



## **Community Grants for Clinical Trials Enrollment Request for Applications**

The Houston Affiliate of Susan G. Komen for the Cure® fulfills its mission to save lives and end breast cancer forever by empowering people, ensuring quality care for all and energizing science to find the cures. By offering grants to enhance the capacity of National Cancer Institute and Department of Defense sponsored breast cancer clinical research conducted in the Komen Houston Affiliate service area, we can increase the number of women enrolled in breast cancer clinical research studies. The Komen Houston Affiliate service area includes Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty and Montgomery counties. Grants are available for two years.

### **Background**

Although there have been major advances in cancer prevention, treatment, and diagnosis, according to the National Cancer Institute (NCI), less than 5 percent of adults diagnosed with cancer each year will get treatment through enrollment in a clinical trial. In light of this, NCI and the Department of Defense (DOD) have underscored the need to increase enrollment in cancer clinical trials and the impact that enrollment has on quality of care and the rate at which new prevention, treatment, and diagnosis options are developed. In addition to the broad gap in overall enrollment, there is further concern that enrolled individuals should be representative of the broader population. Several sub-populations including women, low income individuals, the elderly, and racial and ethnic minorities are not adequately represented in cancer clinical trials.

A diverse range of factors cause patients to be unaware, fearful, reluctant, and/or unable to participate in cancer clinical trials. These factors range from lack of awareness of and distrust for clinical trials to practical concerns such as employment disruption and additional travel associated with participating in clinical trials. Additionally, racial and ethnic populations face cultural barriers, including belief systems that are very different from Western medicine and linguistic barriers. In some cases, health care providers have been identified as directly or indirectly discouraging participation in research studies and clinical trials. Some reasons for this include lack of awareness, misperceptions and concerns about the methods and costs of clinical research or fears over losing control of their patients' care. Through the Community Grants for Clinical Trials Enrollment program, the Komen Houston Affiliate seeks to fund projects that employ effective strategies to overcome these barriers to enrollment and retention in NCI and DOD sponsored breast cancer clinical research studies.

### **Funding Priorities**

The Komen Houston Affiliate seeks to fund projects that implement evidence-based strategies to overcome barriers to enrollment in breast cancer clinical trials for uninsured and medically underserved women. Collaborative projects between institutions and community-based

organizations are encouraged. Based on our community needs assessments, the Komen Houston Affiliate has identified the following funding priorities:

1. Identify and fund programs that provide education to increase awareness, allay fears, dispel misconceptions and address cultural barriers related to breast cancer clinical trials in order to increase enrollment of underserved and minority women in clinical trials.
2. Identify and fund programs that provide support services for underserved and minority women that facilitate participation in breast cancer clinical research studies.
3. Identify and fund education for health care providers that increases awareness of breast cancer clinical trials being conducted in their area and offers providers the tools to easily share information with the patients they serve.
- 4.

For more on the funding priorities, please visit [www.komen-houston.org](http://www.komen-houston.org) for the Community Profile Report.

Inquiries should be directed to Ginny Thompson Kirklin, Mission Director of the Komen Houston Affiliate- [gkirklin@komen-houston.org](mailto:gkirklin@komen-houston.org) or 713.783.9188, ext. 104.

### **Important Dates**

#### **APPLICATION DEADLINE – November 10, 2011**

The ENTIRE application must be sent electronically prior to the deadline to [gkirklin@komen-houston.org](mailto:gkirklin@komen-houston.org). Submit only documents in Microsoft Word or Excel. Each attachment should be clearly identified with the organization's name (or abbreviation) underscored then the application components (i.e. cover page, program description, budget, and supporting documentation).

Additionally, please submit original and twenty (20) copies of each application, and keep grant requests to the page limits stated in the APPLICATION INSTRUCTIONS section below. No spiral bound or stapled materials will be accepted – only paperclips or binder clips.

#### **Applications must be received by 5 p.m. on November 10, 2011 at:**

Houston Affiliate of Susan G. Komen for the Cure®  
5433 Westheimer, Suite 325  
Houston, Texas 77056

#### **MANDATORY GRANTWRITING WORKSHOPS – August 4, 19 or 23, 2011**

The workshops will be held **August 4 and 19 from 8:30 a.m. to 3:00 p.m.** at the United Way of Texas Gulf Coast Community Resource Center located at 50 Waugh Dr., Houston and **August 23 from 8:30 a.m. to 3:00 p.m.** at Memorial Hermann The Woodlands Hospital located at 9250 Pinecroft, The Woodlands, TX 77380. The workshops are free, and food will be provided.

Please RSVP to [grants@komen-houston.org](mailto:grants@komen-houston.org).

Potential grant applicants **must** attend one of the offered sessions.

#### **TECHNICAL ASSISTANCE SESSIONS – September 20 and 21 and November 3 and 4, 2011**

Applicants can schedule 30 minute meetings with the Mission Director to discuss questions and ideas related to their proposed application. Please send an email to [gkirklin@komen-houston.org](mailto:gkirklin@komen-houston.org) to schedule a time.

## **AWARD NOTIFICATION**

Announcement of grants awarded will be made by March 31, 2012. Project directors will be notified of the outcome of the review in writing.

## **GRANT PERIOD**

The grant period for Community Grants for Clinical Trials Enrollment is for two years (April 1, 2012 to March 31, 2014).

## **Funding Information**

- An organization applying for a Community Grant for Clinical Trials Enrollment may request up to \$200,000 for two years (maximum \$100,000 per year).
- Projects associated with National Cancer Institute (NCI) or Department of Defense (DOD) sponsored breast cancer clinical trials will be given priority for funding. This includes studies through the Clinical Trials Cooperative Group Program including, but not limited to, ACOSOG, ECOG, SWOG, NSABP, ACRIN, and RTOG.
- Exceptions for a project that is not DOD or NCI approved clinical research may be considered. If an organization is seeking an exception, the organization must submit a Letter of Intent to the Houston Affiliate of Susan G. Komen for the Cure Attn: Mission Director by September 30, 2011.
- One organization may apply for both types of grants, Community Grants and Community Grants for Clinical Trials Enrollment.

## **ALLOWABLE EXPENSES**

Funds may be used for the following types of program expenses:

- Educational materials
- Clinical services or patient care costs
- Meeting Costs
- Supplies
- Travel
- Other direct program expenses
- Equipment for educational purposes
- Development of educational materials not duplicated by material of Susan G. Komen for the Cure®
- Incentives offered to targeted clients/patients are limited to \$20 per patient, and it is strongly preferred that any incentive offered relate to transportation or nutrition assistance.
- Consultant fees

## **EQUIPMENT**

Equipment costs, if applicable, may not exceed \$5,000 and should be used exclusively on this project. If an organization is seeking more than \$5,000 in equipment funding, the organization must submit a Letter of Intent to the Komen Houston Affiliate Attn: Mission Director by September 30, 2011.

## **SALARIES**

Salaries, if requested, are for personnel related to this project only and not the general work of the organization. Employee fringe benefits are limited to a 25% maximum of an employee's

salary. Fringe benefits and associated costs must be defined within the application.

#### **RATES**

- Screening mammograms will be funded up to Medicare rates.
- Diagnostic and treatment services will be funded up to Medicare rates plus 10%.

#### **FUNDS MAY NOT BE USED FOR FOLLOWING PURPOSES**

- Medical or scientific research (costs for program evaluation are allowed)
- No professional fees (fees charged for a doctor's or nurse's hourly rate)
- Funding for reconstruction surgery
- Indirect costs (rent, electricity, phone, etc.)
- Construction or renovation of facilities
- Political campaigns or lobbying
- Endowments
- Debt Reduction

### **General Restrictions and Conditions for All Applicants**

*Failure to adhere to these guidelines will result in delayed processing or refusal of the application.*

#### **GRANTWRITING WORKSHOPS**

In order to apply for funding for a Community Grant and Community Grant for Clinical Trials Enrollment, an organization representative must attend one of the Grants Writing Workshops in August 2011 as described above.

#### **QUALIFICATIONS**

- Applicants must ensure that all past and current Komen-funded grants or awards are up-to-date and in compliance with Komen requirements.
- Applicants must be a not-for-profit organization (a charitable or educational tax-exempt organization), a government agency, or an Indian tribe located in or providing services in one or more of the following locations: the counties of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty and Montgomery.
- A clinical trial is defined as a type of research study that tests how well new medical approaches work in people. Eligible studies test new methods of screening, prevention, diagnosis, or treatment of breast cancer.
- Applications must be submitted in English.

#### **CONTRACTS**

- The grant contract will be the legal mechanism for funding and all recipients will be required to sign a contract in order to receive any funding.

#### **PAYMENT AND REPORTING**

- The first payment will be made no later than thirty (30) days after the receipt of the fully executed contract. The first progress report is due at the end of the first six (6) months of the contract. The second progress report is due at the end of the first twelve months of

the contract. The second payment will be made no later than thirty (30) days after receipt of satisfactory progress reports. A final report is due within forty-five (45) days of completion of the grant period.

#### **INSURANCE**

Disclosure of insurance coverage is required. If your organization has insurance, provide a copy of your insurance certificate. Komen Houston recommends that grantees maintain commercial general liability insurance.

#### **LETTERS OF SUPPORT AND ADDITIONAL MATERIALS**

DO NOT send additional materials (i.e., reprints or letters of support). These will not be reviewed.

#### **CONFIRMATION OF RECEIPT OF APPLICATION**

Written confirmation of receipt will be sent to the project director following review for compliance to guidelines. Please do not contact the Komen Houston Affiliate regarding the status of the application during the review period.

#### **USE OF EVIDENCE-BASED PROGRAMS/STRATEGIES**

Although it is not required, the use of evidence-based programs/strategies is strongly encouraged and will be weighed by the Grants Review Panel when considering proposal ratings.

#### **Review**

Applications that meet compliance with these guidelines will be submitted for grant review by an independent Grant Review Panel of the Komen Houston Affiliate.

#### **REVIEW PROCESS**

Each grant application will be reviewed by at least three independent reviewers. They will consider each of the following selection criteria:

- **Impact:** Will the project have a substantial impact on the priority selected? How closely does the project align with the funding priorities stated in the RFA? Is the approach culturally appropriate for the intended target population and uses evidence-based strategies or emerging best practices?
- **Feasibility:** How likely is it that the objectives and activities will be achieved within the scope of the funded project? Is the project well planned? Is the budget appropriate and realistic? Does the budget justification explain in detail the reasoning and need for the costs associated with the project?
- **Outcomes:** Does the project have a sufficient and documented plan to evaluate its impact? Does the applicant clearly state what the program expects to accomplish with activities that will support the objectives? Does the applicant have the capacity to implement the evaluation plan as described?
- **Capacity:** Does the organization, Project Director and his/her team have the expertise to effectively implement all aspects of the project? Does the organization have the appropriate infrastructure/operational means to do the project and meet reporting requirements?
- **Collaboration:** Does this project enhance collaboration among organizations with similar or complementary goals? Are the roles of the partners appropriate and relevant?

- **Sustainability:** Is the project likely to be sustained? Are partnerships likely to be sustained past project period? Is the impact likely to be long-term?

The grant application process is competitive, whether or not an organization has received a grant in the past. Funding in subsequent years is never guaranteed.

**\*Failure to follow these guidelines will result in delayed processing or refusal of the application.**

## **APPLICATION INSTRUCTIONS**

**Please submit your application in the order listed below, including attachments. Submit only documents in Microsoft Word or Excel. Use the specified headings and supply the required information.** All applications must be written in English. Please use the forms included in the grant application. Use single-spaced on 8½ inch by 11 inch pages with one inch left and right margins. Font size should be no smaller than 12-point. Use Arial or Times New Roman only. All pages must be numbered sequentially.

Please keep proposals to the page limits stated below. Excess pages may be removed prior to review.

**Note:** Organizations seeking grants for breast cancer research should apply directly to the Susan G. Komen for the Cure headquarters. For more information please visit its web site at [www.komen.org/grants](http://www.komen.org/grants).

Additionally, programs that provide breast health education, screening, treatment, or support services are considered through the Komen Houston Affiliate's Community Grants program. More information can be found on this program at [www.komen-houston.org](http://www.komen-houston.org).

### **A. Cover Sheet** (Form provided.)

1. Completed in its entirety and signed. The signature of approving institutional personnel, other than the project director, is required.

### **B. Basic Study Information** (Not to exceed one page. Form provided.)

1. Briefly describe, in lay terms, the NCI or DOD sponsored breast cancer clinical research trial(s)/study(ies) that will be the focus of this project. Include the title of the trial/study, phase, type of trial/study, eligible participants, purpose, when the trial/study began, sponsor, and protocol ID.

### **C. Organization History and Project Abstract** (Form provided.)

1. Provide a brief history of the organization, mission and how the project fits into the scope of the organization. (Do not exceed 1250 characters.)
2. Provide a brief description of the proposal including the following (Do not exceed 1500 characters.):
  - a. The need for clinical trials enrollment support in your community.
  - b. A description of key activities
  - c. A summary of evaluation measures
  - d. The likely impact of project

### **D. Project Plan or Logic Model** (Not to exceed two pages. Forms provided.)

1. Complete Project Plan or Logic Model for the project.

### **E. Project Narrative** (Not exceed five pages.)

1. Describe the proposed project and the amount requested.
  - Indicate whether the project provides patient support; patient outreach and education; and/or provider outreach and education.
2. Describe the population the project will serve. If applicable, indicate age, race/ethnicity, socioeconomic status, education, geographic area of residence, insurance status, language preference, etc.
3. Please be sure to discuss how your project addresses the funding priorities identified in the Komen Houston Affiliate's Community Profile. If applicable, indicate the barriers to enrollment and retention in clinical research studies experienced by the population to be

served (e.g. lack of awareness, financial constraints, transportation issues, cultural values, beliefs, preferences and/or practices that affect behaviors) and how the project aims to overcome these barriers.

4. Describe project goals and objectives. Objectives should be written as **SMART** objectives.

**Specific** – to what you want to achieve

**Measurable** – how much do you want to achieve?

**Achievable** - are the objectives realistic?

**Results-oriented** – measures outcomes, not activities

**Timely** – By when do you want to achieve the objective?

**“Goals”** are defined in the context of this grant application as broad statements of the ultimate result of the program being undertaken.

- i. **For example:** Reduce breast cancer mortality among women age 40+ in Montgomery County.

**“Objectives”** are defined in the context of this grant application as specific and measurable approaches that the organization expects to accomplish to achieve the goal.

- ii. **For example:** 80% of women 40+ who received one-on-one education will get a mammogram within 3 months.

5. Describe the activities that will be conducted to accomplish the above goals and objectives. Provide a realistic, quarter-by-quarter timeline for implementing the program. Also, describe how your approach uses or adapts evidence-based strategies or promising practices. Explain why you chose this approach.
6. If applying for a grant to provide patient support, indicate which services will be covered and explain how the funds will be administered.

**F. Project Staffing** (Not to exceed one page)

1. Outline the proposed staffing pattern for the project, including the names and titles of individuals who will work directly on the project, and their time commitment to the project.
2. If you propose to fund a new position, describe: the responsibilities of the position; the necessary qualifications; and the hiring process within your institution, including the anticipated time it will take to hire an individual.
3. Identify any collaborating organizations. Describe your relationship with the organizations and detail their roles on the project. Letters of collaboration should be included from all collaborative organizations. See Section M.

**G. Evaluation** (Not to exceed one page plus attachments)

1. Describe the criteria for a successful project, how project measurements will be collected, and the results you expect to have achieved by the end of the funding period.
2. Evaluation should address how project will collect information on the number of individuals educated about and enrolled in breast cancer clinical research.
3. Explain how the project results will be used and if/how they will be disseminated.
4. If applicable, include copies of evaluation forms or surveys to be used with the project.

**H. Budget Form** (Not to exceed one page. Form provided.)

1. Salaries, if requested, must be for personnel related to this project only and not the general work of the applying organization. Employee fringe benefits are limited to a

25% maximum of an employee's salary. Fringe Benefits and associated costs must be defined.

**I. Budget Justification** (Not to exceed one page)

1. Provide written explanations of all items listed on the Budget Form.

**J. Other Funding Sources** (Not to exceed one page.) (Form provided.)

1. List any other funding sources for the proposed project.
2. If request is more than 20% of the organization's entire budget, please provide a copy of the organization's budget.
3. List of other organizations with whom you have grant applications pending for this project.

**K. Internal Control Measures** (Not to exceed one page)

1. Provide a description of internal controls, which will govern the use of proceeds. Examples related to vendor selections (if applicable) and segregation of duties over cash disbursement and payment processing should be included.
2. The Komen Houston Affiliate reserves the right to request financial statements and/or audited financials if needed.

**L. Proof of Non-Profit Status**

1. Attach your organization's federal non-profit/tax-exemption determination letter from the Internal Revenue Service.

**M. Biographical Information** (Not to exceed two pages per person)

1. Include resume or curriculum vitae for project director and each staff member affiliated with the project.

**N. Letters of Collaboration**

1. If applicable, provide letters of collaboration from all collaborating organizations as described in Section E. NOTE: Letters of collaboration may not be more than six months old.

**O. Prior Komen Houston Affiliate Funding Project Summary** (Summary should not exceed one page, not including the previous funding form that is also required)

1. If you are a current or former Komen Houston Affiliate grantee, provide brief information on the following items for the most recent grant you have received:
  - a. Project funded by the grant and date of funding.
  - b. Project objectives with percent to goal, accomplishments and challenges at six months into project (please be specific).
  - c. Approximate number of individuals served through the grant.
  - d. Overall results of project.
  - e. Previous funding by the Houston Affiliate (form provided).

**P. Insurance**

1. Attach the organization's certificate of insurance coverage.