold a full-time faculty appointment with an accredited institution
- Is not required to include % effort but must clearly delineate their mentoring role in the Letter of Support from Lead Mentor/Co-Mentor(if applicable)
- May be a Co-Mentor on multiple PDF applications and a Lead Mentor on ONE separate PDF application
- Is not required to currently conduct breast cancer research, unless the Lead Mentor does not 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. at the time of Full Application submission, **November 9, 2015**
- Is not required to be a U.S. citizen or resident

### Required: Research Plan

The Applicant/PI (the Fellow) 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 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 (PDP) illustrating the Applicant/PI's training and 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 plans to transition to 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 presentation skills are strongly encouraged. The applicant could also address their long term goals, i.e., anticipated timeline for publications, future grant applications and career milestones.

### **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 Postdoctoral Development Plans. A Patient Advocate Mentor may be included and named in the Pre-Application (**due June 17, 2015**) or later when the Full Application is submitted (**due November 9, 2015**).

**Please note: If an applicant is invited to submit a Full Application they will be required to submit a proposed Patient Advocate Involvement Plan as a section of the Full Application Proposal Narrative. Applicants are not required to name a specific Patient Advocate Mentor in the Pre- or Full Application, but if a Patient Advocate is not named in the Full Application, Komen will assign a Patient Advocate to all funded Postdoctoral Fellowships to engage as per their proposed Patient Advocate Plan. Patient Advocates involved in the research project must be designated as a Key Person.**

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 Advocates in Science has developed a detailed guide with suggestions for the inclusion of advocates in research which can be found [here](#) in the [Komen Grant Writing Resources for Young Investigators](#) page.

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](mailto:advocatesinscience@komen.org).



***Patient Advocates bring the patient voice to research***



## OPTIONAL COMPONENTS

### Optional: Mentor Committee

The Applicant/PI may propose a Mentor Committee in addition to the Lead Mentor and Co-Mentor if additional expertise and support is required. 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. A letter from the Lead Mentor describing their role and commitment to advancing the career independence of the Applicant/PI is required. Letters from all members of the Mentor Committee are required only at the time of Full Application submission. **Biosketches are required from members of the Mentor Committee at the time of Pre-Application submission.** If included, Patient Advocates must be designated as members of the Mentor Committee. 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.

### 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>.

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



## 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 and Full Application upon invitation only. Pre-Applications are first 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.

### Pre-Application - Review Criteria

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

<b>Career Development Potential</b>	<ul style="list-style-type: none"><li>• 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?</li><li>• Does the Applicant/PI demonstrate the potential and commitment to effectively leverage his/her Grant to obtain independent funding for continued breast cancer research?</li><li>• Does (do) the Mentor(s) demonstrate significant and personalized commitment to mentoring the Fellow?</li><li>• 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?</li><li>• Is the application well written with attention to grantsmanship, detail, clear presentation of information, and careful adherence to application requirements?</li></ul>
<b>Research Question and Significance</b>	<ul style="list-style-type: none"><li>• 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?</li></ul>
<b>Scientific Approach and Feasibility</b>	<ul style="list-style-type: none"><li>• Does the proposed study hypothesis(es) comprehensively address the overarching research question(s)?</li><li>• Are the specific outcomes/deliverables of the proposed research plan considered feasible with the proposed resources including institution, mentors and collaborators?</li></ul>
<b>Scientific and Patient Impact</b>	<ul style="list-style-type: none"><li>• 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?</li><li>• Is (Are) the research question(s) important to the breast cancer patient and survivor community?</li></ul>

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## 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 PDF 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](mailto: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:

- PDF Basic/Translational
- PDF Clinical

Please refer to page 3 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, Biosketch Template, Cited Publication 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 to 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, financial officer, and signing official directly into the proposalCENTRAL system.

### 6. KEY PERSONNEL

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

Key personnel include the Lead Mentor, Co-Mentor (if applicable), major Collaborators, and any Patient Advocates (if applicable) 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. Advocate Mentors must be listed as Key Personnel.

**Each Key Person must have a level of effort listed in proposalCENTRAL, even if 0%. Patient Advocate Mentors, the Lead Mentor, and members of the Mentor Committee may list 0% effort. Other Key Personnel must list greater than 0% effort.** Please note: Salary support is not allowed for the Lead Mentor or Co-Mentor.

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 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.

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 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.

- 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 can 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 application narrative 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. Cited Publications and Pre-Application Supporting Documents (Biosketches, Letter of Support from Mentor, and Letter of Commitment from Applicant/PI, etc.) 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 to what is currently known about breast cancer in a significant and measurable way.

#### **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 achieve career advancement during the grant term. The description should include items such as 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
- Describe the relationship of the project to the career goals of the Applicant/PI and how the Applicant/PI plans to capitalize on the training provided through the Komen PDF.

### 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/Co-Mentor (if applicable)
5. Letter of Support from Patient Advocate Mentor(s) (if named on Pre-Application)
6. Pre-Application Submission Checklist

Please note: all 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. References must be listed as FULL CITATIONS. Each citation must include names of all authors, publication title, book or journal title, volume number, page numbers, and year of publication.

#### 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 PDF 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
- Patient Advocate Mentor(s) (if applicable)
- Co-Mentor (if applicable)
- Committee Members (if applicable)

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Biosketches should not be included for Other Key personnel, Non-Key personnel, Collaborators, 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 4 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/Co-Mentor (if applicable)

A signed Letter of Support must be submitted by the Lead Mentor and Co-Mentor (if applicable), 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 and Co-Mentor (if applicable) should be submitted. If applicable, the letter may be a combined letter from both the Lead Mentor and Co-Mentor or both mentors may submit individual letters. The letter(s) should address the following:

- Explain the Mentor(s)'s commitment to mentoring the Applicant/PI (Fellow) and plan to support the career development of the Applicant/PI during the grant term.
- Describe the provided space and resources to support the Fellow to successfully complete the research project
- Detail the research, mentorship, leadership and other relevant experience the Mentor(s) possess to effectively mentor the Applicant/PI and help the Applicant/PI attain their stated career goals.
- The Mentor(s)' experience mentoring postdoctoral level researchers, including evidence of successful mentoring outcomes as demonstrated by examples of previously mentored postdoctoral trainees and their current titles/positions.
- The potential and commitment of the Applicant/PI to capitalize on the training to be provided through the Komen PDF.
- Verification that the Fellow is no more than 3 years post-completion of his/her most recent clinical fellowship or 5 years post-completion of his/her most recent residency (for physicians), or 5 years post-completion of his/her most recent PhD.

#### 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 Patient Advocate Mentor 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 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. 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.**

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 is required for all funded Komen Grants. The Advocate Mentor may be included in the Full Application (due November 9) as a Key Person and member of the Mentor Committee. The Patient Advocate Involvement Plan section must be completed in the Full Application Proposal Narrative. **If a specific named Patient Advocate is not included in the Full Application, Komen WILL assign a Patient Advocate to all funded Postdoctoral Fellowships.** For assistance in identifying trained advocates for your application or to discuss including advocates in the proposed research project, contact [advocatesinscience@komen.org](mailto:advocatesinscience@komen.org).

## QUESTIONS?

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

Type of Inquiry	Contact
All <u>programmatic inquiries</u> (including questions related to eligibility, program requirements, Komen policies and procedures, etc.)	<b>Komen Research Programs Help Desk</b> Questions: <a href="http://www.komen.org/researchhelpdesk">www.komen.org/researchhelpdesk</a> Phone: 1-866-921-9678 (Toll-free within the United States and Canada)
All <u>technical inquiries</u> related to the online application system, proposalCENTRAL (including questions related to system access, navigation, document uploads, etc.)	<b>Altum/proposalCENTRAL</b> Email: <a href="mailto:pcsupport@altum.com">pcsupport@altum.com</a> 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:
<b>Principal Investigator (PI)/Applicant</b>	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:		
	<u>CCR</u>	<u>PDF</u>	<u>GTDR</u>
<b>Advocate Mentor/Patient Advocate</b>	Optional at Pre-App; Required at Full App	Optional at Pre-App; Required at Full App	Optional
<b>Collaborator (Key)</b>	Optional	Optional	Optional
<b>Co-Mentor</b>	<i>Not allowed</i>	Optional (1 per grant)	<i>Not allowed</i>
<b>Committee Member</b>	Required	Optional	<i>Not allowed</i>
<b>Co-PI</b>	<i>Not allowed</i>	<i>Not allowed</i>	Optional (1 per grant)
<b>Lead Mentor</b>	Required (1 per grant)	Required (1 per grant)	<i>Not allowed</i>

### *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:		
	<u>CCR</u>	<u>PDF</u>	<u>GTDR</u>
<b>Collaborator (Non-Key)</b>	Optional	Optional	<i>Not Allowed</i>
<b>Graduate Student</b>	Optional	<i>Not Allowed</i>	<i>Not Allowed</i>
<b>Mentor (GTDR)</b>	<i>Not Allowed</i>	<i>Not Allowed</i>	Optional
<b>Postdoctoral Fellow</b>	Optional	<i>Not Allowed</i>	<i>Not Allowed</i>
<b>Research Technician</b>	Optional	<i>Not Allowed</i>	<i>Not Allowed</i>

**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.

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*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.