KOMEN RESEARCH PROGRAMS

Susan G. Komen's mission is to save lives by meeting the most critical needs in our communities and investing in breakthrough research to prevent and cure breast cancer. Komen has set a Bold Goal to reduce the current number of breast cancer deaths by 50 percent in the U.S. by 2026.

Policies and Procedures
for Research and Training Grants
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INTRODUCTION

A Research or Training Grant ("Grant") is provided to support a research project ("Research Project") as presented in a grant application (including approved modifications, if any) and approved for funding by Susan G. Komen ("Komen").

The specific terms and conditions applicable to a Grant awarded by Komen are set forth in these Research and Training Grant Policies and Procedures ("Policies"), as may be revised from time to time and the grant agreement ("Grant Agreement"), which incorporates by reference these Policies.

The Grant Agreement must be signed on behalf of the grantee institution ("Grantee Institution") by an administrative official who has signatory authority (any such person referred to herein as the "ASO") and also must be signed by the principal investigator (("PI"), any co-principal investigator ("Co-PI"), and the postdoctoral lead mentor ("Lead Mentor") if the Grant is for a postdoctoral fellowship. The Grantee Institution, PI, Co-PIs and Lead Mentor (if any) will be collectively referred to herein as the "Grantees."

For purposes of these Policies, if multiple Grantee Institutions or multiple PIs or Co-PIs are involved in a Research Project,

(a) All references to "Grantee Institution" will refer collectively to all the institutions involved; and

(b) All references to "PI" or "Co-PI" will refer collectively to all principal investigators and co-principal investigators involved.

For Grants that involve multiple PIs from multiple Grantee Institutions, Komen requires all the PIs and Grantee Institutions to sign a single Grant Agreement with Komen. Komen will designate a "lead" Grantee Institution to serve as the administrator of the Grant and be responsible for the disbursement of the funds to other participating Grantee Institutions, the management of the budget, and the submission of all Required Documents and Required Grant Reports (as defined below). For Grants that involve consortia/subcontracts, see Section 7.2.1 Consortia and /or Subcontracts below.

1. REQUIREMENTS OF DIFFERENT GRANT MECHANISMS

Each Grant mechanism has unique features and requirements, such as duration, funding levels, recipient designations, eligibility requirements, project requirements, and permitted budget allocations. For applications submitted in response to a Request for Applications ("RFA") or a request for a Letter of Intent (LOI), these features and requirements are detailed in the RFA, LOI requirements and Application Submission Instructions for each Grant mechanism and are incorporated by reference into these Policies.

2. NOTIFICATION OF INTENT TO FUND

Komen will inform an applicant of Komen's intent to fund the Research Project described in an application through a non-binding letter ("Notification of Intent to Fund"), which will include the terms of the potential funding, including whether at the full amount and/or term requested by the applicant, or a partial amount and/or term. The applicant must then inform Komen of the applicant's intent to accept, decline, or provisionally accept the Grant. Provisional acceptance is an option to delay the final decision to accept or decline the Grant for a period of time to be approved by Komen (typically no longer than 90 days), for reasons such as grant application decisions pending from other funders. The applicant must inform Komen of the applicant's decision within the time specified within the Notification of Intent to Fund. Komen may withdraw its funding intention at any time, for any reason, including if the Grant Agreement is not executed within six months of the issuance of the Notification of Intent to Fund.

3. ONLINE PROCEDURES

Grants are managed online through proposalCENTRAL ("pC"). Once an applicant accepts Komen's Notification of Intent to Fund, the PI, any Co-PI(s), any Lead Mentor, the ASO and the designated financial officer ("Financial Officer"), who are named on the submitted grant application will be given authorization to access the official Grant record in pC. The ASO or PI may request additional users to be authorized to access the official Grant record in pC by submitting through pC the Grant Contact Form for review and final approval by Komen.

For technical inquiries related to pC (including questions related to system access, navigation, document uploads,

etc.), contact proposalCENTRAL via email at pcsupport@altum.com or via phone at 1-800-875-2562 (Toll-free U.S. and Canada), or 1-703-964-5840 (International).

4. ORGANIZATIONAL ASSURANCES

Komen does not assume responsibility for the conduct of the Research Project or for the activities of any of the Grantees, since they are under the direction of the Grantee Institution. However, Komen requires assurances that the Grantees will implement the necessary safeguards in the use of human subjects, human biological/anatomical materials, bio-hazardous materials and animals in connection with a Research Project, and will comply with all appropriate laws and regulations governing the conduct of research. For a description of the documentation required in connection with these assurances, see Section 5 Submission of Required Documents below.

4.1 Research Involving Human Subjects

Research Projects involving human subjects will be guided by one of the following statements of ethical principles:

(a) The World Medical Association's Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects;

(b) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or

(c) Other appropriate international ethical standards recognized by U.S. Federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the "Common Rule".

Research Projects must also comply with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the guidelines set forth by the Office of Human Research Protection and applicable state or equivalent international guidelines or regulations.

4.2 Research Involving Human Biological/Anatomical Material

Any research involving the use of human specimens, cells, cell lines or data involving human subjects will comply with the applicable requirements of the National Institutes of Health Office of Extramural Research. Grantees from outside the United States must follow equivalent international guidelines or recommendations governing the use of human biological and/or anatomical materials.

4.3 Research Involving Biohazardous Materials

Research involving the use of recombinant DNA, bio-hazardous materials, genetically engineered mechanisms, human fetal tissues, and/or human anatomical substances must be reviewed and approved by the Grantee Institution's biohazards committee and conform to the relevant U.S. Public Health Service ("PHS") (or international equivalent) guidelines.

4.4 Research Involving Animals

Research involving animals will be guided by the PHS Policy on Humane Care and Use of Laboratory Animals, or the International Guiding Principles for Biomedical Research Involving Animals by the Council for International Organization of Medical Sciences and the International Council for Laboratory Animal Science, or the equivalent guidelines of an international animal welfare board.

4.5 Government Compliance

Grantees must comply with all applicable laws and regulations in connection with their Grant and cooperate with Komen in supplying additional information and complying with any procedures that might be required by a government agency in order for Komen to establish that it has observed all requirements under the law with respect to the Grant.

5. SUBMISSION OF REQUIRED DOCUMENTS

Komen requires submission of certain financial information, applicant information, regulatory documents, and other documentation (collectively referred to as "Required Documents"). All Required Documents must be (i) in English or include an English translation by a certified translator; (ii) submitted in pC and (iii) approved by Komen

prior to the execution of the Grant Agreement. Required Documents include, but are not limited to, the documents described below. Komen reserves the right to request additional documentation from Grantees prior to or after the execution of a Grant Agreement, and also requires renewals, updates, and/or resubmissions of certain Required Documents during the Grant Term.

5.1 Financial Information

(a) Taxpayer Identification Number and Certification (for U.S. Grantee Institutions only) via Institutional W-9 form;

(b) Certificate of Foreign Status of Beneficial Owner for United States Tax Withholding (for foreign Grantee Institutions only) via W-8EXP form;

(c) IRS determination letter or other proof of Grantee Institution's Section 501(c)(3) tax exempt status or, if Grantee Institution is outside of the U.S., proof of Grantee Institution's tax exempt status from the appropriate governmental authority; and

(d) Payment Verification Form (described in Section 7.4 below) signed by Financial Officer or ASO

5.2 Applicant Information from each PI, Co-PI and Lead Mentor (as applicable)

(a) Biographical Narrative;

(b) Promotional Photograph Form; and

(c) Biosketch that includes other sources of funding (current and pending) for each PI, Co-PI and Lead Mentor

5.3 Regulatory Documents

(a) Institutional Review Board (IRB) (or international equivalent) approval for Research Projects involving the use of human subjects (described in Section 4.2 above);

(b) Institution Animal Care and Use Committee (IACUC) (or international equivalent) approval for Research Projects involving the use of animals (described in Section 4.4 above)

The above Regulatory Documents must:

(a) Be issued by the IRB or IACUC (or international equivalent);

(b) Indicate the status of review obtained, i.e., approved or exempt;

(c) Apply to the same studies proposed in the Research Project, however, the Research Project title and IRB/IACUC (or international equivalent) project titles, do NOT need to be an exact match; and

(d) Stipulate approval and renewal and/or expiration dates.

5.4 Other Documentation

Confirmation of Resource Availability: If the Research Project requires the use of a resource, such as a drug, biospecimen, animal model and/or data, which is not owned by the PI, Co-PI(s) or Grantee Institution or is not publicly available, a letter from the owner of the resource must be submitted on institution letterhead and signed by an authorized signatory. The letter should confirm the availability of and access to the resource needed for successful completion of the proposed research.

6. GRANT AGREEMENT EXECUTION

6.1 Good Standing

A PI/Co-PI/ Lead Mentor and their Grantee Institution's Komen-funded Grants (past and current) must be up-to-date and in compliance with all Komen requirements in order to receive a new Grant and enter into a new Grant Agreement.

6.2 Research Project Changes Prior to Grant Agreement Execution

Komen may request changes to the Research Project prior to the execution of a Grant Agreement for reasons, including but not limited to, a reduction in the award amount and/or Grant Term or to resolve an overlap in funding. Upon receipt of such a request by Komen, Grantees shall propose modifications to the Research Project reflecting these requested changes by submitting a Change of Research Plan Request Form, and a Budget Change Request, if appropriate. Such proposed modifications will be reviewed and approved by Komen, in its sole discretion.

6.3 Personnel Changes Prior to Grant Agreement Execution

Komen will not approve a change of PI or Lead Mentor for a Postdoctoral Fellowship Grant prior to the execution of a Grant Agreement.

Requests for changes to level of effort for a PI or Co-PI(s) must be submitted via a Personnel Change Request Form available in pC. Grantees must obtain approval by Komen prior to implementing any changes, which approval shall be at Komen's sole discretion.

6.4 Grantee Institution Change Prior to Grant Agreement Execution

A PI may request a change of Grantee Institution prior to the execution of a Grant Agreement by submitting a Change of Institution Request Form and the Required Documents listed in Section 5 above from the new institution. Such change request will be reviewed and approved by Komen, at its sole discretion. A PI should request the change as soon as possible, as the transfer of the Grant to the new institution typically takes three to six months. A change of Grantee Institution prior to the execution of a Grant Agreement is not permitted for Postdoctoral Fellowships.

6.5 Grant Agreement

After approval of all Required Documents and disposition of any change requests, Komen will circulate to Grantees a Grant Agreement for final signature. The Grant Agreement must be executed by the null and void date noted in the Agreement. The effective date of the Grant Agreement shall be listed on the fully-executed Grant Agreement and shall serve as the start date of the Grant. No expenses may be accrued against the Grant until the Grant Agreement is fully-executed by all the parties, and Komen will not reimburse any costs incurred prior to the effective start date or after the termination or expiration of the Grant Agreement.

6.6 Delay in Grant Start Date

Grantees may request that the start date of the Grant be delayed for up to six months after the date that Komen issues its Notification of Intent to Fund by submitting their request via email to the assigned Komen Research Grants Manager. Grantees must detail the reason for the delay and provide a requested Grant start date. Such requests will be reviewed and approved by Komen, at its sole discretion.

7. FUNDING

7.1 Duration

The Research Project will be supported for the term reflected in the Grant Agreement (the "Grant Term").

7.2 Budget

All Grant funds shall be expended in accordance with the Research Project's approved budget, with the following restrictions:

7.2.1 Consortia and/or Subcontracts

Upon prior written approval of Komen, a Grantee Institution may subcontract with a third party to assist

with a Research Project by establishing a consortium or subcontract, whereby a Research Project is carried out by the Grantee Institution and one or more other organizations that are separate legal entities. In this arrangement, the Grantee Institution contracts with another organization for the performance of a portion of the activities to be conducted for the Research Project. These agreements involve a specific percentage of effort from the consortium's or subcontracting organization's principal investigator and a categorical breakdown of costs, including all budget categories of the original Grant. A budget of all consortium and subcontract costs must be submitted to Komen, and annual expenditures against the consortium or subcontract budget must be provided with the Grantees' financial reports. Grantees will cause all consortia members and subcontractors to comply with the terms and conditions of the Grantees' Grant Agreement with Komen, which incorporates these Policies, including but not limited to the limitations of indirect costs set forth in Section 7.2.5 below.

7.2.2 Research Equipment

Equipment costs cannot exceed 25% of the total direct costs of the Grant. Approved equipment purchased during the Grant Term is intended for the use by the PI, Co-PI, Lead Mentor, staff, and any collaborators. Title of the equipment will be vested in the Grantee Institution conducting the Research Project, and upon completion of the Research Project, the equipment will remain at the Grantee Institution. However, in the event of an approved transfer of a Grant to another institution, the equipment purchased with Grant funds that are necessary for the continuation and success of the Research Project may be transferred to the new Grantee Institution.

7.2.3 Personnel Costs

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

7.2.4 Travel Costs

Travel costs must be directly related to the approved Research Project, reasonable and customary for the intended destination and otherwise in compliance with Grantee Institution's travel policies.

7.2.5 Indirect Costs

For Grant mechanisms that permit Grant funds to be applied to indirect costs, indirect costs may not exceed 25% of the total direct costs reported in each financial report. Indirect costs include all expenses not directly related to the conduct of the Research Project, including, but not limited to, allocated costs such as facilities, technology support, communication expenses, administrative support, etc. Grantees using subcontractors and consortia members must ensure that the indirect costs incurred by each subcontractor or consortia member do not cause the total indirect costs for the Research Project to exceed 25% of total direct costs reported in each financial report.

7.2.6 Clinical Trial Subject Reimbursement or Compensation

Grant funds may be used to compensate an individual who participates in a research project or clinical trial. This may include reimbursement for the subject's time, reimbursement of travel expenses, etc. Compensation amounts and/or reimbursement rates should be established by the PI and should be reasonable given the nature of the study, the nature of the subject's contributions and vulnerabilities and other ethical considerations. Grantee must submit to Komen the approval of such payments from Grantee Institution's IRB, which must reflect the rationale for payments, how the dollar amount was calculated and how and when payments will be made. Upon receipt of the above information, Komen will determine to what extent, if any, the Grant funds may be applied to these expenses.

7.2.7 Expenditures Out-of-Scope of Grant

Komen will not be responsible for:

(a) Any expenditure made prior to the effective date or after the termination of the Grant Agreement,

(b) Commitments made during the Grant Term but not paid within 60 days following the expiration of the Grant Agreement,

(c) Expenditures that are not permitted as described within the RFA or LOI requirements and Application Submission Instructions, or any expenditure that is inconsistent with the approved Research Project budget or that exceeds the total amount of the Grant.

7.2.8 Other Costs to which Grant funds may not be applied

Grant funds may not be applied to graduate and postdoctoral fellow tuition costs (with the exception of graduate student research grants), periodicals or other subscriptions, professional memberships, relocation costs for the PI or other personnel, work visas, or advertising for personnel and other recruitment expenses.

7.3 Payment Schedule

Komen will pay Grantees the Grant funds pursuant to the schedule set forth in the Grant Agreement. Grantees must submit all Required Grant Reports and Required Documents (as defined in Section 8 Required Grant Reports and Required Document Renewals below) when due, which then must be approved by Komen, in order to receive any payments under the Grant Agreement. As part of its oversight of research progress, Komen may adjust the due dates for scientific progress reports and/or financial reports, require interim reports and may delay or reduce scheduled Grant payments based on prior expenditures and progress reported.

7.4 Payment Verification Form

Grantee Institution will be responsible for completing a Payment Verification Form as part of its submission of an application. Grant payments will be transmitted through Automated Clearing House (ACH) or WIRE (international only) transfer to the bank account referenced on the Payment Verification Form. In the event ACH or WIRE transfer are not available, Grant payments will be made by check mailed to the Grantee Institution and will require Grantee Institution's acknowledgment of receipt.

8. REQUIRED GRANT REPORTS AND REQUIRED DOCUMENT RENEWALS

The following reports ("Required Grant Reports") and Required Document updates/renewals are required to be submitted to Komen in connection with a Grant. These reports and renewals must be uploaded to pC using the appropriate form, which can be found under the *Award Details/Deliverables* section in pC.

The format and content requirements for Required Grant Reports and Required Documents may be modified by Komen at any time. Grantees are responsible for reviewing and complying with all requirements in effect at the time the Required Grant Reports and/or Required Documents are due. Grantees may review the current requirements in the *Award Details/Deliverables* section of their Grant file in pC.

8.1 Annual Scientific Progress Report

An annual scientific progress report is due on each anniversary of the Grant start date for the duration of the Grant Term, except for the final year of the Grant Term when a final scientific progress report is due (see Section 8.3 Final Scientific Progress Report below).

8.2 Interim Scientific Progress Report

An interim scientific progress report may be required by Komen at any time during the Grant Term for reasons, including, but not limited to, if Grantees submit a request form for a change to the Research Project or in order to account for delays in scientific progress.

8.3 Final Scientific Progress Report

A final scientific progress report is due 30 days after the end date or early termination of the Grant Agreement.

8.4 Annual Financial Report

An annual financial report that includes an accounting of expenditures incurred solely during the prior 12-month period is due no later than 30 days after each anniversary of the Grant start date for the duration of the Grant Term, except for the final 12-month period of the Grant Term when a final financial report is due (see Section 8.6 below). The due date for the annual financial report is scheduled 30 days after the due date for the scientific progress report to provide adequate time to ensure that reported expenditures reflect a full 12-month period of activity. All expenditures must be reported in United States dollars ($US). In certain circumstances, Grantee may carry forward Grant funds from one 12-month period during the Grant Term to the next 12-month period without

prior written approval from Komen (see Section 9.5 Carry Forward of Funds below).

8.5 Biannual Financial Report

For Grants of $500,000 or more, Komen requires biannual financial reports. A biannual financial report includes an accounting of expenditures incurred solely during the prior 6-month period. For each 12 month period, the first biannual financial report is due no later than 30 days after the 6-month anniversary of the Grant start date to ensure that reported expenditures reflect a full 6-month period of activity. The second biannual financial report is due no later than 30 days after the 12 month anniversary of the Grant to ensure that reported expenditures reflect a full 6-month period of activity. This biannual financial reporting schedule will occur for the duration of the Grant Term, except for the final 6-month period of the Grant Term when a final financial report is due (see Section 8.7 below). All expenditures must be reported in United States dollars ($US). In certain circumstances, Grantee may carry forward Grant funds from one 6-month period during the Grant Term to the next 6-month period without prior written approval from Komen (see Section 9.5 Carry Forward of Funds below).

8.6 Interim Financial Report

Interim financial reports may be required for Grants by Komen at its sole discretion, to report expenditures during a specific term to be set by Komen. All expenditures must be reported in United States dollars ($US).

8.7 Final Financial Report

A final financial report is due no later than 60 days after the end date or early termination of the Grant Agreement. All expenditures must be reported in United States dollars ($US).

8.8 Required Document Renewals

8.8.1 Financial Information

Domestic Grantees are required to submit an updated Payment Verification Form if any of the following information changes during the Grant Term:

(a) Grantee Institution contact information for ASO and Financial Officer; and/or

(b) Automated Clearing House (ACH) or WIRE electronic funds transfer information.

International Grantees are required to submit an updated Payment Verification Form due on the same date as the Annual Financial Report.

8.8.2 Regulatory Documents

Grantees are required to submit renewals (if applicable) of the following Required Documents by the due dates set by Komen in pC:

(a) Institutional Review Board (IRB) approval for Research Projects involving the use of human subjects or the international equivalent;

(b) Institution Animal Care and Use Committee (IACUC) approval for Research Projects involving the use of animals or the international equivalent.

8.8.3 Grant Contact Form

Grantees are required to submit an updated Grant Contact Form if any changes are made to the information contained in the Komen approved form, during the Grant Term.

8.8.4 Biosketches

Grantees are required to submit an updated biosketch that includes other sources of funding (current and pending) for each PI, Co-PI and Lead Mentor on each anniversary of the Grant start date.

8.9 Other Reports and Engagements

With reasonable prior notice to Grantees, Komen may require additional reporting from Grantees and also may require Grantees to participate in site visits, telephone conferences, presentations, other speaking engagements

and other activities. In such cases, Komen shall use good faith efforts to accommodate any Grantees' scheduling conflicts.

8.10 Timely Submission of Required Grant Reports and Required Document Renewals

It is the responsibility of Grantees to submit all Required Grant Reports and Required Document Renewals by the deadlines set in pC. Failure to provide timely and complete reports and/or renewals may result in, among other things, the early termination of the Grant, reimbursement to Komen of Grant funds, and may preclude the Grantees from being eligible for Komen funding in the future.

8.11 Non-Confidential Nature of Reports

All reports, including scientific progress and financial reports are not considered confidential. Komen may contract with third parties who have the necessary expertise to review the reports and evaluate the progress of the Research Project. Further, Komen may share Grant information, including the reports, with donors who have provided financial support for Komen research or with members of the general public. Komen will not be responsible for any damages resulting from the disclosure of the content of such reports. In limited cases in which information provided in a report must be kept confidential, such as information the public disclosure of which may result in a waiver to obtain a patent, Grantees must notify their Komen Research Grant Managers in advance and must clearly identify and mark as "Confidential" only the specific information that requires confidential treatment in the specific reports provided to Komen.

9. DATA SHARING POLICY

To accelerate scientific discovery, research results and data should be made as widely and freely available as possible, while safeguarding the privacy of participants and protecting confidential and proprietary data. Komen's Data Sharing Policy aligns with the NIH's data sharing requirements (https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm), including policies for sharing large-scale genomics data (https://gds.nih.gov/03policy2.html) and clinical trial information (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html), with the following exceptions:

- The policy will apply to all Komen-funded research grants, regardless of awarded amount except for grants that have already submitted an application as of February 1, 2018 (i.e. FY19 Career Catalyst Research Grants and Career Catalyst Research Competitive Renewals) Grants who have submitted applications prior to February 1, 2018 are strongly encouraged to share their data.
- **Final data must be shared** no later than the **date of publication** of research results.

Applicants will be required to provide a data sharing plan as part of their grant application and may request funds necessary for data sharing and archiving in the submitted budget. Grantees will be required to report on progress toward the data sharing plan in both annual and final progress reports.

Key points of the Komen Data Sharing Policy include the following:

9.1 What data should be shared?

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

9.2 When should data be made available?

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

information, must be provided no later than one year after the trial completion date, unless regulatory approval of the product is being sought.

9.2 Where/With whom should data be shared?

- Data should be shared as broadly as possible to the extent consistent with applicable laws, regulations, rules, and policies. Rights and privacy of human subjects must be protected at all times.
- Researchers may select the method(s) for data sharing.
- Data repositories with common standards and an established infrastructure dedicated to the appropriate distribution of data are recommended.
- Large-scale non-human genomic data must be submitted to any widely used data repository; large-scale human genomic data must be submitted to an NIH-designated data repository.
- Clinical trials should be registered at clinicaltrials.gov.

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

10. GRANT CHANGES

Unless specifically stated otherwise in these Policies, all desired changes to the Grant must be submitted for prior approval by Komen using the appropriate change request templates found in pC under the *Award Details/Deliverables* section of the Grant record. Depending upon the change requested, Komen may require that a Grant Agreement Amendment be signed by the relevant parties.

Grantees are strongly encouraged to discuss any desired changes with their Komen Research Grant Managers in advance of submitting a formal request. Grantees must obtain approval by Komen prior to implementing any of the changes referenced below, which approval shall be at Komen's sole discretion.

10.1 Change in Research Project

Changes to the Research Project will not be permitted within the first year of the Grant Term, except at the request of Komen. Change in project title, research design and/or specific aims after the first year require the submission of a Change of Research Plan Request Form. If the budget will change, Grantees must also submit a Budget Change Request Form.

10.2 Change of Grantee Institution

Changes in Grantee Institution for a Postdoctoral Fellowship Grant are not permitted in the first year, except with Komen's prior approval. Any change in the Grantee Institution requires submission of a Change of Institution Request Form, as well as additional documentation, including but not limited to, an interim or annual scientific progress report, interim or annual financial report, and proposed budget for the remaining Grant Term.

The PI should request the change as soon as possible, as the transfer of a Grant to a new institution typically takes three to six months. A Change of Institution request will be reviewed and approved by Komen, by its sole discretion. If Komen approves the Change of Grantee Institution, a new Grant Agreement will be sent for execution by the PI, Co-PI (if applicable), Lead Mentor (if applicable) and new Grantee Institution. The Grant Agreement will detail the funds available to be expended by the new Grantee Institution, and a new reporting and payment schedule, if applicable.

10.3 Change of Personnel or Level of Effort

Changes in the PI for a Postdoctoral Fellowship or Career Catalyst Research Grant are not permitted at any time during the Grant Term. Otherwise, changes in PI are not permitted in the first year, except with Komen's prior approval. All changes in PI or Co-PI require submission of a Change of Personnel Form signed by the PI, Co-PI (if applicable), and ASO. An NIH-formatted biosketch and other Required Documents, as may be requested by Komen, must be provided for all new key personnel.
A change in other personnel does not require prior approval, but notification of the change must be provided to Komen in the upcoming scientific progress report.

10.4 Budget Changes

All Grant funds must be expended in accordance with the Komen-approved budget and subject to the restrictions set forth in Section 7. Notwithstanding the above, Grantees may move up to 20% of total funds (per 12-month period) across budget line items within any single 12-month period of the Grant Term in order to meet specific research requirements without prior approval by Komen. However, no funds may be moved across line items if the result exceeds any maximum allowable cost, as described in Section 7. Such changes should be reported in the next financial report.

Changes exceeding 20% of total funds (per 12-month period) across line items or a change seeking to re-budget funds from a later 12-month period of the Grant Term into a more recent 12-month period of the Grant term require the submission of a Budget Change Request Form and approval of Komen prior to the expenditure of funds.

10.5 Carry Forward of Funds

If the Komen-approved financial report from one 12-month period of the Grant Term shows a remaining balance of Grant funds, Grantees may carry forward these funds to the following 12-month period without prior written approval from Komen. However, if the amount to be carried forward to the next 12-month period is greater than 20% of the annual awarded budget, Komen may require a Budget Change Request Form from Grantee to account for underspending. In addition, Komen may require the Grantees to deplete the current installment of the Grant funds (including any accrued interest thereon) prior to receiving the payment of the next installment of the Grant funds.

10.6 No Cost Extension

A no cost extension ("NCE") changes the end date of the Grant, thereby extending the duration of the Grant Agreement without providing additional funding. A NCE may be requested only in order to complete the Research Project. A NCE may not be granted for any purpose not specifically related to the approved Research Project. A NCE may be granted for any period of time not to exceed 12 months. Only one NCE will be approved per Grant. No expenses maybe incurred during a NCE period until Komen and Grantees have signed an amendment to the Grant Agreement allowing for the NCE.

A NCE request must be made through pC no earlier than 90 days and no less than 30 days prior to the end date referenced in the Grant Agreement by submitting a No Cost Extension Request Form.

10.7 Leave of Absence

Although rare, PI(s) or Co-PI(s) may need to leave their research activities for a defined period of time (e.g., pregnancy, illness, family emergencies, etc.). A leave of absence may not exceed six months and is granted only if the leave will not jeopardize the overall Research Project and the PI and/or Co-PI has put in place effective measures to ensure the success of the Research Project. Grantees must submit a Leave of Absence Form in pC no less than 30 days prior to the leave of absence effective date in non-emergency circumstances, such as maternity leave or sabbatical. Receipt of salary from Grant funds is not permitted during leave.

10.8 Early Termination by Grantees for any Reason

Grantees may request an early termination of their Grant for a variety of reasons, including but not limited to, the completion of a Research Project significantly in advance of the end date of the Grant Term, or a PI's resignation or retirement, etc.

In the event of an early termination, Grantees must submit a letter to Komen on Grantee Institution letterhead that includes the Komen Grant number and title, the reason for the termination, and the requested termination date. The letter must be signed by all parties to the Grant Agreement.

Komen will notify Grantees of its acceptance of the termination. The Grantees must then submit the final scientific progress report within 30 days and a final financial report within 60 days after the date of early termination provided in Komen's notification. After Komen reviews and approves the reports, Grantees will receive an invoice to remit unexpended funds (including any accrued interest thereon), if any. Grantees will remit all unexpended funds within 30 days of receipt of the invoice, in accordance with the instructions provided by Komen in the invoice.

11. ACKNOWLEDGMENT OF KOMEN FUNDING AND KOMEN RIGHTS TO USE RESEARCH PROJECT MATERIALS

11.1 Acknowledgment of Komen Funding

Grantees must acknowledge Komen as a funding source on all publications and in all presentations related to the Research Project, whether during or after the Grant Term, in a clear, unambiguous, and readily-identifiable fashion, using the following acknowledgment: "This research was supported by a grant from Susan G. Komen®" or as otherwise directed by Komen. When possible, Grantees also will include Komen's signature logo and the Grant ID number or other identifying information in the acknowledgment. Komen reserves the right to offer Grant-naming opportunities to donors and corporate partners, and depending on the Grant awarded, Grantees also may be required to acknowledge such donors or partners.

11.2 Permission to use Komen Trademarks in Acknowledgments

Komen grants to Grantees a limited, non-exclusive license to use the Susan G. Komen® name and signature logo (the "Licensed Marks") solely for the purpose of acknowledging Komen's funding of the Research Project. Komen shall retain all right, title and interest in and to the Licensed Marks, all of which shall remain the exclusive property of Komen. Upon Grantee's request, Komen will provide camera-ready artwork of the Licensed Marks.

11.3 Scientific Publications in Peer-Reviewed Journals

During and after the Grant Term, Grantees must upload within 12 months of acceptance for publication all peer-reviewed articles relating to research supported in whole or in part by Komen in the PubMed Central online archive.

Grantees are also encouraged to assist Komen with linking their Komen Grant through NIH's myNCBI portal to any publications that may report results of their Research Project. For assistance with performing this function Grantees may contact their assigned Komen Research Grants Manager.

11.4 Other Publications

During and after the Grant Term, the Grantees must furnish Komen with copies of all other news releases, articles, photographs, and any and all other published material referencing the Research Project or the Grant prior to publication, or as soon thereafter as practical.

11.5 Permission to use Grant Materials

The Grantees authorize Komen to use (a) the Grantees' names and logos for the sole purpose of releasing information regarding the Grant to the general public, and (b) copies of all materials, including but not limited to, pictures of the Research Project team (including the Biographical Narrative and Promotional Photograph Form listed in Section 5.2 above), Research Project summaries and scientific progress reports and other publications created in connection with the Research Project. The Grantees have or will obtain all consents from third parties necessary to authorize such use of such materials.

12. INTELLECTUAL PROPERTY AND ROYALTIES

Discoveries, works of authorship, or inventions derived from research performed, supervised or subcontracted for by the PI, Co-PI or Lead Mentor and Grantee Institution in the performance of a Grant will be subject to Komen's Patent, Intellectual Property, and Technology Transfer Policy as set forth below:
The primary purpose of Komen in funding scientifically meritorious research is to advance its mission to end breast cancer forever. Komen recognizes, however, that Inventions (as defined below) having public health, scientific, business, or commercial application or value may be made in the course of or arising from research supported by Komen. It is the desire of Komen that such Inventions will be administered in such a manner that they are brought into public use at the earliest possible time. Komen recognizes that this may be best accomplished through the filing of applications for registration of patents and/or copyrights in such Inventions and the commercial licensing of such Inventions to third parties.

"Invention" is any discovery, data, material, method, process, device, product, program, software, know-how or other work of authorship in which the Grantee Institution has a proprietary interest, whether or not patentable or copyrightable, that is created, conceived, discovered or reduced to practice in the course of a Research Project or

arises from a Research Project within five years after completion thereof and is made by investigators with paid effort on the Research Project. All Inventions shall be reported to Komen in writing as soon as practicable but in no event later than 60 days after they are reported to the Grantee Institution's office responsible for management of intellectual property.

In the event that the Grantee Institution/investigator desires to file a patent or copyright application or assert any intellectual property right in the Invention, such Grantee Institution/investigator shall notify Komen immediately in writing and, upon Komen's request, shall provide Komen with all documentation relating to the filing or assertion of rights. Komen shall agree to maintain the confidentiality of such documentation by executing a confidentiality agreement mutually agreed to by the Grantee Institution/investigator and Komen.

If the Grantee Institution has an established and applicable patent, intellectual property, or technology transfer policy, and procedure for administering Inventions, Komen will defer to that policy with the following restrictions: Komen shall be granted the non-exclusive, royalty-free license to practice the Invention for non-commercial research purposes. This license will be subject to any restrictions on use or other limitations set forth in any Commercialization Agreement (as defined below) entered into by Grantee Institution/investigator. Komen shall participate in the income (net of any direct out-of-pocket patenting or licensing costs) derived from the Invention, unless Komen waives such right in writing. If Komen elects to participate in the net income, the amount of Komen's share of net income shall be directly proportionate to Komen's proportion of support for the research giving rise to the Invention, but in no event shall exceed 50% of the total net income earned. Komen waives receipt of any income until the net income from the Invention exceeds US$250,000.00. The right of Komen to participate in revenue derived from an Invention may only be waived in writing, and no provision of these Policies shall constitute such a waiver.

In the event that the Grantee Institution/investigator contemplates entering into a license, lease, sale, assignment or revenue-generating agreement relating to an Invention (any of the foregoing, a "Commercialization Agreement"), any such Commercialization Agreement shall be reviewed by Komen. The Commercialization Agreement must include provisions obligating the licensee to commercialize the Invention in a diligent manner and identifying appropriate diligence requirements and milestones, and Grantee Institution shall monitor performance of the licensee. Further, for Inventions made during the course of a Research Project, the Commercialization Agreement must also provide that in accordance with (a)-(c) directly below, if licensee fails to commercialize the Invention in compliance with the diligence requirements and milestones, the Grantee Institution shall have the right to terminate the license and/or convert an exclusive license to a non-exclusive license. To the extent a Commercialization Agreement does not comply with the above requirements, names Komen as a party or subjects Komen to potential liabilities or responsibilities beyond the responsibilities described below, it must be approved by Komen prior to execution.

For Inventions made during the course of a Research Project, Grantee Institution and Komen shall be bound by, and shall comply with the following:

(a) If neither Grantee Institution nor its licensee has not taken effective steps within three years (or whatever is a reasonable longer time in the circumstances) after issuance of a patent or a clear determination of commercial value in an Invention that is being administered by the Grantee Institution/investigator, whichever occurs first, to bring the Invention to practical or commercial application through licensing or otherwise on terms that are reasonable in the circumstances; and

(b) If, upon written request by Komen, neither Grantee Institution nor its licensee has shown reasonable cause why it or its licensee should retain title to and all rights in the administration of the Invention for a further period of time, then, unless no other parties have superior rights (as provided under this Policy), Komen may require the Grantee Institution:

    (i) To license (on an exclusive basis where possible) said patent or intellectual property right to Komen with the right to grant sublicenses;

    (ii) To cancel any outstanding exclusive licenses;

(iii) To grant licenses under said patent or intellectual property right on a non-exclusive, royalty-free basis or on such other terms that are reasonable in the circumstances to third parties; and/or

(iv) To compel such other reasonable disposition of the Invention rights as may be mutually agreed upon in writing by Komen and the Grantee Institution.

(c) Any dispute between Grantee Institution and Komen concerning Komen's above-referenced rights will be resolved, if possible, through negotiation. At a minimum, such negotiations will include 1) a meeting between Grantee Institution, Komen and the licensee (if any) to discuss a revised commercialization timeline and the reason the Grantee Institution and/or licensee did not meet the diligence requirements and milestones; and 2) a negotiation between senior officials of Grantee Institution and Komen. Notwithstanding any provisions in the Grant Agreement, if negotiations fail to resolve the issue, it shall be submitted to binding arbitration, subject to the following:

(i) The arbitration shall be administered by JAMS, in accordance with JAMS rules and procedures, except as provided otherwise herein.

(ii) The arbitration shall be commenced by filing a demand for arbitration with JAMS and with the other party to this agreement.

(iii) There shall be one neutral arbitrator mutually agreed upon by both parties within 30 days after initiation of arbitration, and if the parties are unable to agree upon an arbitrator, the arbitrator shall be selected in accordance with JAMS rules.

(iv) The arbitration shall be limited to the single issue of determining whether Komen may require Grantee Institution to dispose of the Invention rights as described in (b) above.

(v) The parties to the arbitration shall be the Grantee Institution, Komen, and, if Grantee Institution elects, the licensee (if any).

(vi) The arbitration shall be limited to one day, with no discovery (subpoenas may be issued to compel the appearance of witnesses and the production of documents at the arbitration).

(vii) The expenses and fees of the arbitrator and the administrative fees of the JAMS shall be divided equally between the parties. Each party shall pay its own counsel fees, witness fees, and other expenses incurred for its own benefit.

(viii) Arbitration shall not be utilized if Grantee Institution is prohibited by law from submitting itself to binding arbitration.

No patent or patent application, copyright or other intellectual property right will be abandoned without prior notification to Komen and without giving Komen the opportunity to take title to the Invention to the extent permitted by law. If the Grantee Institution has no established and applicable patent, intellectual property, or technology transfer policy, and procedure for administering Inventions, Komen shall have the sole right to determine the disposition of the Invention rights in a manner consistent with this Policy. In such cases, Komen may, in its sole discretion, elect to do one or more of the following:

(a) Have a patent and/or copyright application filed, and decide to whom it shall be assigned. In such case, the Institution and inventor shall execute all documents necessary to assist in the filings and the assignment;

(b) Decide that patent or copyright should be or not be filed;

(c) Release the Invention to the inventor or inventor's designee;

(d) Submit the Invention to a qualified organization for administration and licensing;

(e) Determine by negotiation the fair share of royalty income to be paid to the inventor, the Grantee Institution, Komen, and any other parties who contributed funds that supported the Invention; or

(f) License or make other arrangements for the application and use of the Invention on an exclusive or non- exclusive, royalty-free basis as seems reasonable in the circumstances.

Notwithstanding any other provisions of this policy, if an Invention is derived from research funded by the joint support of Komen and an agency or department of the United States government, Komen shall defer to the patent, intellectual property, or technology transfer policy of that agency or department upon receipt of a written statement notifying Komen of such policy and procedure and identifying the rights and interests of Komen in the Invention.

If any Invention is funded by the joint support of Komen and a health agency or funding organization, other than an agency or department of the United States government, and that other agency or organization has an intellectual property policy that conflicts with Komen's policy, the other agency/organization, the investigator, the Grantee Institution, and Komen shall negotiate in good faith a mutually satisfactory disposition of the Invention rights.

APPENDIX A

APPENDIX A – GRANT AGREEMENT FOR RESEARCH AND TRAINING GRANTS

KOMEN RESEARCH PROGRAMS

Susan G. Komen's mission is to save lives by meeting the most critical needs in our communities and investing in breakthrough research to prevent and cure breast cancer. Komen has set a Bold Goal to reduce the current number of breast cancer deaths by 50 percent in the U.S. by 2026.

Grant Agreement

for Research and Training Grants

Susan G. Komen
5005 LBJ Freeway, Suite 250
Dallas, Texas 75244
Research Programs Help Desk: 1-866-921-9678
Email: researchprograms@komen.org
Website: www.komen.org/researchhelpdesk

SUSAN G. KOMEN®

Grant Agreement for Research and Training Grants

Principal Investigator Last Name,	***First Name,***	***Middle Initial***	***Degree***	***Grant Number***

Effective as of [start date] through [end date]

Grantee Institution	***Grant Term***
	US$[**amount**]
Research Project Title	***Grant Amount***

In consideration of the above-referenced grant ("Grant") from The Susan G. Komen Breast Cancer Foundation, Inc. d/b/a Susan G. Komen ("Komen") and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the above-referenced Principal Investigator ("PI") and the Grantee Institution (collectively, the "Grantees") and Komen agree to comply with the following terms and conditions. All terms not defined herein shall have the meanings assigned to them in Komen's *Research and Training Grant Policies and Procedures,* issued on March 30, 2018*,* as may be revised from time to time (the "Policies"). At Komen's discretion, this Agreement shall be deemed null and void if not executed by all the parties on or before [date].

1. **Policies:** The Grantees represent that they have read and understood the Policies, which are incorporated herein by reference and deemed an integral part of this Agreement. Komen may revise the Policies at any time, with 30 days' prior notice via email to the Grantees and shall post the revised Policies in pC. In the event of any conflict between the Agreement and the Policies, the terms of the Agreement shall prevail.

2. **Certifications, Representations and Covenants:**

(a) The Grantees certify that to the best of their knowledge, the information provided in their grant application (the "Application") is complete and true. The Grantees agree to promptly notify Komen of any changes to the information provided in the Application.

(b) The Grantees represent and agree that any research or activities conducted in connection with the project funded hereunder (the "Research Project") that might involve human subjects comply with the Health Insurance Portability & Accountability Act of 1996 (HIPAA); have been approved by an Institutional Review Board (IRB), or international local ethics board equivalent; will be performed by institutions or entities with an Office of Human Research Protection (OHRP) assurance or international equivalent; and will be guided by one of the following statements of ethical principles: (i) The World Medical Association's Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects; (ii) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or (iii) other appropriate international ethical standards recognized by U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

(c) The Grantees agree that any research involving the use of human specimens, cells, cell lines or data involving human subjects will comply with the applicable requirements of the National Institutes of Health Office of Extramural Research. Grantees from outside the United States agree to comply with the guidelines established by an international equivalent governing the use of human biological and/or anatomical materials.

(d) The Grantees agree that wherever applicable, the research protocol will be reviewed and approved by the Grantee Institution's biohazards committee and conform to the relevant Public Health Service ("PHS") guidelines. Grantees from outside the United States agree that they will comply with the guidelines established by an international equivalent governing the use of bio-hazardous materials.

(e) The Grantees represent that any research involving animals has been approved by an Institutional Animal Care and Use Committee (IACUC) or international animal welfare board equivalent; and agree that the research will be guided by the current PHS Policy on Humane Care and Use of Laboratory Animals or the International Guiding Principles for Biomedical Research Involving Animals.

(f) The Grantee Institution represents that it has in effect an up-to-date written and enforced administrative process to identify and manage financial conflicts of interests and agrees to follow this process with respect to the Research Project. At Komen's request, Grantee Institution will provide Komen with information and/or documentation evidencing Grantee Institution's compliance with this process.

(g) The Grantees represent that they have not accepted and will not accept funding from another source which results in an overlap in funding for the Research Project.

(h) Each signatory for each entity that is a party to this Agreement represents in his or her capacity as an authorized signatory of such party, and not individually, that he or she has the capacity and has been duly authorized to execute this Agreement on behalf of the entity so indicated and that no additional authorization or approval is required.

(i) Each entity party represents that it has all the requisite power and authority to execute, deliver and perform this Agreement and consummate the transactions contemplated hereby. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized and approved by all required action on the part of such party. This Agreement has been duly and validly executed and delivered by each party and constitutes the legal, valid and binding obligation of such party, enforceable against it in accordance with its terms.

(j) The Grantee Institution represents that none of the execution and delivery of this Agreement by the Grantee Institution, the consummation of the transactions contemplated hereby or compliance by the Grantee Institution with any of the provisions hereof conflict with, or result in any violation of or default under (with or without notice, the lapse of time or both) or give rise to a right of termination or cancellation under any provision of: (i) the certificate of formation of the Grantee Institution; (ii) any contract or permit to which the Grantee Institution is a party or (iii) any applicable law or any order of any governmental body.

3. **Reports:** The Grantees will provide Komen with scientific progress reports and financial reports for the Research Project in the format required by Komen and in accordance with the schedule set forth in the Policies.

4. **Grant Payments, Use and Remittance of Funds:**

(a) For Grants under $500,000.00, Komen will disburse the first 12-month period's approved budgeted Grant funds within 30 days of the effective date of this Agreement. For each subsequent 12-month period, excluding the final 12-month period of the Agreement, Komen will disburse 100% of the approved budgeted funds for such 12-month period after review and approval of a satisfactory and timely scientific progress

report and financial report for the prior 12-month period, updated IACUC/IRB approvals (as applicable), and any other documents requested by Komen for its approval. For the final 12-month period of the Agreement, Komen will disburse 60% of the approved budget funds after review and approval of a satisfactory scientific progress report and financial report for the prior 12-month period, updated IACUC/IRB (as applicable), and any other documents requested by Komen for approval. The remaining 40% of funds will be disbursed upon receipt of a satisfactory final scientific progress report, final financial report, and any other documents required by Komen.

(b) For Grants of $500,000.00 or more, Komen will pay Grant fund installments on a bi-annual basis. Komen will disburse 50% of the first 12-month period's approved budgeted Grant funds within 30 days of the effective date of the Agreement and the remaining 50% upon review and approval of a satisfactory biannual financial report due after the first six months and any other documents required by Komen for its approval.

For each subsequent 12-month period, excluding the final 12-month period of the Agreement, Komen will disburse 50% of the approved budgeted funds after review and approval of a satisfactory annual scientific progress report and a biannual financial report for the prior period, updated IACUC/IRB approvals (as applicable), and any other documents required by Komen for its approval. The remaining 50% of the approved budgeted funds will be disbursed upon the review and approval of a satisfactory biannual financial report and any other documents required by Komen.

For the final 12-month period of the Agreement, Komen will disburse 60% of the approved budgeted funds after review and approval of a satisfactory annual scientific progress report and biannual financial report for the prior period, updated IACUC/IRB (as applicable), and any other documents required by Komen for approval. The remaining 40% of funds will be disbursed upon review and approval of a satisfactory final scientific progress report, final financial report, and any other documents required by Komen.

(c) Notwithstanding the provisions of (a) and (b) above, Komen may require the Grantees to deplete the current installment of the Grant funds (including any accrued interest thereon) prior to receiving the payment of the next installment of the Grant funds.

(d) The Grant funds shall be used exclusively for the Research Project, as described in the budget in the Application; provided, however, that the Grantees at their discretion and without a formal request may move up to 20% of total Grant funds across budget line items. Notwithstanding the above, Grant funds may not be moved across budget line items, if the result exceeds any maximum allowable cost set for a budget line item, such as equipment or indirect costs. Any accrued interest on Grant funds shall be accounted for by the Grantees and used solely for the Research Project.

(e) The Grant funds awarded hereunder may not be obligated or expended prior to the effective date of this Agreement or subsequent to the termination of this Agreement, except to liquidate authorized obligations in accordance with the Policies.

(f) After Komen's review of the final scientific and financial reports, Komen shall send Grantees an invoice for unexpended Grant funds. Within 30 days after receipt of the invoice, Grantees shall remit all unexpended Grant funds (including any accrued interest thereon) to Komen pursuant to the instructions in the invoice.

5. **Early Termination:**

(a) The Grantees may terminate this Agreement for any reason upon written notification to Komen and in accordance with the Policies. Within 30 days of the early termination date agreed to by Komen, the Grantees shall provide Komen with a final scientific progress report, which shall include all information available as of the termination date. Within 60 days of the early termination date agreed to by Komen, the Grantees shall provide Komen a final financial report, and after Komen's approval of the final financial report, reimbursement of

all unexpended funds (including any accrued interest thereon).

(b) If any of the Grantees should fail to perform or be in breach of any of the representations, covenants, or obligations contained in this Agreement, or anticipatorily breach this Agreement, and such default is not curable or such default is curable but remains uncured for 30 days after written notice thereof has been given to the Grantees, Komen, at its sole election, may immediately terminate this Agreement with written notice to the Grantees.

(c) Komen has the right to terminate this Agreement immediately in the event of the occurrence of any one or more of the following events:

(i) Grant funds cannot reasonably be expended in accordance with the budget;

(ii) Komen does not receive a scientific progress report and/or financial report when due and/or such report(s) do not contain the required information or the information included does not reflect that satisfactory progress has been made on the Research Project, as determined by Komen in its sole discretion;

(iii) The personnel and/or the Research Project change(s) and any or all of these changes are not previously approved in writing by Komen;

(iv) Grantee Institution loses or changes its status as a governmental organization described in Section 170(c)(1) or a nonprofit organization described in Section 501(c)(3) of the Internal Revenue Code (or for non-U.S. Grantee Institutions, the international equivalent);

(v) Grantee Institution or PI is debarred from the receipt of federal or state funding;

(vi) PI is absent from or leaves the Grantee Institution without 60 days prior notification to and receipt of written approval from Komen;

(vii) PI transfers to another institution without consensus among Komen, PI, and original and new Grantee Institutions about the transfer of the Research Project;

(viii) Grantee Institution and PI fail to receive and maintain the IRB and/or IACUC (or other clearly designated appropriate bodies of Grantee Institution) approval of the Research Project or any other required approvals;

(ix) Grantee Institution or PI fails to comply with the obligations under "Intellectual Property and Royalties" and "Required Grant Reports and Required Document Renewals" in the Policies and other material terms and conditions of this Agreement; or

(x) Grantee Institution or PI commits a willful breach of this Agreement or an act of gross negligence or willful misconduct in connection with the Research Project.

(d) In the event of an early termination due to a breach under Section 5(b) or any of the events referenced in Section 5(c), the Grantees shall provide Komen within 30 days after the termination date a final scientific progress report, which shall include all information available as of the termination date; and within 60 days (i) a final financial report; (ii) reimbursement for the full amount of funds granted that have been expended in connection with and subsequent to a breach under Section 5(b) or any of the events referenced in Section 5(c); and (iii) a refund of all unspent funds (including any accrued interest thereon) as of the termination date.

(e) Komen has the right to terminate this Agreement immediately in the event it has a reasonable good faith basis to believe there has been scientific misconduct, financial or administrative impropriety, or fraud committed by PI or the Grantee Institution. In the case of an early termination under this provision, the Grantees shall provide Komen within 30 days after termination a final scientific progress report and within 60 days after termination a final financial report and reimbursement of all Grant funds (including any accrued interest thereon).

6. **Compliance with Laws:** The Grantees agree to comply with all applicable laws and regulations in connection with the Grant and the Research Project. The Grantees agree that the Grant funds awarded hereunder shall be expended in accordance with all applicable anti-terrorist financing and asset control laws, statutes, and executive orders, including but not limited to the U.S. Patriot Act and U.S. Executive Order No. 13224; all U.S. sanctions laws and regulations; the Foreign Corrupt Practices Act of 1977, as amended, and other applicable anti-bribery laws and regulations.

7. **Liability and Insurance:**

(a) Grantee Institution shall be responsible for all aspects of the research, investigation, funding, and administration of or in connection with the Research Project.

(b) To the extent permitted under the international, federal, state, and local laws which govern the Grantee Institution, the Grantee Institution shall indemnify and hold Komen harmless from and against any and all costs, losses, or expenses, including reasonable attorneys' fees, that Komen may incur by reason of the Grantee Institution and/or PI's negligence or misconduct or any third-party claim arising out of or in connection with the Research Project. If this provision is prohibited under the laws that govern the Grantee Institution, then this provision shall be deemed unenforceable and shall have no force and effect.

(c) In the event of any dispute arising out of this Agreement, the parties shall use good faith efforts to resolve their differences amicably. In the event they are unsuccessful, the parties agree not to commence litigation until attempting to resolve their dispute through mediation. Either Komen on the one hand or the Grantees on the other hand may initiate the mediation process with 30 days prior written notice to the other party. Mediation of the dispute shall be completed within 15 days of commencement, unless the parties extend the time by mutual agreement or unless the mediator declares the parties to be at an impasse.

(d) Grantee Institution shall be required to maintain adequate liability insurance comparable to coverage held by institutions of similar size and nature, covering the PI, employees, officers, and agents of Grantee Institution for the duration of the Research Project. Komen may request to be provided certificates evidencing the insurance coverage at any time during the Grant Term.

8. **Record Keeping Requirements and Audit:** The Grantees agree to maintain accurate and complete records for this Grant and any Inventions related thereto, for a period of five years from the earlier of the termination or expiration of this Agreement and agree that Komen may conduct an audit of such records at any time, during regular business hours as reasonably requested in advance and in writing by Komen.

9. **Relationship of Parties and No Guarantee of Additional Support:** The nature of this arrangement is a funding agreement, and no employment, partnership, joint venture, or agency relationship is created. The Grant is accepted by the Grantees with the understanding that Komen is not obligated to provide any additional financial support, or other support in connection with the Research Project or for any other reason.

10. **Modification of Agreement:** Komen reserves the right to modify the terms or conditions of this Agreement with 30 days' prior notice via email to the Grantees and shall also post the modifications in pC.

11. **No Third Party Beneficiaries:** No provisions in this Agreement shall in any way inure to the benefit of any third party.

12. **Entire Agreement; Severability:** This Agreement supersedes all prior understandings or oral or written agreements between the parties regarding the subject matter hereof and constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof. The finding by any court of competent jurisdiction that any provision of this Agreement or part thereof is unenforceable shall not affect the enforceability of the remaining provisions of this Agreement. If and to the extent any provision of this Agreement is found to be prohibited under, contrary to, or ineffective under any existing or future law, this Agreement shall be considered amended to the smallest degree necessary to make this Agreement conform to such law and be effective there under.

13. **Assignment:** None of the Grantees may assign any rights or obligations under this Agreement without Komen's prior written consent. In the absence of such prior written consent, any such assignment will be void.

14. **Survival:** The terms of Sections 2, 3, 4, 6, 7, 8, 11 and 14 of this Agreement and the provisions of "Submission of Required Documents", "Required Grant Reports and Required Document Renewals", "Acknowledgment of Komen Funding and Komen Rights to use Research Project Materials" and "Intellectual Property and Royalties" in the Policies shall survive the termination of this Agreement. The Grantees hereby acknowledge and agree that after the termination or expiration of this Agreement, they will comply with their continuing obligations as set forth in the aforementioned provisions.

15. **Counterparts:** This Agreement may be executed by the parties hereto in counterparts, including by facsimile transmission, each of which when so executed shall be deemed an original and all of which together shall constitute one and the same Agreement.

AGREED TO AND ACCEPTED:

GRANTEE INSTITUTION:_____

Signing Official Signature: _____

Signing Official Printed Name: _____

Signing Official Title: _____

Date:_____

PRINCIPAL INVESTIGATOR:

Principal Investigator Signature: _____

Principal Investigator Printed Name: _____

Principal Investigator Title: _____

Date:_____

THE SUSAN G. KOMEN BREAST CANCER FOUNDATION, INC.

d/b/a SUSAN G. KOMEN:

Signing Official Signature: _____

Signing Official Printed Name: _____

Signing Official Title: _____

Date: _____

APPENDIX B

APPENDIX B – KEY ELEMENTS TO CONSIDER IN PREPARING A DATA SHARING PLAN UNDER NIH EXTRAMURAL SUPPORT

APPENDIX B: KEY ELEMENTS TO CONSIDER IN PREPARING A DATA SHARING PLAN UNDER NIH EXTRAMURAL SUPPORT

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

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

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

What data will be shared?

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

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

Who will have access to the data?

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

- Will the general public have access to some or all of the data?
- Will access to certain data or certain components of the data be restricted to qualified researchers, e.g., to address specific rules, laws, regulations or policies (e.g., IRBs, human subjects, informed consent, etc.)?
- If data access is restricted, what are the justifications/criteria for restricting access (e.g., relevant laws (local, State, Federal, etc.), regulations, rules, institutional policies, IRB approvals, and consent documents)?
- What will researchers who seek to obtain data need to do to comply with any data access restrictions?
- Are there any limitations on release of data that may be considered “sensitive”?
- What data sharing agreements will be necessary to appropriately restrict the transfer of protected, sensitive, or confidential data to others and to require that data be used only for research purposes?

- Who will be operationally responsible for ensuring that no personally identifiable information is made available (e.g., principal investigator, independent curator)?

Where will the data to be shared be located?

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

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

When will the data be shared?

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

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

How will researchers locate and access the data?

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

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

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