



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

The Komen Tissue Bank Challenge: Using Normal Tissue to Fight Breast Cancer

2019-2020 LETTER OF INTENT INSTRUCTIONS

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

KEY DATES

Application System Opens:	August 27, 2019
Letter of Intent Due:	September 25, 2019, by 1 p.m., Eastern Standard Time
Letter of Intent Decision:	November 11, 2019
Application Due (by invitation):	December 16, 2019
Presentation Date (by invitation):	February 27-28, 2020
Award Notification:	On or around April 15, 2020

THE KOMEN TISSUE BANK CHALLENGE: USING NORMAL TISSUE TO FIGHT BREAST CANCER

Komen is excited to announce a new funding opportunity for researchers to use a unique resource: [The Susan G. Komen® Tissue Bank at the IU Simon Cancer Center](#) (Komen Tissue Bank, or KTB), a one-of-a-kind biorepository containing breast tissue and blood products from donors that show no evidence of breast cancer at the time of donation. Since 2007, over 8,000 women have donated their blood or tissue to help the research community. To leverage this valuable resource, we are seeking the best ideas in innovative research to move the field of breast cancer forward.

All proposals **must** use samples or data derived from the Komen Tissue Bank. Examples of research questions that would be appropriate for the KTB Challenge include, but are not limited to:

- Are there changes that take place in the normal breast, including the microenvironment, that increase the risk of developing metastatic breast cancer?
- How do established risk factors (e.g. obesity or alcohol consumption) impact normal breast biology and contribute to breast cancer development?
- How do gene mutations shared between family members (e.g. mothers and daughters) influence breast cancer development?
- How do environmental or socio-economic factors contribute to disparities in breast cancer risk?
- Are there unique characteristics in the breast tissue of women who never develop breast cancer?

Komen Tissue Bank Resources

It is a goal of the Komen Tissue Bank to acquire biomolecules and tissue specimens from the entire continuum of breast development from puberty to menopause. Resources available include:

- Fresh Frozen Tissue, Formalin-Fixed, Paraffin-Embedded (FFPE) Tissue, and Cryopreserved Tissue from over 5,300 women.
- Blood products including whole blood, plasma, serum, and DNA from lymphocytes from over 8,000 women.
- Richly annotated medical and demographic data for each donor, including breast cancer risk factors, family history, hormone use, and gynecologic and pregnancy information. The complete donor survey can be found here: <https://bit.ly/2P2hXRk>
- Annual medical follow up data (since 2014), including updates regarding pregnancy/breastfeeding, cancer and other diseases, and genetic testing.
- Unique cohorts of samples including BRCA mutation carriers, related family members, and over 300 serial donors.
- The Virtual Tissue Bank, featuring downloadable data (including genomic, proteomic, and histology data) generated by researchers using KTB samples.
- Cell lines representing normal counterparts of intrinsic subtypes of breast cancer.

Please note that the KTB is a normal tissue bank and **does not have any tumor samples** and the number of women who donated and report developing cancer later is very small (~60 donors).

Additional information regarding KTB resources can be found in the KTB Sample and Data Fact Sheet (Appendix A) and at <https://komentissuebank.iu.edu/>.

KOMEN TISSUE BANK CHALLENGE REVIEW PROCESS

Komen will use a multi-step review process to select the most innovative and promising proposals for the KTB Challenge, beginning with the submission of a Letter of Intent (LOI). Each Letter of Intent is reviewed for eligibility, compliance with submission guidelines, and responsiveness to this funding announcement. Each Letter of Intent that does not meet eligibility, submission, or responsiveness requirements will be withdrawn with no opportunity for appeal. All remaining LOIs will be reviewed by a committee of scientific experts, using the criteria noted below.

- Will the proposed research question and specific aims use KTB resources in an innovative way that will improve the understanding, treatment, or detection of breast cancer?
- Do the proposed aims and approaches comprehensively address the overarching research question and represent an impactful use of KTB resources?
- Does the applicant possess or have access to the necessary scientific expertise and resources to successfully complete the project and achieve the goals described?

Applicants will be notified of their LOI status via email. Select applicants will be invited to submit an application with additional details for the proposal, including a project budget, patient advocate involvement plan, and additional letters of support/collaboration. Each application will be reviewed by our committee of scientific experts, and the highest ranking applicants will be invited to present their proposals in a “Power-Pitch” during the KTB Competition scheduled for February 27, 2020. Presentation requirements will be provided at the time of invitation. **Attendance and presentation at the KTB Competition on February 27, 2020 is required for award eligibility. Applicants with approved LOIs will be asked to hold this date to ensure they are able to attend this meeting.**

ELIGIBLE APPLICANTS/DESIGNATED RECIPIENTS

Applicants/PIs and institutions must conform to the following eligibility criteria to apply for the KTB Challenge. Eligibility must be confirmed in writing by the institution at the time of the LOI submission (September 25, 2019).

Grants will be awarded to a single Principal Investigator (PI). ***Co-Principal Investigators (Co-PIs) are not allowed***, however collaborators or co-investigators are permitted.

Applicant/PI

- Must have a doctoral degree, including M.D., Ph.D., Dr.P.H., D.O., or equivalent.
- Must hold a full-time faculty appointment with an accredited institution.
- May only submit ONE KTB LOI per funding cycle.
- Must not hold any grants that overlap scientifically or budgetarily with the proposed KTB Challenge project.
- Must have adequate space and facilities to conduct the proposed research and protected time for research, as verified by the Letter of Institutional Support.
- Must ensure that all past and current Komen-funded Grants are up to date and in compliance with all Komen requirements; e.g., progress report submissions, IRB approvals, etc. by the Application due date (**December 16, 2019**).
- Is not required to be a U.S. citizen or resident.

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 total funding up to \$200,000, for up to 2 years. The \$200,000 budget may be divided over one or two years.

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.
- 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 LOI Research Plan and Impact Statement (described below) may not exceed **two pages** in total length. Please refer to page 8 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 leverage KTB resources to address the research question. A clear and concise statement of the research question, hypothesis(es), and specific aims of the Research Project must be included. The LOI may contain a brief description of the experimental methods, relevant preliminary data or background, or other detail as needed, within the two page limit.

Required: Impact Statement

The Applicant/PI must specifically state how their proposal and specific aims will directly address the goals of the KTB Challenge, and how the KTB resources will impact the study. The statement must also describe how this Research Project will improve the understanding, treatment, or detection of breast cancer. The Impact Statement must be included within the two page limit.

Required at Application: Letter of Resource Availability from the Komen Tissue Bank

All applicants invited to submit an application will be required to provide a letter from the Komen Tissue Bank confirming that they will have access to the KTB resources needed for this study. Following invitation, applicants should reach out to the Komen Tissue Bank to discuss their project and confirm resource availability. No letters of resource availability are required at the time of LOI submission.

Required at Application: Patient Advocate Involvement Plan

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.**

A Patient Advocate Involvement Plan is not required at LOI, but will be required at Application. Failure to include a Patient Advocate at Application will result in administrative withdrawal with no opportunity for appeal.

Utilizing Patient Advocates as a part of their project will enable Komen Applicants/PIs 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 proposal 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.

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 Advocates 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/2IBg8vC>

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 at Application: ORCID Identifier

The Principal Investigator will be required to include an ORCID (Open Researcher and Contributor ID) identifier upon Application submission (December 16, 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/>.

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, September 25, 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 "**Komen Impact Grants**" 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.

2. DOWNLOAD TEMPLATES & INSTRUCTIONS

The 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 8-9 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 major Collaborators and Patient Advocate (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(s) 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.

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-D) is limited to **two pages in total**. Please refer to the Letter of Intent Narrative Template for document and image formatting requirements.

Applicants/PIs may not exceed the two 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, including relevant background information or preliminary data.
- Describe the specific aims of the study to address the stated hypothesis.

Section C: Research Plan

Address the following items:

- Briefly describe the experimental approaches that will be used to complete the specific aims.
- Describe how the proposed study leverages KTB resources to address the research question.
- Describe the relevant resources or collaborations necessary to complete the research project.

Section D: Impact Statement

Applicants/PIs must specifically and clearly state how this proposal will leverage KTB resources to improve the understanding, treatment, or detection of breast cancer. **Applicants/PIs who do not clearly address these goals will not be invited to submit an Application.**

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 any Key Personnel or Non-Key Personnel.

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

Optional: Letters of Support from Collaborators

Applicants are encouraged to provide letters of support from collaborators with their LOI. A signed Letter of Support may be submitted by a Collaborator, on Institution Letterhead, describing their role and commitment to the project.

Uploading the attachments into your Letter of Intent

Once you have converted your documents (Letter of Intent, Applicant/PI Biosketch, and/or Letter of Support from Collaborators) 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.
 - Letters of Support from Collaborators (Optional)
 - Describe Attachment Field – Enter “*your last name_Letter of Support from Collaborator*”, e.g. Smith_Letter of Support from Collaborator.
 - Select Appropriate Attachment Type – Letter of Support from Collaborator
 - 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 meritorious and appropriately aligned with Komen’s research mission 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 December 16, 2019.**

QUESTIONS?

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

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

Komen Tissue Bank (KTB) Sample and Data Fact Sheet

The Komen Tissue Bank is the only biorepository in the world containing breast tissue and blood products from women who do not show evidence of breast cancer at the time of donation.



KTB RESEARCH RESOURCES

Biobank Resources:

- **5352** Tissue (& Blood) Donors*
- **8423** Blood Only Donors

*Each donor contributes several aliquots of each sample type (see diagram)

Virtual Tissue Bank Resources:

- **4706** H&E Images
- **1266** Donors with Mammograms
- **21** Experiments with Returned Data
- **50** Manuscripts Published Based on KTB Samples

<https://virtualtissuebank.iu.edu>

Please be aware the KTB is a normal tissue bank and **does not have any tumor samples**, and the number of women who donated and report developing cancer later is very small.

Cell Lines Available:

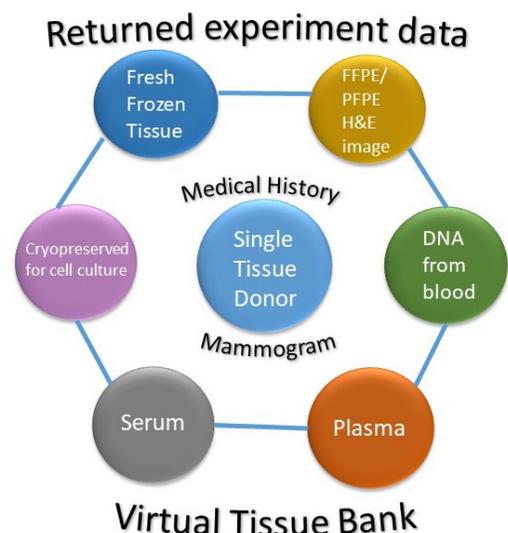
Several cell lines have been cultivated from KTB cryopreserved breast tissue samples by KTB Chief Scientific Officer Hari Nakshatri, PhD. These cell lines represent normal counterparts of intrinsic subtypes of breast cancer and are enriched for luminal progenitor cells (CD49f+/EpCAM+) and express luminal markers such as FOXA1 and GATA3. PROCR+/EpCAM- cell lines are also available.

If you are interested in learning more about these cell lines, please contact Dr. Nakshatri at hnakshat@iupui.edu.

The [Virtual Tissue Bank](#) houses data returned from research using KTB samples as well as an intuitive search tool to filter and sort by specific sample characteristics including clinical annotation, sample type and availability of data.

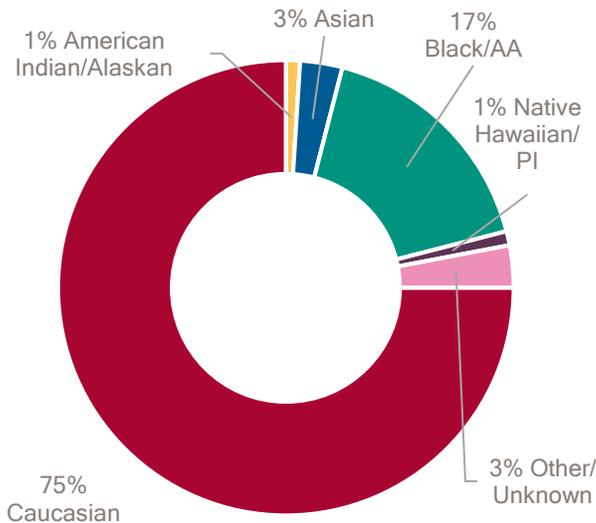
Most tissue donors will have an H&E image of their FFPE/PFPE blocks as well as race/ethnicity SNP data showing genetic ancestry stored in their in their record.

Search results can be easily downloaded for further manipulation. Additional software is required to view H&E images (Aperio) and mammograms (DICOM). Some clinical data is not available in the VTB but can be accessed by KTB staff.



If you have any questions not answered by this information, please feel free to contact KTB's COO, Jill Henry: jihenry@iupui.edu /317-278-2829.

Race of KTB Tissue Donors



8% of KTB tissue donors are of Hispanic ethnicity.

Limited and Unique Cohorts:

- Groups of related family members who have donated to the KTB
- Ashkenazi Jewish women (~175 tissue donors/~100 blood only)
- ~100 BRCA (and other) mutation carriers*
- ~35 Pregnant/breastfeeding/involuting*
- ~60 Donors who later developed breast cancer* – NOTE: Tumor samples are not available from these women
- ~300-400 Serial Donors (donated multiple times)

*Collaboration required for some cohorts.

KTB Medical Follow Up:

Collected annually from donors since 2014 with a response rate of over 50%. Questions asked include updates regarding pregnancy/breastfeeding, any diseases, any cancers (including breast cancer), testing for genetic risk for breast cancer, and any blood relatives diagnosed with breast or ovarian cancer. **From this data one can discern who has NOT gone on to develop breast cancer based on medical follow up responses.**

More information for researchers is available on the [KTB's website](https://komentissuebank.iu.edu) (https://komentissuebank.iu.edu) including: Sample acquisition FAQ, cost recovery schedule (includes aliquot size), SOPs for sample acquisition, link to the Virtual Tissue Bank and a list of published research using KTB samples.

Medical History Available:

Early Life Questions:

- address
- body shape/size
- puberty

Demographics:

- age
- height/weight
- marital status
- work status
- education level
- income
- race/ethnicity
- Ashkenazi Jewish
- smoking/drinking current & history

OB/GYN information:

- menstrual status
- luteal/follicular phase
- any surgeries
- pregnancy & breastfeeding

Medications including:

- birth control
- HRT
- infertility

Comorbidities

Cancer history including blood family relatives

Mammogram & biopsy history

Tested for genetic risk/mutations

Breast cancer treatment if applicable

Physical activity information

The entire questionnaire can be found here:

<https://bit.ly/2P2hXRk>



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>.