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

CAREER CATALYST RESEARCH GRANTS

Redefining Metastatic Breast Cancer through Liquid Biopsy

2019-2020 LETTER OF INTENT ANNOUNCEMENT AND INSTRUCTIONS

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

TABLE OF CONTENTS

KEY DATES

Application System Opens:	June 7, 2019
Letter of Intent Due:	July 10, 2019, by 1 p.m., Eastern Standard Time
Letter of Intent Decision:	July 29, 2019
Application Due:	September 25, 2019, by 1 p.m., Eastern Standard Time
Award Notification:	On or around April 15, 2020

At Susan G. Komen®, we are committed to saving lives by meeting the most critical needs in our communities and investing in **breakthrough research to prevent and cure breast cancers**. Our Research Program is an essential driving force for achieving this mission.

We are fully committed to changing the unacceptable reality that more than 41,000 women and men will die from breast cancer (BC) each year. To convey the urgency of our mission, we've set a goal to cut that number in half by 2026. We know we can't do it alone, and that it will only be accomplished through innovative research into metastatic and aggressive breast cancers, combined with a multifaceted approach to address the reasons why certain people and communities are more likely to die from the disease.

CAREER CATALYST RESEARCH GRANTS

For over 10 years, Career Catalyst Research (CCR) Grants have fostered promising breast cancer researchers who are in the early stages of their faculty careers by providing support for up to three years of "protected time" for research career development under the guidance of a Mentor Committee. It is expected that following the successful completion of a CCR Grant, awardees will launch independent research careers, successfully compete for subsequent research project funding, and emerge as key leaders in the fight against breast cancer.

2019-2020 (FY20) Career Catalyst Research Topic: Redefining Metastatic Breast Cancer through Liquid Biopsy

The goal of the FY20 CCR Grant is to support outstanding research seeking to use liquid biopsy techniques to improve treatment, detection, and understanding of metastatic breast cancer. All proposals must have a primary focus on liquid biopsies in breast cancer as described below. Letters of Intent that lack a significant focus on liquid biopsies or metastatic breast cancer will be administratively withdrawn.

A liquid biopsy is defined as the collection and analysis of a sample of blood to detect cancer cells or pieces of DNA from cancer cells that are circulating in the blood. When compared to tissue biopsy, liquid biopsy offers a non-invasive approach to improve the care of patients, if we can unlock the potential of this technology for breast cancer. Liquid biopsies could inform clinical decision-making in a number of ways, including early detection of metastatic disease even before symptoms arise, real-time monitoring of metastatic breast cancer treatment response, and more personalized treatment plans for metastatic breast cancer patients.

To unlock the potential of liquid biopsies for patients, Komen requests Letters of Intent for research projects that address one of the following focus areas. Applicants are required to submit their Letter of Intent under ONE of the focus areas below. Each applicant may only submit one Letter of Intent, submission to multiple focus areas is not permitted.

1. Refining treatment of metastatic breast cancer

The goal of this focus area is to support studies that leverage liquid biopsy approaches to improve the treatment of metastatic breast cancer. Appropriate studies for this mechanism include, but are not limited to:

- Using liquid biopsies to track the response of metastatic breast cancer to therapy, including host immune response to immunotherapy approaches, genomic responses, or resistance mechanisms.
- Using liquid biopsies to identify and validate circulating biomarkers that will predict response to therapy and optimize therapeutic interventions for metastatic breast cancer.
- Combining liquid biopsy techniques and data science methods to gain new insights into the biology or treatment of metastatic breast cancer.

2. Early detection of metastatic breast cancer

The goal of this focus area is to support studies that will use liquid biopsies to develop new approaches to detect new or recurrent metastatic breast cancer as early as possible, before standard symptoms may be detectable. Appropriate studies for this mechanism include, but are not limited to:

- Development and testing of novel liquid biopsy technologies and methods for early detection of metastatic breast cancer.
- Identification and validation of liquid biopsy diagnostic or prognostic circulating biomarkers, including micro-metastases, for the earliest possible detection of metastatic breast cancer.
- Using liquid biopsy techniques and analyses to predict metastatic breast cancer recurrence, including identification of tumor dormancy or treatment-resistant cancer cells.

All proposals ***must*** employ samples or data derived from liquid biopsies, and clearly focus on reducing metastatic breast cancer mortality through improved treatment or early detection of breast cancer metastases.

Applications that fit the focus area as detailed above and include studies that address *metastatic breast cancer disparities*, or leverage *data science* to better understand and treat metastatic breast cancer are **highly encouraged**.

For these purposes, *metastatic breast cancer disparities* research is defined as research investigating the biologic, behavioral, social and systems contributors to late-stage (metastatic) breast cancer in population groups affected by breast cancer disparities. This may include the identification, validation and testing of biological and/or socioeconomic factors that contribute to breast cancer disparities in metastatic breast cancer. 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 metastatic breast cancer.

Data science includes artificial intelligence and other analytical methods applied to data aggregated from multiple sources (Electronic Health Records, other clinical data, administrative databases, large data repositories, genomics and other -omics data, etc.).

Letters of Intent addressing topics other than the focus area, as described above, will be administratively withdrawn from consideration without an opportunity for appeal. Applicants/PIs may only submit ONE LOI per funding cycle.

ELIGIBLE APPLICANTS/DESIGNATED RECIPIENTS

Applicants/PIs, Mentors, and Institutions must conform to the following eligibility criteria to apply for a CCR Grant. Eligibility must be confirmed in writing by the Institution at the time of the Letter of Intent submission (July 10, 2019). It is the responsibility of the Applicant/PI to ensure that the Institutional Letter of Support clearly outlines eligibility by the Application due date (September 25, 2019).

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

Applicant/PI

- Must have a doctoral degree, including M.D., Ph.D., Dr.P.H., D.O., or equivalent.
- Must currently hold a full-time faculty appointment or have a formal offer letter from the Institution that confirms position and start date by the Application due date **(September 25, 2019),** documented by the Applicant/PI Biosketch and Letter of Institutional Support.
- Must not have held any faculty appointment, including non-tenure and tenure track appointments combined, for more than a total of **8 years** by the Application due date **(September 25, 2019)**, documented by the Applicant/PI Biosketch and Letter of Institutional Support. All positions that are considered as "Faculty" positions by the Applicant/PI's institution (or prior institution) count towards the **8-year** limit. This may include positions such as Instructor, Research Fellow, or other non-tenure track faculty positions as appropriate. All faculty positions and terms must be verified by the Letter of Institutional Support.
- May only submit ONE LOI per funding cycle.

- Must not simultaneously hold any other Grant awarded by Susan G. Komen. Such Grants must end within 3 months of receiving a Notification of Intent to Fund or the funding will be withdrawn.
- Must not currently be or have been a Principal Investigator on an existing NIH R01 grant or their equivalent as of the date of Award Notification **(April 15, 2020)**.
- Must conduct the proposed research and training at the Lead Mentor's institution, which may be located anywhere in the world.
- Must have adequate space and facilities to conduct the proposed research and protected time for research, as verified by the Letter of Institutional Support by the Application due date **(September 25, 2019)**.
- 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. by the Application due date **(September 25, 2019).**
- Is not required to be a U.S. citizen or resident.
- Applicants/PIs located outside of the U.S. or proposing research to be conducted outside of the U.S. will also be considered eligible if they clearly state in the Letter of Intent how the proposed research will lead to a reduction in breast cancer deaths.

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 agree to adhere to Komen's Policies and Procedures for Research and Training Grants, which may be downloaded along with the Letter of Intent Templates in proposalCENTRAL.

FUNDING INFORMATION AND GRANT TERM

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

Budgets are not required to be submitted with the Letter of Intent. However, Applicants/PIs should take note of the following budget guidelines:

- Personnel on the Research Project are limited to a base salary at or below $250,000 per year.
- Level of effort committed to the proposed Research Project does not determine salary level; salary levels are determined by the Applicant/PI's institutional policies.
- Reasonable compensation of advocates is allowed when advocates perform services that would otherwise be a contracted expense.
- Research Technicians may be included as salaried personnel on the Research Project.
- Reasonable travel costs ARE allowed for purposes specifically related to the proposed Research Project for the PI and Key Personnel conducting the research (e.g. Postdoctoral Fellow or Graduate Student).
- Publication costs and meeting-related poster printing costs ARE allowed for purposes specifically related to the proposed Research Project.
- Reasonable coursework and training expenses (i.e., laboratory management courses, trans-disciplinary training, etc.) related to the career and professional development of the Applicant/PI ARE allowed; tuition towards a degree-granting program is NOT allowed.
- Equipment costs are limited to no more than 25% of total direct costs.
- Professional membership dues or subscription dues are NOT allowed.
- Graduate Students and Postdoctoral Fellow tuition costs are NOT allowed; stipends and salaries to Graduate Students and Postdoctoral Fellows are permitted.
- Visa costs are NOT allowed.
- Indirect costs cannot exceed 25% of total direct costs (including any indirect costs paid through subcontracts or consortia). 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, telephone/communication expenses, technology support, computer usage fees, administrative support, etc.

LETTER OF INTENT REQUIREMENTS

The Letter of Intent Research Plan and Impact Statement (described below) may not exceed **one page** in total length. Please refer to page 11 for detailed document requirements.

Required: Research Plan

The Applicant/PI must propose a research plan that describes the research question and how the Research Project will lead to a reduction in breast cancer deaths by 2026. A clear and concise statement of the research question, hypothesis(es), and specific aims of the Research Project must be included. The Research Plan must be included within the one page limit.

Required: Impact Statement

The Applicant/PI must specifically state how their proposal and specific aims will directly address the goals of the CCR research topic, Redefining Metastatic Breast Cancer using Liquid Biopsy, as stated above. The statement must also describe how this Research Project will lead to a reduction in breast cancer deaths by 2026. The Impact Statement must be included within the one page limit.

Applications that address metastatic breast cancer disparities, or leverage data science to better understand and treat metastatic breast cancer are highly encouraged. If applicable, the applicant must concisely justify within the Impact Statement how their liquid biopsy research project addresses metastatic breast cancer disparities and/or includes data science. For these purposes, *metastatic breast cancer disparities* research is defined as research investigating the biologic, behavioral, social and systems contributors to late-stage (metastatic) breast cancer in population groups affected by breast cancer disparities. This may include the identification, validation and testing of biological and/or socioeconomic factors that contribute to breast cancer disparities in metastatic breast cancer. 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 metastatic breast cancer. *Data science* includes artificial intelligence and other analytical methods applied to data aggregated from multiple sources (Electronic Health Records, other clinical data, administrative databases, large data repositories, genomics and other -omics data, etc.).

Required: Lead Mentor

The Lead Mentor must be at the same institution as the Applicant/PI and serve as the onsite representative for the entire Mentor Committee. Only one mentor may serve as the Lead Mentor for an Applicant/PI.

- Must hold a full-time faculty appointment with an accredited institution (at the same institution as the Applicant/PI).
- Must currently conduct breast cancer research, or alternately, at least one member of the Mentor Committee must have breast cancer research experience.
- Is not required to be a U.S. Citizen or resident.

A Letter of Support from the Lead Mentor is not required at LOI submission, but must be submitted with the Application.

Required: Mentor Committee

The Applicant/PI must propose a Mentor Committee, typically consisting of 3-5 mentors, including the Lead Mentor and a Patient Advocate Mentor. The primary purpose of the Mentor Committee is to provide the research, scientific, clinical, management, and leadership guidance necessary to foster the Applicant/PI's career advancement and assist in the successful development of the proposed Research Project. All members of the Mentor Committee are not required to currently conduct breast cancer research but should provide expertise, leadership or support to the Applicant/PI and proposed Research Project. It is strongly encouraged that the Lead Mentor be considered an expert in breast cancer research, but in the absence of this expertise at least one member of the Mentor Committee must fulfill this requirement. Members of the Mentor Committee are not required to include % effort.

Required at Application: Patient Advocate Mentor

Susan G. Komen® has a strong commitment to including breast cancer Patient Advocate Mentors to provide the patient perspective in the design and implementation of both Research Projects and Career Development Plans. If an Applicant/PI is invited to submit an Application, a Patient Advocate Mentor must be named as Key Personnel and a member of the Mentor Committee for submission of the Application **(September 25, 2019)**. While Applicants/PIs are strongly encouraged to name a Patient Advocate Mentor in the Letter of Intent **(due July 10, 2019)**, it is not a requirement for Letter of Intent submission.

Utilizing Patient Advocate Mentors during the development of your CCR LOI and Application will help to enable you, as a Komen Applicant/PI, to become more aware of what is impactful research from the patient perspective, including their emphasis on the urgency to find cures. The patient will be able to offer you feedback on the relevance of your proposed research, provide the patient perspective and insight as you describe the potential impact your proposed work could have on the patient community.

There are many ways to engage advocates in your Research Project, from the development of an LOI or Application, to the dissemination of results. Patient Advocate Mentors can:

- be involved early in the development of the Research Project to provide input about its relevance and impact to patients.
- review the Letter of Intent 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 disseminating the importance of the results of the Research Project using lay language that will be better understood by the general public.

Who can serve as a Patient Advocate Mentor? 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).
- 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.

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 LOI or Application or to discuss including a Patient Advocate Mentor in the proposed Research Project, contact advocatesinscience@komen.org.

Required at Application: ORCID Identifier

The Principal Investigator will be required to include an ORCID (Open Researcher and Contributor ID) identifier upon Application submission **(September 25, 2019).** ORCID 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/.

KOMEN RESEARCH PROGRAM

Susan G. Komen has sustained a strong commitment to supporting research that will identify and deliver cures for breast cancer. Komen is the world's largest breast cancer organization outside of the federal government, funding more breast cancer research than any other nonprofit while providing real-time help to those facing the disease. Since its founding in 1982, Komen has funded more than $988 million in research and provided more than $2.2 billion in funding to screening, education, treatment, and psychosocial support programs. Komen has worked 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 better approaches for early detection and diagnosis, understanding metastasis and recurrence, and developing novel therapies for all stages of breast cancer, ***with the goal of supporting work that has significant potential to lead to new treatments and technologies that will reduce the number of breast cancer deaths in the U.S. by 50 percent by 2026.***

LETTER OF INTENT RESEARCH FOCUS

The Letter of Intent must adhere to the research focus area of Redefining Metastatic Breast Cancer through Liquid Biopsy, as defined in this announcement (pages 3 - 4). Letters of Intent that do not satisfy the requirements below will be administratively withdrawn without opportunity for appeal.

- The proposed research question and specific aims must clearly and directly address metastatic breast cancer by advancing liquid biopsy techniques and analysis.
- The proposal narrative must clearly denote how the Research Project will lead to a reduction in breast cancer deaths by 2026.

LETTER OF INTENT REVIEW PROCESS

Susan G. Komen® utilizes a multi-step approach to Grant application and review that first requires submission of a Letter of Intent (LOI), and upon invitation only, submission of an Application.

Each Letter of Intent is administratively reviewed for eligibility, compliance with submission guidelines, and responsiveness to the research focus specified in this announcement. Applicants/PIs whose Letters of Intent are appropriately responsive to the goals of this announcement will be invited to submit Applications. Each Letter of Intent that does not meet eligibility, submission, or responsiveness requirements will be administratively withdrawn with no opportunity for appeal.

Applicants/PIs will be notified of Letter of Intent review decisions via email. Applicants/PIs invited to submit an Application will then be granted access to the Application site in proposalCENTRAL. Any Applicant/PI who will not meet ALL eligibility criteria including faculty term limits, as listed on page 4, by the Application due date, September 25, 2019, will be administratively withdrawn at the Letter of Intent stage and WILL NOT undergo scientific review.

LETTER OF INTENT SUBMISSION INSTRUCTIONS

Administrative Requirements

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

Failure to adhere to these instructions will result in any Letter of Intent being administratively withdrawn from consideration, without appeal.

Letter of Intent Submission Deadline

Letters of Intent must be completed by 1pm, EST (U.S.) on **Wednesday, July 10, 2019**, using the proposalCENTRAL website at https://proposalcentral.altum.com.

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

Extensions to the Letter of Intent 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

To start a LOI, go to https://proposalcentral.altum.com/default.asp. If you are a new user of proposalCENTRAL, follow the "CREATE ONE NOW!" link under "Need an account?" and complete the registration process.

If you are already registered with proposalCENTRAL, login at https://proposalcentral.altum.com/default.asp with your username and password. If you have forgotten your password, click on the "Forgot your password?" link. Provide your email address in the space provided; your username and password will be sent to you by email.

Once you are logged in, please click the "Professional Profile" tab at the top (green tab fourth from left). Please complete steps 1-9 or update with current information. Your name, degrees, title, and institution for the LOI will be pulled from this page in proposalCENTRAL.

To start a Letter of Intent, select the "Grant Opportunities" tab (gray tab second to the right). A list of applications will be displayed. Find "**Susan G. Komen Career Catalyst Research**" and click the "Apply Now" link (second to last column) to create your Letter of Intent.

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

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

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

Letter of Intent Sections

The following information is required to submit a complete Letter of Intent. Numbers correspond to the 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 title must be entered and saved before additional sections may be accessed.

   Research Focus Area

   Please select ONE appropriate focus area for the research proposed from the dropdown menu:

   - Refining treatment
   - Early detection

2. DOWNLOAD TEMPLATES & INSTRUCTIONS

The CCR Letter of Intent Announcement and Instructions document, the Policies and Procedures, and all templates can be downloaded from this page.

You must download and complete the Letter of Intent Template and Biosketch Template. 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 Letter of Intent Template and Biosketch Template, 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 Letter of Intent. See pages 11-12 for instructions on how to complete and upload the templates.

3. ENABLE OTHER USERS TO ACCESS THIS PROPOSAL.

This is optional for the Letter of Intent. If a person is added in this section, they must be a registered user in proposalCENTRAL before you can grant access to your LOI.

4. APPLICANT/PRINCIPAL INVESTIGATOR (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.

5. INSTITUTION & CONTACTS

Enter information regarding the lead institution, signing official, and financial officer directly into the proposalCENTRAL system. If institutional information is incorrect, contact the person listed on the page or proposalCENTRAL.

6. KEY PERSONNEL - **Do not list the Applicant/PI as Key Personnel in this section.**

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

Komen defines a Key Person as an individual who contributes to the scientific development or execution of a Research 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 Research 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, the Lead Mentor, and members of the Mentor Committee may list 0% effort. Other Key Personnel must list greater than 0% effort. Salary support is not required for Key Personnel.

Add new contacts by entering the email 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 Research Project. When entering contact information, do not use personal addresses for the Key Person.

NON-KEY PERSONNEL

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

Add new contacts by entering the 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 Research Project. When entering contact information, do not use personal addresses for the Non-Key Person.

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

7. ATTACH NARRATIVE AND SUPPORTING DOCUMENTS

Please read this entire section for complete instructions on naming and uploading attachments.

Letter of Intent Template

Download the template from proposalCENTRAL and fill in the following sections. The Letter of Intent (Sections A-C) is limited to **one page in total**. Please refer to the Letter of Intent Narrative Template for document and image formatting requirements.

Applicants/PIs may not exceed the one page limit for the Letter of Intent. References and biosketches are not included in this page number limit.

Section A: Title (81 Character limit):

Applicants/PIs should enter the title of their proposal exactly as it is entered in proposalCENTRAL.

Section B: Research Question and Specific Aims

Address the following items:

- Describe the proposed research question and hypothesis.
- State the specific aims of the study to address the stated hypothesis.
- Describe how the proposed study aligns with research focus described in this LOI Announcement.

Section C: Impact Statement

Applicants/PIs must specifically and clearly state how this proposal will address the goals outlined in this LOI Announcement, leading to a reduction in breast cancer deaths by 2026. **Applicants/PIs who do not clearly address these goals will not be invited to submit an Application.**

If applicable, applicants addressing metastatic breast cancer disparities or leveraging data science (please refer to page 4 for definitions) in their proposals must concisely describe the disparity addressed, or how data science is being leveraged, within the Impact Statement.

Applicant/PI Biosketch

The Applicant/PI must submit a biosketch to confirm all current and past academic positions. Biosketches must be no more than 5 pages each and in NIH format. A template is available for download on the proposalCENTRAL website.

Biosketches should not be included for the Lead Mentor, Patient Advocate Mentor, Members of the Mentor Committee, other Key Personnel, Non-Key Personnel, Collaborators, Research Technicians, etc.

The Applicant/PI biosketch is not included in the Letter of Intent one page limit.

Letter of Institutional Support

A signed Letter of Institutional Support must be submitted and signed by the department chair, on Institution Letterhead. If the department chair is also the Lead Mentor for the application, this letter must be submitted by the Dean. This letter may not be provided by the Lead Mentor. The Letter should describe the institution's support of the Applicant/PI's proposal, and must include all of the following information:

- Confirmation of the date and specific title of Applicant/PI's current faculty appointment, or confirmation of a pending faculty appointment.
- The total number of years the Applicant/PI has held a non-tenure or tenure track faculty appointment at the current institution and all previous institutions, if applicable. If the Applicant/PI has held a non-tenure or tenure track faculty position at institutions and/or departments other than their current appointment, the current institution should confirm these previous appointments as faculty and their duration in the Letter.

Uploading the attachments into your Letter of Intent

Once you have converted your documents (Letter of Intent and Applicant/PI Biosketch) to PDF files, the next step is to upload the files to your online Letter of Intent.

- Make certain that the converted PDF files are closed on your computer.
- Select Section 7) Attach Narrative and Supporting Documents. Select the "Attach Files" button.
- Enter the information below for each of the required documents:
    - Letter of Intent
        - Describe Attachment Field - Enter "*your last name*_LOI", e.g. Smith_LOI.
        - Select Appropriate Attachment Type – Letter of Intent.
    - Applicant/PI Biosketch
        - Describe Attachment Field – Enter "*your last name*_Biosketch", e.g. Smith_Biosketch.
        - Select Appropriate Attachment Type – Applicant/PI Biosketch.
    - Letter of Institutional Support
        - Describe Attachment Field – Enter "*your last name*_Letter of Institutional Support", e.g. Smith_Letter of Institutional Support.
        - Select Appropriate Attachment Type – Letter of Institutional Support
- Only PDF attachments are permitted for this Letter of Intent submission.
- Click on the "click here to 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.
- Click on the "Upload and Continue" 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. You can view your file by clicking the download button to the left of the File Name Open and review your uploaded file. Click the "Back" Button to take you to the Section 7 Main Screen. To Delete the file, click the Delete button to the far right, then click yes.

8. **VALIDATE.** Validate the Letter of Intent on proposalCENTRAL. This is an essential step. A Letter of Intent 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 email will be sent to you confirming your submission.

Once your Letter of Intent is submitted you may view it by accessing the "Submitted" selection in the dropdown menu next to Proposal Status under the Proposals tab. The status column will show "Submitted" and the date submitted. You may need to refresh your browser screen after submitting the Letter of Intent to see the updated status.

APPLICATION SUBMISSION

Only Applicants/PIs with a Letter of Intent deemed appropriately aligned with Komen's annual research focus areas will be invited to submit an Application. Instructions on how to submit an Application will be provided on the Letter of Intent decision date listed above under 'KEY DATES'. **Applications are due on September 25, 2019**.

QUESTIONS?

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

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