





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.

GRADUATE TRAINING IN DISPARITIES RESEARCH GRANTS

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	3
KOMEN RESEARCH PROGRAM	3
GRADUATE TRAINING IN DISPATIRIES RESEARCH GRANTS	3
ELIGIBILITY REQUIREMENTS	4
FUNDING INFORMATION AND GRANT TERM	4
APPLICATION REQUIREMENTS	5
OPTIONAL COMPONENTS	7
PRE-APPLICATION REVIEW PROCESS	8
PRE-APPLICATION SUBMISSION INSTRUCTIONS	9
Administrative Requirements	9
Pre-Application Submission Deadline	9
Getting Started in proposalCENTRAL	9
<u>Title Page</u>	10
<u>Download Templates & Instructions</u>	10
Applicant/Principal Investigator (PI)	10
Institution & Contacts	10
Key Personnel	10
Non-Key Personnel	11
Narrative and Supporting Documents	11
<u>Validate</u>	15
Submit	15
FULL APPLICATION SUBMISSION	15

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 incidence and mortality within the decade.

GRADUATE TRAINING IN DISPARITIES RESEARCH GRANTS

Graduate Training in Disparities Research (GTDR) Grants are intended to establish and/or to sustain a training program for graduate students who are seeking careers dedicated to understanding and eliminating disparities in breast cancer outcomes across population groups.

By providing funding to outstanding training programs, 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 focused on disparities in breast cancer outcomes.

The research training program should be designed to meet the following goals:

- Attract graduate students, specifically those from populations affected by disparities in breast cancer outcomes, into research careers.
- Empower these students with the skills and knowledge necessary to effectively explore the causes of differential breast cancer outcomes and develop interventions to reduce and eliminate such disparities.

ELIGIBLE APPLICANTS/DESIGNATED RECIPIENTS

Applicants/PIs, Co-PIs, and Institutions must conform to the following eligibility criteria to apply for a GTDR Grant. Eligibility requirements must be met at the time of Full Application submission, November 9, 2015.

GTDR Grants will be awarded to a single Principal Investigator (PI) or a PI and Co-Principal Investigator (Co-PI) to support a <u>minimum</u> of 3 Graduate Students/Trainees (those in a masters and/or doctoral program) per year. The PI or Co-PI must serve as the primary Mentor for the Trainees, but additional Mentors may be specified in the application.

Applicants/PIs, Co-PIs

- Must have a doctoral degree, including MD, PhD, DrPH, DO, or equivalent
- Must currently hold a full time faculty appointment with an accredited institution
- Must currently conduct breast cancer disparities research
- Must make a specific time commitment (the level of effort cannot be 0%) to supervise the education and advancement of Trainee(s) Note: Level of effort committed to the proposed project does not determine salary level. Salary levels are determined by the applicant's institutional policies.
- Cannot be the Principal Investigator (PI) or Co-Principal Investigator (Co-PI) on more than one Komen GTDR grant (or Post-baccalaureate Training in Disparities Research Grant) at a time; if such a grant is currently held, the grant term must expire or be relinquished before the start of the new GTDR grant, if funded.
- 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 or by the time of Full Application submission, November 9, 2015
- Are not required to be U.S. citizens or residents

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 \$135,000 per year (direct costs only) for up to three years (\$405,000).

Budgets are not required to be submitted during the Pre-Application phase, but the following Budget Guidelines should be noted:

- Allowable costs include Trainee stipends, Mentors' salaries, training materials, travel to annual Trainee meeting, and other associated training costs including tuition
- 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
- Personnel on the project are limited to a base salary at or below \$250,000 per year
- Equipment costs are limited to no more than 25% of direct costs
- Indirect costs are NOT allowed under this mechanism
- Visa costs are NOT allowed
- Professional membership dues and subscription dues are NOT allowed

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



APPLICATION REQUIREMENTS

Required: Training Program

The proposed research training program should leverage the current training and research activities available at the applicant institution or provide new training opportunities that are not currently offered. The program should provide a combination of didactic coursework and hands-on laboratory, clinical and/or public health research experience. An overall common set of training components may be defined for all participating Trainees, but a process for working with students at different educational levels (pre-masters, pre-doctoral) to identify their individualized training needs should be described. Mentoring plans and processes for monitoring progress should be discussed. The program should include faculty experienced in breast cancer disparities research and who demonstrate that they are willing and available to work with Trainees. Applicants/PIs will be expected to define the core training objectives for all Trainees in their program.

If the Pre-Application is for the continuation of a GTDR (or PBTDR) program currently funded by Komen, the successes and challenges of the existing program should be briefly described in the Pre-Application.

Applications proposing training programs that are not clearly designed to meet the GTDR goals as outlined in this RFA will be administratively withdrawn from consideration and will not be reviewed or scored.

Required: Measures of Training Success

Applicants/PIs will be expected to define general program milestones and measures of training success for all Trainees. Additionally, applicants will be expected to define a process for identifying individualized measures of training success. Metrics may include, but are not limited to: assessments of skill development; measures of training and/or career progression, research contributions, etc. Examples of success may include courses completed, honors and awards, research publications or presentations, and evidence of continued work in the field of breast cancer disparities research after completion of the program.

Required: Mentors

Applicants/PIs and program faculty should have a strong track record in breast cancer disparities research and successful mentoring of graduate-level students. Examples of success may include the research training record of the program faculty (e.g., productive scientific careers of former Trainees). Multiple Mentors may be involved in the program with each focusing on specific aspects of the training. For such collaborations, these roles should be briefly defined in the Pre-Application. Members of the Mentor Committee, except for the Applicant/PI, are not required to include % effort.

Required: Trainees

Applicants/PIs are not required to specifically name Trainees at the time of Pre- or Full Application submission. However, the number of Trainees and desired characteristics of Trainees, such as academic level, race/ethnicity, career goals, etc., must be specified in the Pre-Application and evidence should be provided to demonstrate that such students can be recruited into the training program. If specific Trainees have been identified at the time of Pre- or Full application submission, only the descriptive characteristics relevant to all potential Trainees should be provided. Specific Trainees may change over the course of the grant term and Trainee stipends may be partially or fully supported by the grant.

- A <u>minimum</u> of 3 Trainees must be supported by the grant <u>each year</u>; specific Trainees can change as students graduate or are admitted to the program, etc.
- Trainees must be enrolled in a masters, combined masters/doctoral, or doctoral degree program at time of support by the Grant
- Those trainees from populations affected by disparities in breast cancer outcomes are strongly preferred
- Trainees are not required to be U.S. citizens or residents

Strong preference will be given to programs that provide a solid plan for recruiting Trainees from populations affected by disparities in breast cancer outcomes. Applicants/PIs should outline the sources, availability, demographics and qualifications of prospective Trainees, including the criteria for Trainee selection.

Required: Annual GTDR Trainee Meeting

Trainees and Pls will be required to participate in one annual GTDR Trainee meeting per grant term. This meeting is organized by Susan G. Komen and designed to augment the training experience with symposium-style lectures and interaction with other GTDR Trainees and Mentors, as well as experts in the field. Costs for travel and meeting participation may be included in the application budget. Trainees will be required to prepare presentations and other materials for these meetings. Participation in all annual GTDR Trainee meetings is encouraged.



Komen has invested \$89 million in research to understand and address breast cancer disparities

OPTIONAL COMPONENTS

Optional: Patient Advocate Involvement

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. Advocates involved in the proposed 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 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.

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 how to become a patient advocate and the attributes appropriate for that role can be found here assistance in identifying trained advocates or to discuss including advocates in the proposed research project, contact advocatesinscience@komen.org.

Optional: Use of Komen Tissue Bank

The Susan G. Komen Tissue Bank at the IU 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

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.

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:

Training Plan	 Will the overall objectives of the training program and the combined research and didactic training provide the knowledge and research skills necessary to subsequently make a difference in disparities in breast cancer outcomes? If the application is for the continuation of a PBTDR/GTDR program currently funded by Komen, have the development, successes, and challenges of the existing program been adequately described?
Training	• Is there an adequate description of the research institution as well as the department (if
Environment	applicable) in which the GTDR training program will be integrated?
and	
Feasibility	Is there adequate institutional support for the proposed training program's goals and
reasibility	objectives to ensure successful implementation and Trainee recruitment and training?
	Was the existing (if applicable as a renewal) training plan and environment discussed,
	along with challenges, successes and potential changes?
Mentors	Does the proposed Mentoring team possess the research and training expertise and the
	time needed to develop and successfully implement this training program?
Prospective	• Is the pool of potential Trainees that will be targeted for recruitment appropriate?
Trainees and	
Recruitment	Is the recruitment plan well defined and appropriate?
Significance	Do the objectives, design and focus of the proposed training program address critical and
Significance	Do the objectives, design and rocas of the proposed training program address dritted and
and	timely issues in breast cancer disparities research?
Disparities	
Impact	

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 submitted by 1pm, EST (U.S.) on Wednesday June 17, 2015, using the proposalCENTRAL website at https://proposalcentral.altum.com.

Applicants/PIs 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/PIs 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 "Graduate Training in Disparities Research Grants" 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 <u>not</u> 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.

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 the proposalCENTRAL system while working on the templates.

Upload the completed template files to your online application. See page 14 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 office, and signing official directly into the proposalCENTRAL system.

6. KEY PERSONNEL

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

Key Personnel include Co-PIs, Collaborators, and any Patient Advocates (if applicable) who are integral to the execution of the training program.

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%. Advocates and the Co-PI may list 0% effort. Other Key Personnel must list greater than 0% effort. **Salary support is not required for Key Personnel.**

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.

Non-Key Personnel

For GTDR Grants, Non-Key Personnel includes ONLY the additional Mentors described in the pool of Mentors in the grant application. Add new contacts by entering the e-mail address of the Non-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. A Non-Key person may have 0% effort. 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

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.

Pre-Application Template

The Pre-Application Narrative (Sections A-F) is limited to 3 pages. Applicants/PIs 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 Institutional Support, and Letter of Commitment from Applicant/PI) are not included in this page number limit.

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 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 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 Institutional Support, 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: Training Program (1 page recommended)

Describe the proposed training program, paying particular attention to the following:

- Describe the overall objectives of the training program and how the combined research and didactic training will provide the knowledge and research skills necessary to study disparities in breast cancer outcomes.
- If the application is for the continuation of a PBTDR/GTDR program currently funded by Komen, successes, and challenges of the existing program should be briefly described.

Section C: Training Environment and Feasibility (0.5 pages recommended)

Describe the training environment, paying particular attention to the following:

- Briefly describe the research institution
- Briefly describe the department (if applicable) in which the GTDR training program will be integrated.
- Describe the institutional support for the proposed training program's goals and objectives and how this support will ensure successful implementation and Trainee recruitment and training.
- Describe the availability of necessary institutional resources to support the training program and ensure its success.

Section D: Mentors (0.5 page recommended)

Describe the Mentor(s), paying particular attention to the following:

• Explain how the proposed Mentoring team possesses research and training expertise necessary to develop and successfully implement this training program.

Section E: Prospective Trainees and Recruitment (0.5 page recommended)

Describe the prospective Trainee pool and ability to recruit, paying particular attention to the following:

- Identify the number of Trainees that will be supported each year (a minimum of 3 Trainees must be supported each year of the grant).
- Describe the pool of potential and appropriate Trainees from which the program can recruit, including the qualifications, demographics, and academic level of the prospective Trainees.

Section F: Significance and Disparities Impact (0.5 page recommended)

Clearly and concisely answer the following questions:

- Describe how the objectives, design and focus of the proposed training program address critical issues in breast cancer disparities research.
- Following completion of this training program, how will the Trainee(s) be well positioned to conduct research that will contribute to reductions in breast cancer disparities?

Pre-Application Supporting Documents

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

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

<u>Please note: any additional documents that are uploaded to the application and are not listed below will be</u> 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 Letter of Commitment must be submitted by the Applicant/PI and the Co-PI (if applicable), on Institution Letterhead, describing how the PI and Co-PI (if applicable) will be able to commit the level of effort required to implement the training program and their strong track record of mentoring successful research scientists. In this letter, describe the Applicant/PI's experience in breast cancer disparities training and research.

3. Biosketches

Required for the following Key Personnel:

- Applicant/PI
- Co-PI (if applicable)
- Patient Advocates (if applicable)

Biosketches should <u>not</u> be included for Other Key Personnel, Non-Key Personnel (including Mentors), Collaborators etc. These will be required at the time of Full Application submission.

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 are required for ALL Advocates. Such biosketches may be submitted in any format. Biosketches are not required for Non-Key Personnel.

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

4. Letter of Institutional Support

A signed Letter of Support must be submitted by the department chair, on Institution Letterhead. If the department chair is also a PI, Co-PI, or Mentor for the application, this letter must be submitted by the Dean – this letter may not be provided by the PI, Co-PI, or Mentor. The letter must include the following information:

- Describe the institutional support for the proposed training program's goals and objectives and how this support will ensure successful implementation and Trainee recruitment and training. Include any institutional measures that will be taken to help establish and ensure success of the training program.
- Describe the availability of necessary institutional resources to support the training program and
 ensure its success. This includes financial resources and other support that will be provided to
 implement and ensure success of the program.

5. Letter of Support from Patient Advocate(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(s)'s relevant experience and qualifications as a breast cancer patient advocate.
- Explain the active role that the Patient Advocate 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'.

Please note: For FY16 Full Applications we will require the Principal Investigator and Co-PI (if applicable) 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/.

QUESTIONS?

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

Type of Inquiry	Contact
All programmatic inquiries (including questions	Komen Research Programs Help Desk
related to eligibility, program requirements, Komen policies and procedures, etc.)	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	Altum/proposalCENTRAL
application system, proposalCENTRAL (including questions related to system access,	Email: pcsupport@altum.com
navigation, document uploads, etc.)	Phone: 1-800-875-2562 (Toll-free U.S. and Canada), or
	+1-703-964-5840 (Direct Dial 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:		
	<u>CCR</u>	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.