
The mission of Susan G. Komen is to save lives by meeting the most critical needs in our communities and investing in breakthrough research to prevent and cure breast cancer.

# Training Researchers to Eliminate Disparities (TREND) Grants

## 2019-2020 REQUEST FOR APPLICATIONS

Susan G. Komen
5005 LBJ Freeway, Suite 526
Dallas, Texas 75244
Email: www.komen.org/researchhelpdesk
Website: www.komen.org

## KEY DATES

| | |
|---|---|
| Application System Opens | August 27, 2019 |
| Application Due | October 17, 2019, by 1:00 PM, Eastern Time (US) |
| Award Notification | On or around April 15, 2020 |

## TRAINING RESEARCHERS TO ELIMINATE DISPARITIES GRANTS

Training Researchers to Eliminate Disparities (TREND) Grants are intended to establish and/or to sustain an innovative training program for graduate students, who are seeking careers dedicated to understanding and eliminating disparities in breast cancer outcomes across population groups, specifically those from diverse backgrounds affected by disparities in breast cancer outcomes including minority populations.

For these purposes, breast cancer disparities research is defined as research investigating the biologic, behavioral, social, and system-related contributors to breast cancer in population groups affected by poor patient outcomes. This may include the identification, validation and testing of biological and/or socioeconomic factors that contribute to breast cancer disparities. This may also include identification of health services and public health interventions that address the causes of disparities in care and outcomes across population groups in breast cancer.

The field of disparities research has significant challenges, including a lack of resources to support comprehensive research projects, limited data sets to clearly address research questions, a shortage of people trained to solve these problems, and no venue through which scientists and patient advocates can collaborate to overcome these barriers. This results in later diagnosis, different responses to treatments, and not participating in clinical trials due to systemic bias.

For over 10 years, to address some of these challenges, Komen has provided funding to outstanding training programs to ensure that a diverse pool of highly trained scientists, particularly those from minority populations, will emerge as the next generation of leaders in the field of breast cancer research focused on disparities in breast cancer outcomes. Komen supports exceptionally creative training programs for students of diverse backgrounds to support innovative breast cancer disparities research.

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

- Attract graduate students, specifically those from minority populations affected by disparities in breast cancer outcomes, into research careers.
- Develop novel and creative methods to 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.

The TREND program represents an evolution of the Graduate Training in Disparities Research (GTDR) grant program. Institutions with current or previous GTDR grants are encouraged to apply to the TREND program as a Renewal as noted below.

### 1. Renewal:

A Renewal is an application submitted by an Applicant/PI that has an active Komen GTDR (Graduate Training in Disparities Research) Grant at the same institution or if the TREND Application would serve as a continuation of a previously funded Komen GTDR Grant at the same institution. A Current Komen GTDR Statement must be submitted with the Renewal Application.

### 2. New Submission:

A New Submission is a TREND project or Applicant/PI that has not previously been funded by Komen.

A list of previously awarded GTDR/TREND programs can be found here:
http://ww5.komen.org/ResearchGrants/FundedResearchGrants/

## COMMITMENT TO ELIMINATING BREAST CANCER DISPARITIES

Susan G. Komen funds the brightest minds and the best breast cancer research – research that has the potential to reduce breast cancer deaths within the decade. Through support of research proposals focused on populations who experience disparities, and researchers seeking outcome-based answers, we will be able to more effectively eliminate breast cancer outcome disparities. **Moreover, by supporting more disparities research, we can begin to tackle larger challenges in the field, such as growing the pool of health disparities data through research and data-sharing, improving representation of minority populations in clinical trials, and broadening the impact of high-quality disparities research studies.**

## ELIGIBILITY

Applicants/PIs, Co-PIs, and institutions must conform to the following eligibility criteria to apply for a Training Researchers to Eliminate Disparities (TREND) Grant. **Eligibility requirements must be met at the time of application submission (October 17, 2019).**

TREND Grants will be awarded to a single Principal Investigator (PI) or a PI and Co-Principal Investigator (Co-PI) to support a minimum of 3 Graduate Students/Trainees per year (those in a masters and/or doctoral program). Additional participants in the program may include any postdoctoral fellows or early career faculty seeking a better understanding of disparities research (Trainees). 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 are not required to specifically name Trainees at the time of 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 Application and evidence should be provided to demonstrate that such trainees can be recruited into the training program. If specific Trainees have been identified at the time of 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.

### Applicants/PIs, Co-PIs

- Must have a doctoral degree, including M.D., Ph.D., Dr.P.H., D.O., 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 TREND grant at a time; if such a grant (TREND) is currently held, the grant term must expire or be relinquished before the start of the new TREND 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 or by the time of Application submission, October 17, 2019.
- Are not required to be U.S. citizens or residents.

### Trainees

- Those from populations affected by disparities in breast cancer outcomes are strongly encouraged. A minimum of 3 Trainees must be supported by the grant each year; specific Trainees can change as students graduate or are admitted to the program, etc.
- Must be enrolled in a masters, combined masters/doctoral, or doctoral degree program at time of support by the Grant.
- Postdoctoral fellows or early career faculty may also participate in the coursework and training upon request to Komen. A clear case should be presented for how the training will further their research and bring a disparity focus to their project.
- Are not required to be U.S. citizens or residents.

### Primary Institution

- Must be a non-profit institution or organization anywhere in the world.
- May not be a governmental agency (i.e. NIH, NCI etc.) within any country.
- Must serve as the administrator of the Grant funds and will hold responsibility for the management of the budget, disbursement of the funds to other participating institutions (if any), and submission of all required documents and reports.
- Must agree to adhere to Komen's Policies and Procedures for Research and Training Grants which may be downloaded along with the Application Templates in proposalCENTRAL.

### Consortia/Subcontract Institutions

- Other participating institutions may be non-profit institutions or industry partners. However, industry partners may not be compensated for any fees or costs not directly related to the Research project.
- It is expected that the primary institution will enter into subcontracts with participating institutions (if any). Assurances that these contractual agreements have been executed will be required prior to initiation of the Grant.

## 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. Note, final funding decisions and amounts rest with Komen Leadership.

Budgets are not required to be equivalent across each year of the Grant, but rather should reflect the costs appropriate to support the training program each year. Applicants must follow the following budget guidelines:

- Allowable costs include Trainee stipends, Trainee (including postdoctoral fellow and early career faculty) tuition, mentors' salaries, training materials, travel to the annual Trainee meeting, and other associated training costs.
- Salary costs are not permitted for postdoctoral fellows or early career faculty members.
- Research Project costs are not permitted for postdoctoral fellows or early career faculty members.
- Personnel on the project are limited to a base salary at or below $250,000 per year.
- Reasonable compensation of advocates is allowed when advocates perform services that would otherwise be a contracted expense. Compensation may be in the form of per-hour compensation, or honoraria.
- Travel costs ARE allowed for purposes specifically related to the proposed Research Project and must be in line with the Applicant's Institution travel policies.
- Equipment costs are limited to no more than 25% of total direct costs.
- Professional membership dues or subscription dues are NOT allowed.
- Publication costs and meeting-related poster printing costs ARE allowed for purposes specifically related to the proposed Research Project.
- Visa costs are NOT allowed.
- Indirect costs are NOT allowed. Indirect costs include all expenses not directly related to the conduct of the Research Project, including, but not limited to, allocated costs such as facilities, technology support, communication expenses, administrative support, etc.

## APPLICATION REQUIREMENTS

### Required: Training Plan

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, postdoctoral fellow, or early career faculty) 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 TREND Application is a Renewal of a GTDR program currently or previously funded by Komen, the successes and challenges of the existing program should be described in the Current Komen GTDR Statement. This supporting document is required for all Renewal Applications. Requirements for the Current Komen GTDR Statement can be found on page 17.

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

### Required: Program Evaluation Plan

Applicants/PIs will be expected to provide an evaluation of the program's effectiveness, including measures of Training Success, throughout the grant term. The evaluation plan should outline the goals and objectives of the program, as well as the process for measuring progress and success against those objectives. The plan should include measurable outcomes and milestones by which accomplishments of the objectives can be assessed. Metrics may include, but are not limited to, assessments of recruitment, trainee program completion, training success, assessments of skill development, measures of training and/or career progression, research contributions, program perception, etc. Applicants/PIs should also include courses/curriculum that have been integrated into the department and will continue to be offered after program completion. 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 cancer disparities research and successful mentoring of graduate-level students and/or postdoctoral fellows. 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 Application. Members of the Mentoring Committee, except for the Applicant/PI, are not required to include percentage of effort.

### Required: Trainees

Applicants/PIs are not required to specifically name Trainees at the time of 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 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 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 minimum of 3 Trainees must be supported by the Grant each year; 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.
- Postdoctoral fellows or early career faculty may also participate in the coursework and training upon a formal request to Komen. A clear case should be presented for how the training will further their research and bring a disparity focus to their project.
- Those Trainees from populations affected by disparities in breast cancer outcomes are strongly encouraged.
- 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 Breast Cancer Disparities Research Summit

Trainees and Applicants/PIs will be required to participate in one Annual Breast Cancer Disparities Research Summit 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 TREND Trainees and Mentors, as well as experts in the field. Costs for travel and meeting participation may be included in the Application budget. Trainees may be required to prepare presentations and other materials for these meetings. Participation in all Annual Breast Cancer Disparities Research Summits is encouraged.

### Required: 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 research projects. As part of this ongoing effort**, Komen REQUIRES that at least one Patient Advocate(s) be included and named as Key Personnel on all grants at Application (due on October 17, 2019)**. Applicants are encouraged to include an additional Patient Advocate who may better speak to, or have experience with, breast cancer disparities.

NOTE: Failure to include a Patient Advocate on the Application will result in administrative withdrawal with no opportunity for appeal.

1. **Komen requires that at least one Patient Advocate(s) be included as Key Personnel for all TREND grants.**
    - The named Patient Advocate must submit a **Letter of Support** (see Appendix D) detailing their role and commitment to the proposed project.

2. **Each applicant must complete the Patient Advocate Involvement Plan (Section F) in the Application Narrative template.** This plan, which outlines how the Applicant will involve the Patient Advocate, is a required component of the application narrative. The involvement of the Patient Advocate may also be addressed in other sections of the application where appropriate.

Utilizing a Patient Advocate as a part of their project will enable Trainees to become more aware of how their research is relevant to patients, to emphasize the urgent need to find cures, and to learn from patients' perspectives. Patient Advocates may also have direct experience with disparities in breast cancer care and provide important insight to guide the research project.

There are many ways to engage advocates in your research project. Patient Advocates can:

- be involved early in the development of the Research Project to provide input about its relevance and impact to patients.
- review the Application to help articulate the importance of the Research Project to breast cancer patients.
- be invited to attend lab meetings or give presentations to provide the patient point of view and a different perspective to the Research Project.
- be included in clinical trial development, provide input on potential barriers to accrual, and help develop patient education materials.
- assist in articulating the impact of the findings of the Research Project using lay language that will be better understood by the general public.

Komen Advocates in Science have developed a detailed guide with suggestions for the inclusion of advocates in research which can be found in proposalCENTRAL and in Appendix B and C.

Who can serve as a Patient Advocate? Read more here. In summary, those who:

- have been diagnosed with breast cancer; have a known genetic mutation; or have a strong personal connection or experience with breast cancer (i.e., family, friend, caregiver).
- can represent a collective breast cancer patient/survivor perspective (i.e., insights and experiences of other breast cancer survivors).
- actively involved in the broader breast cancer research advocacy community.
- have a basic understanding of the science of breast cancer and are involved in the broader breast cancer research advocacy community.

- do not have a conflict of interest (i.e. a financial or personal relationship) that may bias their patient perspective. Patient Advocate Mentors may be employed by your institution so long as the above is not an issue.
- Advocates are not required to be an AIS member. Information about AIS and joining AIS is at http://sgk.mn/2lBg8vC

A guide for how to become a Patient Advocate and the attributes appropriate for that role can be found in proposalCENTRAL and in Appendix B.

Komen is happy to offer a previously recorded webinar that was hosted by members of Komen Advocates in Science on ***How Advocates and Researchers can Work Together on Komen Funded Research***. Please view this webinar for tips on how to involve patient advocates as you develop your research proposal and plan the research objectives.

For assistance in identifying trained advocates for your Application or to discuss including a Patient Advocate Mentor in the proposed Research Project, contact advocatesinscience@komen.org.

**Required: Data Sharing Policy for Research Grants**

To accelerate scientific discovery, research results and data should be made as widely and freely available as possible, while safeguarding the privacy of participants and protecting confidential and proprietary data. As noted above, the sharing of data related to minority populations and other disparities will be key to addressing disparities in breast cancer outcomes. Komen's Data Sharing Policy aligns with the NIH's data sharing requirements (https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm), including policies for sharing large-scale genomics data (https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/) and clinical trial information (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html), with the following exceptions:

- The policy will apply to all Komen-funded research grants, regardless of awarded amount.
- **Final data must be shared** no later than the **date of publication** of research results.

**Each applicant must complete the Data Sharing Plan (Section H) in the Application Narrative template.** Applicants may request funds necessary for data sharing and archiving in the submitted budget. Grantees will be required to report on progress toward the data sharing plan in both annual and final progress reports. Key points of the Komen Data Sharing Policy include the following:

What should be considered for data sharing?

- All data from basic, translational, clinical, and other types of research studies should be considered for data sharing. This includes laboratory research and all clinical trials, regardless of study phase, type of intervention, etc.
- Final research data, especially unique data, along with metadata and descriptors-- i.e., all material necessary to document, support, and validate research findings--must be shared.

When should data be made available?

- Data should be made available as soon as possible and for as long as possible. Data must be released no later than the time of publication of the main findings from the final dataset, although possible exceptions will be made to protect patentable and other proprietary data.
- Clinical trials must be registered at clinicaltrials.gov no later than 21 days after enrollment of first participant and updated at least once a year. Summary results, including adverse event information, must be provided no later than one year after the trial completion date, unless regulatory approval of the product is being sought.

Where/With Whom should data be shared?

- Data should be shared as broadly as possible to the extent consistent with applicable laws, regulations, rules, and policies. Rights and privacy of human subjects must be protected at all times.
- Researchers may select the method(s) for data sharing.
- Data repositories with common standards and an established infrastructure dedicated to the appropriate distribution of data are recommended.

- Large-scale non-human genomic data must be submitted to any widely used data repository; large-scale human genomic data must be submitted to an NIH-designated data repository.
- Clinical trials should be registered at clinicaltrials.gov.

As research results should be broadly available to the research community to further research, for assistance in formulating a meaningful data sharing plan, please refer to Appendix E.

### 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.

## APPLICATION REVIEW PROCESS

Each Application will be reviewed by a panel of three scientists with appropriate expertise and a patient advocate, along with additional experts as necessary to conduct a thorough review of the proposed project. Scientist, advocate, and special reviewers (as needed) assess the strengths and weaknesses of each application based on the defined review criteria, described below.

Applications that are deemed most meritorious will proceed to discussion and final scoring by the Peer Review committee, facilitated by the Chairperson. Applications that are non-competitive will be triaged and will not be discussed or receive a final score. The Scientific Advisory Board (SAB) reviews the results of peer review and issues a recommendation for funding to Komen Leadership. It is important to note that the SAB does not conduct a re-review of individual grant applications, but rather focuses on the most highly ranked applications and their alignment with Komen's strategic objectives. Komen Leadership approves the final slate of research projects to be funded. Please see Appendix A: Notification Process for full details about accepting a Komen Grant.

## APPLICATION REVIEW CRITERIA

The Applicant/PI must address the following criteria in the Application narrative.

| | |
|---|---|
| **Training Plan** | • Will the overall objectives of the training program and the combined research and didactic training provide the knowledge and research skills, including relevant coursework, seminars, and research opportunities, necessary to conduct a career in disparities in breast cancer outcomes?<br>• If the TREND application is for the continuation of a GTDR program currently funded by Komen, have the development, successes, and challenges of the existing program been adequately described in the Current Komen GTDR Statement?<br>• Does the proposed training program include a well-designed mentoring plan that will be tailored to each Trainee? Is enough time dedicated to mentoring? Will Trainees in different programs or stages receive appropriate guidance?<br>• Does the evaluation plan outline outcomes that are appropriate to the goals of the training program, and does it include specific metrics and plans for measuring these outcomes?<br>• If breast cancer survivors/advocates were consulted in the development of the Training Plan, will their involvement impact the research or career development of the Trainees? If so, how?<br>• |

| | |
|---|---|
| **Scientific and Disparities Impact** | • Do the objectives, design and focus of the proposed training program address critical and timely issues in breast cancer disparities research? Following completion of this training program, will the Trainee(s) be well positioned to conduct research that will contribute to reductions in breast cancer disparities?<br>• Does the proposed plan represent an innovative and creative approach to training students in breast cancer disparities research? |
| **Training Environment and Feasibility** | • Is there an adequate description of the research institution as well as the department (if applicable) in which the TREND training program will be integrated?<br>• Is there adequate institutional support for the proposed training program's goals and objectives to ensure successful implementation and Trainee recruitment and training? |
| **Mentors** | • Does the proposed mentoring team possess the research and training expertise and the time needed to develop and successfully implement this training program?<br>• Will the Mentors be able to commit the level of effort needed to implement the training program? |
| **Prospective Trainees and Recruitment** | • Is the pool of potential Trainees that will be targeted for recruitment appropriate and adequate?<br>• Is the number of Trainees proposed for support by the grant described (a minimum of 3 Trainees each year)? Are the selection criteria well-defined?<br>• Are the recruitment procedures, Trainee selection criteria, Trainee selection process, and retention strategies sufficient to recruit and retain high quality Trainees from diverse populations affected by disparities including appropriate minority populations? |

## APPLICATION SUBMISSION INSTRUCTIONS

### Administrative Requirements

Applicants/PIs must follow the 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.**

Overlap in funding is NOT permitted as indicated in Komen's Policies and Procedures, found in proposalCENTRAL. Awarded grants will be reviewed for any overlap prior to approval for contracting.

### Application Deadline

Applications must be completed by **1pm, EST (U.S.) on October 17, 2019,** using the proposalCENTRAL website at https://proposalCENTRAL.altum.com.

Applicants are strongly encouraged to complete, review, and submit their Application with sufficient time to allow for technical difficulties, varying time zones, human error, loss of power/internet, sickness, travel, etc.

Extensions to the 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

Go to https://proposalcentral.com/ to access the login page.

If you are a new user of proposalCENTRAL, follow the "Create One Now" link under Application Login and complete the registration process. After you register, complete your Professional Profile (green tab fourth 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 Username/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 an Application, select the "Grant Opportunities" tab (gray tab furthest to the right). A list of Applications will be displayed. Find **"Training Researchers to Eliminate Disparities"** and click the "Apply Now" button (second to last column) to create your 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 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

## APPLICATION SECTIONS

The following information is required to submit a complete 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 become accessible.

**Submission Type**

Please select the appropriate submission type for the TREND Application from the dropdown menu:

- Renewal
- New Application

### 2. DOWNLOAD TEMPLATES & INSTRUCTIONS

The Request for Application, the Komen Policies and Procedures for Research and Training Grants, and all templates can be downloaded from this page.

You must download and complete the following templates for supporting documents (see pages 14-18):

- Application Narrative Template
- Supporting documents that require templates:
    I. Biosketch Template
    II. Payment Verification Form
    III. Budget Justification Template
    IV. Contract/Consortium Budget (if applicable)

Click the "Download" link to save each of the templates to your computer. **See pages 14-18 for a complete list of required supporting documents required to submit an Application.**

Use your word processing software (e.g., MS Word, WordPerfect) to complete the templates on your computer and then convert templates to PDF format. You do not need to be connected to the internet or proposalCENTRAL while working on the templates.

Upload the completed template files to your online application.

See page 19 for instructions on how to complete and upload the templates.

**3. ENABLE OTHER USERS TO ACCESS THIS PROPOSAL**
Optional.

**4. APPLICANT/PI**
This information will pre-populate from the Professional Profile Page. If any changes need to be made to the Applicant/Principal Investigator (PI) information, click the green Professional Profile tab or the blue Edit Professional Profile button.

The Principal Investigator and Co-PI must 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/.

Please include any other name you may be known by professionally on the Applicant/PI page. This information is required to Validate the application. If not applicable, please enter N/A.

The percentage of effort the Applicant PI must also be included on this page. This must be greater than 0%.

**5. INSTITUTION & CONTACTS**
Enter information regarding the Primary Institution, Signing Official, and Financial Officer directly into proposalCENTRAL system. If institutional information is incorrect, contact the person listed on the page or proposalCENTRAL.

**6. KEY PERSONNEL**
**Do not list the PI or prospective Trainees as Key Personnel in this section.**

| PERSONNEL ROLES | |
|---|---|
| | **TREND** |
| **Patient Advocate Mentor** | Required |
| **Collaborator (Key)** | Optional |
| **Mentor (Non-Key)** | Optional |
| **Co-PI** | Optional |

**Key Personnel**
Key Personnel include Co-PIs, Collaborators, and any Patient Advocate Mentors (required) 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. **Each Key Person must have a level of effort listed in proposalCENTRAL (0-100%).** Patient Advocate Mentors 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 email address of the Key Person you wish to add. Click 'Add Contact' button. 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**
For TREND 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 email 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/home addresses for the Non-Key person.

Add new contacts by entering the email address of the Non-Key Person you wish to add. Click 'Add Contact' button. 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/home addresses for the Non-Key Person.

***Biosketches are required for all Key Personnel. All Patient Advocate Mentors are considered key personnel and should submit their biosketches. Biosketches are NOT required for Non-Key Personnel.***

**7. ABSTRACTS**

**Abstracts**
Applicants are required to provide both lay and scientific abstracts of the proposed research project. The lay abstract should be written in language understandable to a non-scientist -- the lay and scientific abstracts MUST NOT be identical. These abstracts must be entered into the appropriate fields in the Abstracts and ORCID section of the proposalCENTRAL Application. Abstracts are limited to 3000 characters each, including spaces; special characters and formatting cannot be saved.

Once the abstract text is entered and saved please review it to be sure that it is not truncated due to character restriction.

**8. BUDGET PERIOD DETAIL**
Budget amounts for each year must be entered online in the Budget Period Detail section in proposalCENTRAL.

Funding Guidelines
Applicants/PIs may request funding of up to $135,000 per year up to three years.

Note, final funding decisions and amounts rest with Komen Leadership. Budgets are not required to be equivalent across each year of the Grant, but rather should reflect the costs appropriate to support the training program each year. Applicants/PIs must follow the following budget guidelines:

- Allowable costs include Trainee stipends, Trainee tuition (including postdoctoral fellow and early career faculty), Mentors' salaries, training materials, travel to annual Trainee meeting, and other associated training costs.
- Salary costs are not permitted for postdoctoral fellows or early career faculty members.
- Research Project costs are not permitted for postdoctoral fellows or early career faculty members.
- Personnel on the project are limited to a base salary at or below $250,000 per year.
- Reasonable compensation of advocates is allowed when advocates perform services that would otherwise be a contracted expense. Compensation may be in the form of per-hour compensation, or honoraria.
- Travel costs ARE allowed for purposes specifically related to the proposed Research Project and must be in line with the Applicant's Institution travel policies.
- Equipment costs are limited to no more than 25% of total direct costs.
- Professional membership dues or subscription dues are NOT allowed.
- Publication costs and meeting-related poster printing costs ARE allowed for purposes specifically related to the proposed Research Project.
- Visa costs are NOT allowed.
- Indirect costs are NOT allowed. Indirect costs include all expenses not directly related to the conduct of the Research Project, including, but not limited to, allocated costs such as facilities, technology support, communication expenses, administrative support, etc.

In the Budget Period Detail, click on the appropriate Budget Period button at the top of the page. Please enter a Period 1 (Year 1) start date of 8/1/2020 and ending 7/31/2021 – this is NOT the official start date, but simply a placeholder to enter your Budget.

- For Period 1, in the Personnel Cost section, type the name of each person that will receive salary on the grant for all **Key AND Non-Key Personnel.** Include the % effort, base salary, Requested Salary, and Requested Fringe for each person. This section should include Salaries and Fringe for the Applicant/PI and any other Key Persons, including Advocates, as well as Non-Key Personnel on the grant such as "Research Technician" or "Postdoctoral Fellow". If the name of the person is not known, please include their title or role on the project.
    - Click the red Save button located at either the top or bottom of the page to save your entry.
- In the Personnel Cost section, click the "Add Name" button again and type "Total Stipends and Other Personnel Costs" to add one line for all Stipends and Other Personnel Costs, as applicable. This line item is not required but is an option for Institutions that must report Stipends separate from Salary.
    - Click the red Save button located at either the top or bottom of the page to save your entry.
- For Non-personnel Costs, enter a general description of the expense and the amount of the expense. For example, under Supplies, include a general breakdown of supplies that will be purchased for each year of the grant. Budget detail will also be required on a separate template.
    - Enter only total direct contractual/consortium costs, by institution name, (budget detail will be required on a separate template) in this section. Contractual/consortium indirect costs should be included under the Indirect Cost section.
    - Click the red Save button located at either the top or bottom of the page to save your entries.

Your budget entries will automatically populate the table in the Budget Summary section, as noted in Section 9 below.

### Budget Justification Instructions

Sufficient justification of proposed expenditures must be uploaded to the Proposal Narrative and Other Attachments section of proposalCENTRAL, using the Budget Justification template provided. Exact amounts should be indicated in the Budget justification for each year of the Grant and should match amounts indicated in proposalCENTRAL.

For **personnel** justification, please describe the specific roles/responsibilities of the Applicant/PI, along with each Key and Non-Key Person on the project, their base salary, percent effort, requested salary and requested fringe. Please create separate sections in order to separate Key and Non-Key Personnel. If the person's level of effort and/or salary changes between budget periods, please explain/justify the changes. Please list specific roles/responsibilities and percent effort of ALL Personnel involved in the project, even if they are not requesting salary or fringe support.

No personnel on the project may have a base salary above US$250,000 per year.

For **Non-personnel** expenditures please provide sufficient justification for expenditures in each category listed in this section, paying specific attention to the following:

- Name, expertise, and roles of consultants, including the need for their expertise in the context of the proposed program.
- Listing of equipment that will be purchased, in what grant year (Period) it will be purchased, and why the equipment is needed for the proposed program.
- General breakdown of supplies that will be purchased for each year of the grant and why the supplies are needed.
- Breakdown of travel expenses for each grant year, including the reason, expense, and traveler for each trip. Please note that Mentors and Trainees are required to attend at least one TREND Annual Meeting.
- Outline any Patient Care and/or Other Direct Costs and justify their need in the context of the proposed project.
- Outline and justification of animal care costs, as applicable.

### Contract/Consortium Budget Instructions

**Separate budgets and budget justifications must be provided for all contract/consortium institutions.** These budgets should be completed using the Contract/Consortium Budget template and uploaded to the Proposal Narrative and Supporting Documents section in proposalCENTRAL.

Separate budget justifications for all contractual/consortium agreements must also be submitted using the Budget Justification Template. Please refer to Budget Guidelines and Instructions above when completing these budgets and justifications.

**9. BUDGET SUMMARY**

Budget entries from Budget Period Detail sections will automatically populate the table in this section.

**10. ORGANIZATION ASSURANCES**

The assurances/certifications on this page are made and verified by the signature of the institutional official signing the application. If accepted, IRB, IACUC and/or Institutional Biosafety Committee approvals (as applicable) for the existing research project must be submitted to Komen within six months of Notification of Intent to Fund.

Awarded Grants will not be initiated prior to receipt and approval of all required Organizational Assurances.

**11. PROPOSAL NARRATIVE & OTHER ATTACHMENTS**

Completed templates and supporting documents must be converted to PDF prior to being uploaded to the proposalCENTRAL system and must not be password or security protected or they may not convert properly.

**The following elements are required components of the Application: Application Narrative and Supporting Documents.**

#### Application Narrative – 9-page limit

Complete the following sections using the downloaded template. Below is a description of the narrative content that **MUST** be included in the Application. The total narrative can be no more than 9 pages, including figures and tables. Section I – Cited Publications does not count toward the 9-page Application Narrative limit.

The following sections are required in the Application narrative, and MUST not be eliminated, combined, or otherwise altered. Failure to follow these guidelines will result in Administrative Withdrawal of the Application without appeal.

#### 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

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.
- An overview of the current and anticipated research projects that will be made available to Trainees.
- The current and anticipated coursework, seminars, and other training components that will be made available to Trainees.
- Clear identification of courses, programs, and resources to be developed with funding through this grant mechanism. These must be differentiated from those that currently exist at the institution and will be made available to the Trainees, but will not be supported through funding from this grant mechanism.

### Section C: Significance and Disparities Impact

This section will be reviewed by advocate and scientific reviewers. 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. Why is (are) the research question(s) important to the breast cancer patient and survivor community?
- 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?
- Describe how the program represents an innovative and creative approach to training students in breast cancer disparities research.

### Section D: Training Environment and Feasibility

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

- Briefly describe the research institution.
- Briefly describe the department (if applicable) in which the TREND 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.
- If the Training Program is a continuation of a currently or previously funded Komen TREND Grant, you must submit a Current Komen TREND Statement as described below.

### Section E: Mentoring Plan

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.
- How the mentoring plan will meet the needs of Trainees at different educational levels (pre-masters, pre-doctoral) and identify their individualized training needs and career goals.
- How the Mentor(s) will work together synergistically to meet the goals of the program.
- General planned role(s) for Mentors in the program should be described, but individual roles can be described in the Mentor letters of support, if applicable.
- Research and training qualifications of the Mentor(s), including areas of research expertise should be documented in the Mentors' biosketches.

### Section F: Prospective Trainees and Recruitment

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.
- How prospective Trainees will be recruited to the program.
- The criteria by which Trainees will be selected.

### Section G: Program Evaluation Plan

Describe the evaluation plan, including:

- Detail general program milestones, anticipated outcomes and metrics that will be used to measure success for all Trainees and list those specific to pre-masters and pre-Ph.D. Trainees, as applicable. Examples of successful outcomes 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. Metrics may include, but are not limited to: assessment of skill development, measures of training and/or career progression, research contributions, etc.
- Describe the process that will be used to monitor program milestones and measure key outcomes.

### Section H: Data Sharing Plan

Please provide details on how your data will be shared as per Komen's Data Sharing Policy details on page 7 - 8. Specifics including what data will be shared, who it will be shared with and when it will be shared are required. The Applicant/PI should specifically discuss data that will benefit the disparities research community, and how this data will be shared. Data sharing will be a key component to advancing research focused on improving outcomes for populations that experience disparities in outcomes and for minority populations.

Please reference Appendix E for further details on elements to consider when preparing a Data Sharing Plan.

### Section I. Cited Publications (does not count towards 9-page Narrative limit)

List publications cited in the Application Narrative. There is no limit to the number of publications that can be cited. References must be listed on the Cited Publications Template and numbered and formatted according to the example on the Cited Publications template and below. Previous work published by the Applicant/PI may be included but this list should not be a complete list of the PI's publications. The cited publications should include impactful publications that support the proposal. Cited Publications/References are not included in the Application Narrative 9-page limit.

### Application Supporting Documents

The following documentation is required to support the Application Narrative:

I. Statement of Commitment from Applicant/PI
II. Statement of Commitment from Co-PI (if applicable)
III. Current Komen GTDR Statement (Required for Renewal Applications)
IV. Biosketches for Key Personnel and Mentors
V. Letters of Support
    i. Letter of Institutional Support
    ii. Letter of Support from Patient Advocate Mentor
    iii. Letter of Support from Mentor(s) (if applicable)
    iv. Letter of Support from Collaborator(s) (optional)
    v. Letter of Resource Availability (if applicable)
VI. Payment Verification Form
VII. Clinical Trial Protocol (if applicable)
VIII. Budget Justification
IX. Contract/Consortium Budget (if applicable)
X. Signed Signature Page (submitted after validate)

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

### I. Statement of Commitment from Applicant/PI

A signed Statement of Commitment must be submitted by the Applicant/PI, on Institution Letterhead, describing how the PI 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 statement, describe the Applicant/PI's experience in breast cancer disparities training and research.

### II. Statement of Commitment from Co-PI (if named on the application)

A signed Statement of Commitment must be submitted by the Co-PI (if applicable), on Institution Letterhead, describing how the Co-PI 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 statement, describe the Co-PI's experience in breast cancer disparities training and research.

### III. Current Komen GTDR Statement (Required for Renewal Applications)

A Current Komen GTDR Statement must be submitted as part of a Renewal Application. This statement can be a maximum length of two (2) pages on Institution Letterhead. Statements exceeding two pages will cause the application to be administratively withdrawn. The Statement should contain the following information:

- Successes and challenges of the program.
- Which parts of the program were supported by the previous grant and will be continued and any new elements to be added.
- Progress of former Trainees, including completion of post baccalaureate degrees, acceptance into highly selective research training, or career positions with a focus in breast cancer disparities research.

### IV. Biosketches

Research biosketches are required for the Applicant/PI, Co-PI, Patient Advocate Mentors, Collaborators, Mentors (as applicable), and any other **Key Persons** named in the application.

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

Biosketches must be no more than 5 pages each and in NIH format. A template is available for download on the proposalCENTRAL website. Both the updated (as of 2017) NIH format and all previous NIH biosketch formats are acceptable. Patient Advocate Mentor biosketches may be submitted in any format.

Biosketches are not included in the Application Narrative 9-page limit.

### V. Letters of Support

**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 Mentor for the application, this letter must be submitted by the Dean – this letter may not be provided by the Applicant/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.
- Brief description of the research institution, including other resources that will be available to participants of this program, such as classes, equipment, and work space.

**Letter of Support from Patient Advocate Mentor(s)**

A signed Letter of Support must be submitted by the named 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 Mentor may have with research or research proposals.

**Letter of Support from Mentor(s) (Optional)**

If Mentors are listed as Non-Key Personnel on the application, they have the option of submitting a signed Statement of Commitment, on Institution Letterhead, describing how said Mentor will be able to commit the level of effort required to help implement the training program and their strong track record of mentoring successful research scientists.

**Letter(s) of Support from Collaborators (Optional)**
A signed Letter of Support may be submitted by a Collaborator, on Institution Letterhead, describing their role and commitment to the project.

**Letter of Resource Availability**
If the Applicant expects to use a resource NOT owned by the Applicant or Applicant institution or NOT publically available, a Letter of Resource Availability signed by the owner of the resource must be submitted. This letter should confirm the availability of and the Applicant's access to such resources as drugs, biospecimens, animal models, and/or data needed for successful completion of the proposed research.

### VI. Payment Verification Form
The Payment Verification Form must be completed listing the ACH or wire transfer instructions to be used, if Grant is awarded. Form must be signed by the institution's Financial Officer.

Please put the Application number in the Komen Grant or Application Number section.

### VII. Clinical Trial Protocol, if applicable
If the application proposes a clinical trial that is scheduled to begin **within the first year of the Grant term**, a submission of a full clinical trial protocol is required. Clinical trial protocols should be submitted in a format appropriate for IRB and/or FDA approval.

*Komen defines **clinical** research as hypothesis driven, patient-oriented research for which an **investigator directly interacts with human subjects/patients**. 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*.

If samples will be utilized from an existing trial, a Letter of Resource Availability must be submitted to confirm the availability of and the Applicant's access to the samples. Please see the Letter of Resource Availability section for more information.

### VIII. Budget Justification
The Budget Justification template must be completed according to the instructions on page 13.

### IX. Contract/Consortium Budget, if applicable
The Contract/Consortium Budget template must be complete, if applicable, according to the instructions on page 13.

### X. Signed Signature Page
After 'Validating' the Application (see page 19), print the designated signature page, sign and upload the signed page to complete the application.

**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.
- A "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.

**12. 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.

**13. PRINT SIGNATURE PAGES**
After successfully passing the validate check you are ready to print the signature pages.

Use the print button "Print Signature Pages and attached PDF Files." Click this button to print the signature pages. Use your browser print option to print the signature pages and obtain the appropriate institution signatures.

After applicable institutional signatures have been received, save the signature pages as a PDF file and upload into your application as described in the Uploading the attachments into your application section.

**Note:** Data that you entered in the other sections of the proposal are automatically included in the signature pages. If information is missing in the signature pages, it could be because you have not entered the information in one of the proposal sections OR the information is not required for this grant program. If the institution's Employer Identification Number (EIN) is not completed on the signature page, please request your institution to provide that information in their proposalCENTRAL profile.

**14. SUBMIT**
After successfully passing the validate check and uploading the signed signature pages, 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. You may need to refresh your browser screen after submitting the application to see the updated status.

## CONTACT INFORMATION FOR QUESTIONS

| Type of Inquiry | Contact: |
|---|---|
| All **technical** inquiries related to the online application system, proposalCENTRAL (including questions related to system access, navigation, document uploads, etc.) | **Altum/proposalCENTRAL**<br>Email: pcsupport@altum.com<br>Phone: 1-800-875-2562 (Toll-free U.S. and Canada), or +1-703-964-5840 (Direct Dial International) |
| All **program** inquiries, including questions related to eligibility, program requirements, Komen policies and procedures, etc. | **Komen Research Programs Help Desk**<br>Questions: http://www.komen.org/researchhelpdesk |

# Appendix A: Notification Process

Applicants who have been approved by the Komen Leadership for funding will receive a Notification of Intent to Fund (NOITF) via email on or around April 15, 2019. Such intent to fund is contingent upon the Applicant successfully passing through the legal vetting process wherein Komen ensures that the Applicant does not appear on lists of known supporters of terrorist activities and providing all required documents which are approved by Komen.

Applicants typically are given 14 days after receipt of the NOITF to indicate that they: accept, contingent accept (they will accept the grant if they do not receive other funding that has an overlap in specific aims and for which they are awaiting notification, or decline the funding), though Komen reserves the right to modify this deadline as necessary and reserves the right to rescind the NOITF for any Applicants who do not reply to the Notification in a timely manner or who fails to pass the vetting or review of required documents process.

### Submission of Required Documents

Komen requires submission of certain financial information, Applicant information, and regulatory documents (collectively referred to as "Required Documents") prior to execution of a Grant Agreement. Examples include, but are not limited to:

- Institutional Review Board (IRB) and/or Institution Animal Care and Use Committee (IACUC) Regulatory documents indicating approval
- Updated biographical narrative and picture for each PI and Lead Mentor (if applicable).
- Updated biosketch for each PI and Lead Mentor (if applicable). Please provide an updated version from the one submitted during the application stage.
- Grant Contact Form
- IRS W-9 or W8-BEN Form. Note: Institutions that has never received a grant from Komen before will need to provide proof of Institution's tax exempt status (or international equivalent) as a non-profit institution.
- Payment Verification Form.

Required Documents will be requested by Komen through proposalCENTRAL (pC) and must be approved by Komen prior to the execution of the Grant Agreement.

### Evaluation for Duplicative Funding

Grantees may not receive funding from any other source that would result in an overlap in funding for the same research and/or training activities being conducted with funding from Komen. Applications for research funding require Applicants to list all other research support including project title, specific aims, funding amount, duration, and source. Potential overlap in support is reviewed prior to awarding a Grant and is monitored annually throughout the term of each Grant. It is the PI's responsibility to report all sources of funding to Komen.

### Deviations from Submitted Applications

Komen does not allow funded applications to alter the Specific Aims, approach, personnel or other aspects of the research project that would lead to a significant deviation from the proposal that has been peer reviewed and approved for funding by Komen Leadership.

### Applicant/PI Good Standing

Grantees' past and current Komen-funded Grants must be up to date and in compliance with all Komen requirements prior to the execution of a Grant Agreement.

# Appendix B: Guidelines for Advocate Involvement in Komen Funded Research

Komen is strongly committed to including breast cancer research advocates in the design and implementation of Komen-funded research projects. Advocates provide essential patient perspectives and are real life experts on living with breast cancer 24/7.

This guide, developed by Susan G. Komen® Advocates in Science (AIS), suggests ways to effectively involve advocates in Komen- funded research. For more assistance in identifying trained advocates or questions about involving advocates in a research project, please contact advocatesinscience@komen.org.

### Who can serve as a research advocate?

- Advocates who have been diagnosed with breast cancer; have a known genetic mutation; or have a strong personal connection or experience with breast cancer (i.e., family, friend, caregiver).
- Advocates must represent a collective breast cancer patient/survivor perspective (i.e., insights and experiences of other breast cancer survivors).
- Advocates should be actively involved in the broader breast cancer research advocacy community.
- Advocates should have a basic understanding of the science of breast cancer and the peer review research process.
- Advocates are not required to be an AIS member. Information about AIS and joining AIS is at http://sgk.mn/2lBg8vC

### Identifying a research advocate

- The AIS program has advocate members across the US and in other countries. For help in finding an advocate, contact our program staff at advocatesinscience@komen.org.
- Ask for recommendations from collaborators, who have worked with research advocates.

### How research advocates can be effectively involved in research

- Research advocates should be involved early (and often) in developing a research project.
- Researchers and advocates should develop a mutually beneficial relationship. For example: researchers educate advocates about their project; advocates educate researchers about patients' concerns and experiences. For a copy of the "Building advocate⇔researcher relationships to strengthen research" toolkit, contact advocatesinscience@komen.org.
- Advocates can review early drafts of applications to identify possible patient concerns. Do not wait until the last minute to work with an advocate. Be respectful of her/his time, commitment and expertise.
- Advocates can provide regular input about the project. As advocates learn more about a research project, they may identify additional ways to assist. Their collective patient perspectives help focus the research on what matters to patients.
- Researchers and advocates should communicate regularly to keep informed about the project's progress. Use email, phone calls, and team meetings – whatever works best for the researcher and the advocate.
- Advocates work closely with researchers to ensure terminology used is clear for all audiences. For a copy of "Writing a Lay Abstract," contact advocatesinscience@komen.org.
- Tax dollars, donors and investors fund research. Effectively sharing results with the general public benefits the breast cancer research field. Patients and funders want to know how your research may ultimately improve patients' care and survival.
- Advocates and researchers should work together to determine the advocate's role and responsibilities.
- For testimonials from Komen Scholars about how they have involved advocates, contact advocatesinscience@komen.org.

**What roles can a research advocate fill on a research project?**

Advocates have a wide range of skills, experience and knowledge to enhance a research team's work. Advocates may have specific suggestions on how they can contribute to a project. Some possibilities are described below. For a copy of the "Patient Advocate Involvement Plan – Suggestions for Researchers," contact advocatesinscience@komen.org.

### Possible Advocate Roles in the Application's Development

- Provide feedback on a project's impact on patients by identifying the research's translation potential (i.e., how meaningful or important the outcome(s) could be to patients).
- Work with researchers to develop and review the application's Innovation and Significance section. Advocates can help assure this section highlights the project's importance to breast cancer patients and their families.
- Work with the research team to develop and review the lay abstract and other portions of the application to assure terminology is understandable to a general, non-scientific audience; and conveys the project's potential overall impact on breast cancer research and patient care.
- Help define their role during the project's implementation, annual reporting, and articulating the impact of the research findings.

### Possible Roles of Advocates in Research Project Implementation

- Work with researchers to develop plain language summaries highlighting the project's potential impact on patients.
- Be a community ambassador speaking about the research and its potential significance to patients. Public speaking engagements are an excellent opportunity for advocates and researchers to co-present. Refer to Komen Scholar Testimonials for further guidance. Contact advocatesinscience@komen.org for these testimonials.
- Assist researchers in connecting with their local Komen Affiliate and the broader breast cancer community.
- Work with researchers to create educational materials, events, webinars and teleconferences for local, regional, and national groups and organizations to inform them about the research and its importance to breast cancer patients.
- Participate in research project team's update/planning meetings, seminars and other events essential to the project's success.

### Possible Roles of Advocates in a Clinical Project (involving clinical trials)

- Work with the project team to design and develop the clinical trial to identify potential barriers to accrual and/or retention.
- Help develop patient-focused education materials. For instance: co-author study brochures to give a short, easy-to- understand description of the clinical trial.
- Review the clinical trial's proposed design. Provide a breast cancer patient point-of-view regarding eligibility criteria, frequency of invasive testing, costs, logistical requirements, and patient feelings when deciding whether to participate.
- Help define how the patient experience will be monitored. For example, developing patient reported outcomes (PROs) or questionnaires; or identifying topics for personal interviews. As appropriate, provide assistance and support throughout the study accrual period, including ways to address recruitment or retention issues.
- Help develop and review the language used in Informed Consent forms, questionnaires, and other documents for patients. Advocates help maximize readability and sensitivity to patient concerns and needs.
- Review the Informed Consent process to assure patients have ample opportunities to discuss and truly understand the nature of the research, what they are expected to do, the risks/benefits, their costs, and what information they will receive on the clinical trial's progress, completion, and results.

## Possible Roles of Advocates in a Training Project for Junior Faculty, Postdoctoral Researchers, and Graduate Students

- Advocates can help make a research project more patient-focused and likely to positively impact the lives of breast cancer patients. Researchers can learn more about what is critical to patients.
- Provide a patient point-of-view in mentoring committees and project presentations. Advocates add a different, more poignant perspective to your project and its relevance to patients.
- Review publications and communications. Advocates help clarify why the research is critical and relevant to patients and the community.

### How often should the research team meet with the research advocate(s) listed in the application?

- Frequency of meetings should be driven by the project plan and the schedules of the people involved.
- The application should include mutually agreed upon details on how often the research team will meet with the advocate(s) and the type(s) of meetings that will occur.

### Should research advocates be compensated?

Compensation will vary depending on the extent and nature of the advocate's involvement.

- Reasonable compensation is allowed when advocates perform services that would otherwise be a contracted expense. Compensation may be a salary, per-hour compensation, or honoraria.
- Offer to cover out-of-pocket expenses incurred to attend meetings and conferences identified in the project application (e.g., travel expenses, conference fees, mileage, parking, etc.). All meetings and conferences must be directly related to the proposed training or research plan.
- Researchers and advocates should agree on compensation and expenses to be reimbursed. These should be identified and supported in the budget justification section of the application, especially project and/or consulting fees.

### Advocates must provide a Letter of Support and Biosketch

- A biosketch (no more than 5 pages in an NIH or other acceptable format) should be submitted for advocates listed as key members of the research team. Examples are provided on the Komen website at http://sgk.mn/2lBg8vC.
- All advocates, listed on your project, must submit a Letter of Support. Their letter should identify their level of commitment to and role(s) in the project. An example is provided on the Komen website at http://sgk.mn/2lBg8vC.

# Appendix C: Patient Advocate Involvement Plan

## Overview

Komen has a strong commitment to including breast cancer research advocates to provide the patient perspective in the design and implementation of research projects funded through the Komen Research Grant Program. A Patient Advocate Involvement Plan section must be completed in the Application Narrative. For assistance in identifying trained advocates or to discuss including advocates in the proposed research project, contact advocatesinscience@komen.org.

Below are some ideas and suggestions to consider as you develop your Patient Advocate Involvement plan. It is not necessary to include every item below, just the items that are relevant to your project. Refer to the "Guidelines for Advocate Involvement in Komen Funded Research" document for additional information.

## Research Involvement

- Describe how an advocate provided input while you were writing your application. For example, mention if they reviewed and edited sections of the application. Discuss whether it was valuable and how it helped you strengthen the application especially with regard to the potential impact your research will have on patients.
- Describe the advocate's role as a member of your Mentor Committee (if applicable), and whether the advocate will be invited to attend all Mentor Committee meetings.
- Describe if the advocate will be invited to attend any meetings/seminars where research described in your proposal will be presented. Discuss how often these will occur.
- If your research project includes a clinical trial, describe how the advocate will assist you in developing the trial design. Discuss how the advocate may assist you in identifying patient-focused benefits and/or risks for participants, and potential challenges or barriers to accrual.
- Describe how you will update the advocate on progress of your research. It is suggested that updates occur at least annually (or more often) to seek input about how the work that has been completed so far is relevant to patients. Also, you can ask the advocate for feedback about what is planned for the next year.

## Community Involvement

- If the advocate is involved with the local Susan G. Komen Affiliate, they could assist you in making a connection with the Affiliate and offer opportunities to participate in community events, like presenting your research as a poster or talk to convey the significance of your work for the patient community.
- Describe how the advocate could assist you in developing and presenting your research in plain language.

## Experience of Patient Advocate Mentor

- Describe the strengths the advocate will bring to your research. You can find information about their previous experiences in their biosketch.
- If you have prior experience working with the advocate, describe your experience and what was gained during collaboration.

## Personal Impact on your Career Development

- Add a personal statement on why involving a patient advocate in your research and training will impact your individual understanding of breast cancer.
- Describe how working with a patient advocate may impact your future work.
- Describe how you will continue involving patient advocates even after Komen funding has ended. Describe how your experience with an advocate may influence your future career in breast cancer research.
- In what way will having an advocate mentor influence your career decisions about continuing to conduct breast cancer research.

# Appendix D: Patient Advocate Letter of Support

## Overview

As a part of the researcher's application, your letter of support will demonstrate your enthusiasm and support for the proposed research project. Your letter can help strengthen the application by providing the advocate perspective on why the research is important to patients. It is an important piece of the application package that researcher and advocate peer review panelists find very helpful.

Below are some ideas and suggestions to consider as you develop your letter of support. Be sure that the content of your letter is tailored to the project. It is not necessary to include every item below, just the items that are relevant to the project you are supporting. Some additional idea generators are contained in the "Guidelines for Advocate Involvement in Komen Funded Research" document.

## Format

- Use personal letterhead if you have it. If not, include your name, address, phone # and email address.
- Maximum of two pages, include page number if more than one page
- Date the letter
- Address the letter to Susan G. Komen, Dallas, TX
- Salutation: Dear Komen Reviewers
- Sign the letter and either fax it or submit a scanned copy to the researcher; your signature is needed in the submission

## Introductory Paragraph

- Include the name of the researcher and the title of the application
- Indicate your commitment to serving as an advocate on the project

## Body of Letter (2-4 paragraphs)

- Research
    - Give a short one- or two-sentence summary of the research
    - Describe why you believe the research is important to patients
- Your Advocacy Experience
    - Survivorship
    - Advocate involvement (organization, your title if you have one, areas of focus)
    - Involvement with the local Susan G. Komen Affiliate, including any community events
    - Reasons why you are interested in supporting breast cancer research
    - Experience that you have in collaborating with researchers
    - Experience that you have in serving as an advocate or consumer reviewer in the peer review process (Komen, DoD, other)
- The Researcher
    - Describe how you have worked with the researcher to-date on this project
    - If you have worked with the researcher before, briefly describe your experience
    - Comment on the strengths of the applicant that you have observed, and indicate confidence in their ability to conduct the research

- Your Role if Project is Funded
    - Discuss how you will continue to provide input on patient perspective throughout the project, and in what way(s)
    - Describe the nature of your role and the frequency of your meetings as a member of the researcher's Mentor Committee.
    - Describe if you will attend and/or co-present with the researcher at any meetings/seminars where research results will be shared. Include comments regarding where the presentations or meetings would occur, and how often they might happen.
    - Discuss how you will keep current on progress of the research, including nature and frequency of meetings.
    - Discuss how you will assist the researcher in connecting with Komen and the breast cancer community.

## Closing Paragraph

- Discuss your perception of the impact the research will have on patients, short- and long-term
- Describe why you believe that the research should be conducted and why is should be funded
- Restate your commitment to support and collaborate with the researcher on the project
- Thank Komen for their consideration of the application

# Appendix E: Data Sharing Plan

## KEY ELEMENTS TO CONSIDER IN PREPARING A DATA SHARING PLAN UNDER NIH EXTRAMURAL SUPPORT

Research results developed with NIH funding should be broadly available to the research community for furthering research. This resource document is intended to assist applicants by outlining certain key elements that should be addressed in any data sharing plan.

While the precise content of a data sharing plan may vary depending on the data being generated and collected, addressing the basic questions of What, Who, Where, When, and How can assist researchers and research administrators in formulating a meaningful data sharing plan that communicates essential information about:

- What data will be shared?
- Who will have access to the data?
- Where will the data to be shared be located?
- When will the data be shared?
- How will researchers locate and access the data?

### What data will be shared?

To optimize the benefits of data sharing, ***final research data along with metadata and descriptors should be shared to make sharing meaningful and usable by other researchers.*** In describing what data will be shared, a data sharing plan should indicate:

- What types of data are to be collected in the study and shared (e.g., genetic, physiological, clinical, medical history, etc.)?
- Will the study include unique data that cannot be readily duplicated (e.g., large surveys that are too expensive to replicate; studies of unique populations, such as centenarians; studies conducted at unique times, such as a natural disaster; studies of rare phenomena, such as rare metabolic diseases; etc.)?
- Will individual-level data or raw data also be shared, and if so, will the whole data set be shared? Will aggregate data (e.g., summary statistics or tables) also be shared? Will the analytical methods used (tools and parameters) be defined?
- What data quality control measures will be implemented?
- What data documentation will be shared (e.g., metadata, descriptors, schema) so that others can understand and use the dataset and to prevent misuse, misinterpretation, or confusion?
- What commonly accepted data standards or standardized vocabularies will be used to enable others to interpret the data and improve interoperability with other data system?
- What format will be used to encode the data? Will this format be consistent with extant, commonly used standards?
- In addition to final research data, what other data will be available?

### Who will have access to the data?

To maximize the benefits of data sharing, ***data should be shared as broadly as possible to the extent consistent with applicable laws, regulations, rules, and policies.*** In describing who will have access to data, a sharing plan should indicate:

- Will the general public have access to some or all of the data?
- Will access to certain data or certain components of the data be restricted to qualified researchers, e.g., to address specific rules, laws, regulations or policies (e.g., IRBs, human subjects, informed consent, etc.)?
- If data access is restricted, what are the justifications/criteria for restricting access (e.g., relevant laws (local, State, Federal, etc.), regulations, rules, institutional policies, IRB approvals, and consent documents)?
- What will researchers who seek to obtain data need to comply with any data access restrictions?

- Are there any limitations on release of data that may be considered "sensitive"?
- What data sharing agreements will be necessary to appropriately restrict the transfer of protected, sensitive, or confidential data to others and to require that data be used only for research purposes?
- Who will be operationally responsible for ensuring that no personally identifiable information is made available (e.g., principal investigator, independent curator)?

### Where will the data to be shared by located?

To minimize additional administrative workloads for sharing of data, ***data repositories with common standards and an established infrastructure dedicated to the appropriate distribution of data would generally be ideal for data sharing.*** In determining where data to be shared will be located, a data sharing plan should indicate:

- Will an existing database, data repository, data enclave, or archive be used to store and disseminate the data (e.g., dbGaP, National Database for Autism Research (NDAR)), and if so, how the policies and procedures in place for others to access the data are consistent with applicable NIH policies?
- Will a new repository need to be developed, and if so, who/what will maintain the repository?
- Will the data be distributed directly by an investigator to those who request it (e.g., through an electronic file)?

### When will the data be shared?

To optimize the timely and broadest usage of data, ***data should be made available as soon as possible and for as long as possible***. In determining the timeframes for data sharing, a data sharing plan should indicate:

- The schedule for release of data:
    - What data, if any, will be shared prior to publication?
    - What data will be shared upon acceptance for publication?
    - If using a repository, when will data be submitted to the repository?
- Will data from ongoing longitudinal studies be releases in increments as data become available?
- Will the timing of data sharing be specifically linked to other relevant policies concerning the timing of release of data (e.g., NIH GWAS policy, ClinicalTrials.gov, specific requirements in funding opportunity announcement (FOA))?
- How will data maintenance and access be ensured after the award ends?
    - Will there be support for continued sharing of data (e.g., through grant applications, administrative supplements, or other sources) or planned migration of data to another database, data repository, etc.?

### How will researchers locate and access the data?

To optimize usage of the data, ***researchers need to be able to easily identify locations of relevant data and to be able to easily access the data***. In describing how researchers will learn about, locate, and access the data, a data sharing plan should indicate:

- What steps will be taken to help researchers know what the data sets exist?
    - Will registries, repositories, indexes, word-of-mouth, publications, and/or other approaches be used to publicize the availability and accessibility of the data?
    - Will these be linked and cross-referenced so other researchers can readily find them?
- How will the data be accessed (web service, ftp, etc.)?

For additional questions or if you require further information on sharing of data and/or other research resources under NIH funding agreements, please contact the NIH Office of Extramural Research (OER) via email at Sharing@nih.gov or you may also refer to the NIH websites at https://grants.nih.gov/policy/sharing.htm and https://grants.nih.gov/policy/intell-property.htm for NIH sharing policies and related guidance.