RESEARCH FUNDING GUIDELINES

Single or Collaborative Grants Supporting
Patient-centered Phase I and Phase II Clinical Trials

GATEWAY FOR CANCER RESEARCH℠

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1. Organizational Overview

A. History

Since 1991, Gateway for Cancer Research has been creating a world in which a cancer diagnosis is no longer feared. Founded by Richard J Stephenson as part of a personal quest to transform cancer by empowering patients with integrative therapies and innovative treatment options, Gateway has supported over 120 clinical trials in under 25 years.

B. Vision

To shape a world in which a cancer diagnosis is no longer feared.

C. Mission

To fund meaningful and breakthrough clinical trials worldwide that help people living with cancer to feel better, live longer, and conquer cancer TODAY!

2. Focus of Research Investments[1]

A. Patient-Centric

We focus on the patient. Gateway has always honored the *people* at the heart of a clinical trial; people whose enrollment helps us find better treatments for all. It is important to recognize that we fund research that benefits patients and not only science. Therefore, we invest in clinical trials that place patient outcomes and well-being at the heart of study design and implementation, emphasizing support for those trials that have the greatest potential to reach clinical practice or change treatment guidelines for future patients.

B. Innovative Clinical Trials

Gateway focuses its investments on truly innovative human clinical trials, which test integrative methods of treatment to advance the field beyond more conventional, toxic therapies. For individual patients as well as the future of cancer treatment, clinical trials represent the best probability of ending cancer while minimizing negative impacts on quality of life. We invest in clinical trials in the following basic research areas for all cancer types:

- Integrative Medicine[2]
- Novel use/combination of existing drugs; and/or
- New therapy/drug discoveries

Further, we seek to bring urgency to the somewhat tedious and slow process of cancer research for those patients who are looking for treatments today and are faced with difficult decisions without good options. Therefore, Gateway will place increasing emphasis on the funding of research that includes truly innovative concepts or approaches with a high potential for success, including:

- Personalized medicine that identifies who may benefit from investigational intervention (e.g. genetic, molecular targets); and/or

[1] See Attachment A for Gateway's Glossary of Key Terms, as needed for clarification.
[2] Integrative Medicine studies must focus on accelerating treatment and not quality of life alone.

- New and emerging treatment modalities, such as immunotherapy, targeted drugs and other more nascent therapies, which may be combined with complementary therapies.

For Gateway, personalized medicine (precision medicine) is defined as: Treatment precisely customized to the characteristics of each individual's tumor and host. Personalized medicine may include complementary therapies, immunotherapies, genomic therapies, and patient preferences. Personalized medicine may include N-of-1 studies, but is not limited to these types of studies. In oncology, personalized medicine and precision medicine are interchangeable.

C. Integrative Oncology

Believing patients' best option to fight cancer is through an integrative oncology model, Gateway strives for a balanced research portfolio consisting of 40% novel use/combination of existing drugs, 40% integrative therapies, and 20% new therapy/drug discoveries. Also, we are always seeking to stimulate cutting-edge research that attempts to use combination therapy. Note: The share of investment in new drug discoveries is lower because the likelihood of failure is high and the development phase is commonly years, if not decades away.

3. Funding Requirements

All grantee organizations funded by Gateway must meet the requirements listed at the time of application, as well as throughout the term of the grant contract[3], if received.

A. Phases of Research

Gateway supports phase I and II clinical studies that are treatment-based and focused on therapeutic approaches that have the potential to change the standard of care for human cancer patients. This includes traditional and integrative therapies, including: Integrative Medicine, novel use/combination of existing drugs; and/or new therapy/drug discoveries.

1) Gateway does **not** fund:
    i. Studies that focus only on pharmacokinetics with no clinical activity;
    ii. Basic research and pre-clinical research in animals; or
    iii. Early prevention, detection, retrospective, educational studies, or Comparative Effectiveness Research (CER) studies.

2) Translational research with human bio specimens (human tissue samples, blood, urine, etc.) may be considered if:
    i. It directly leads to or supports the clinical trial in the grant application; and/or
    ii. It is used to interrogate the tissues of patients within a trial to understand actual patient response[4] or toxicities experienced to inform future work.

[3] See Attachment B for Gateway's Master Terms and Conditions for all grantee contracts.
[4] Specifically, in an effort to identify patient responders from non-responders and to move towards more personalized and targeted therapies, special focus will be placed on investigation of super-responders.

B. Geographic Location of Grants

Since Gateway is interested in accelerating the pace of cancer research, we will consider funding requests from organizations conducting high quality research outside of the United States, provided that they are able to:

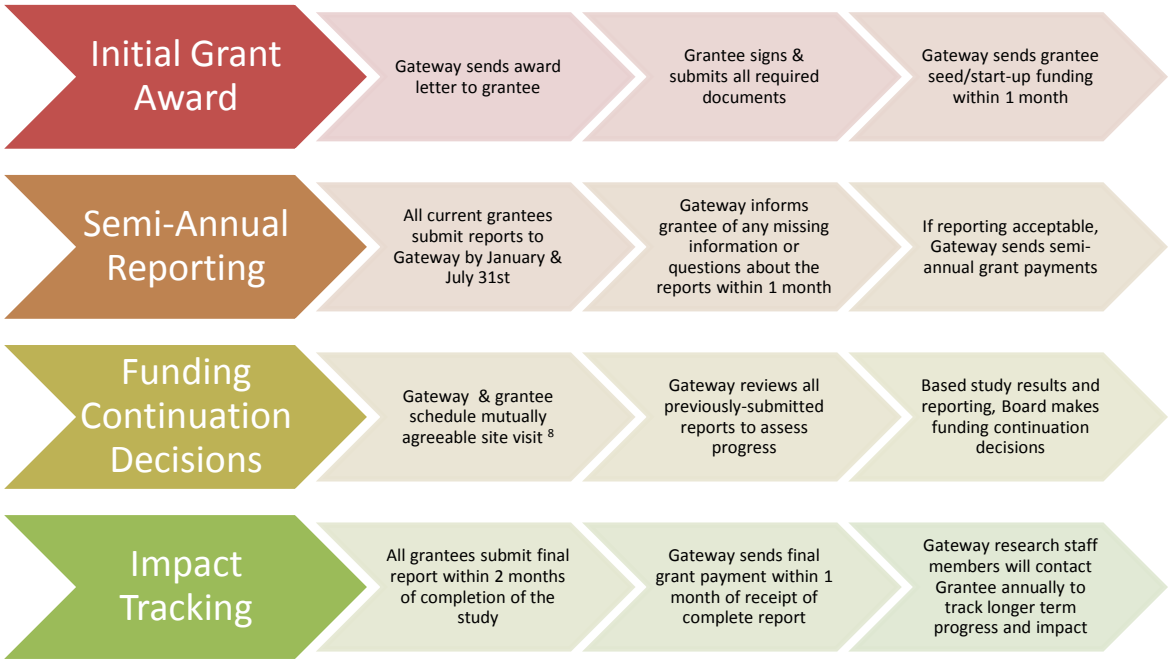
1) Demonstrate a clear fit with Gateway's focus on funding patient-centered, Phase I & Phase II clinical trials;
2) Adhere to all Gateway contract provisions; and
3) Submit all application, reporting, documentation and regulatory approvals in English and using US Dollars as the monetary unit.

C. Outcome Reporting

Each study funded must be prepared to provide progress and financial reports to Gateway on a semi-annual basis for the duration of the grant contract. This reporting will include, as appropriate, consultation with patient representatives[5], as well as robust patient-centered outcomes that include comprehensive quality of life measures, response to treatment, and survival rates. In addition, grantees are required to submit a final study report that captures the results of the study in its entirety, including achievement of expected milestones, patient impact, total expenditures, plan for publication/sharing of findings, and anticipated next steps for the study. Finally, grantees are asked to respond to annual Gateway brief follow-up contacts to track the longer term impact of the funded study. (See Attachment C for more details about the reporting.)

In general, the Gateway award and reporting process will proceed as summarized in the chart below, with all documents, semi-annual and final reports submitted via the Gateway online grant management system (GMS)[6]. Also, as grantees expend the funding allocated for each year, Gateway will review the reports submitted to date, in order to determine if the grant will be continued[7] for a second or third year within the original grant term.

[5] See Attachment A (glossary) for definition.
[6] New grantees will not be required to submit reports during the first quarter of their grant, and will instead wait until the next six month report.
[7] These decisions will be based upon two key factors: 1) meeting study milestones (chiefly accruals); and 2) responsiveness to Gateway communications and reporting requirements.
[8] At Gateway's discretion.



4. Requests for Funding

Gateway has a rolling request for funding process that is conducted in two stages through a Letter of Intent (LOI) and then, if invited, a full application. All applicants must submit their LOI's and applications via Gateway's online Grant Management System found at: https://gatewaycr.fluidreview.com

A. Letter of Intent

Through Gateway's Letter of Intent submission process, initial study ideas are reviewed for alignment with Gateway's stated mission and vision. By eliminating study ideas inconsistent with our mission and purpose, researchers save the time it takes to prepare full applications. On its most basic level, the Letter of Intent (LOI) will include questions about the basic project description (in English), the grant request, your fit with Gateway's basic funding guidelines, and contact information. Upon complete submission of all required information for the Letter of Intent, staff members will review and decline all submissions that do not meet the above basic funding requirements. (Please see Attachment D for a summary of LOI content.)

Should the LOI meet basic requirements, it will be reviewed and evaluated by a subset of the Gateway Board of Scientific Counselors to determine if it is a strong enough fit with Gateway's funding guidelines to continue to the next phase of the application process. After this review, you will be notified of next steps, including submission of our full grant application for funding, which is by invitation only. *Approximately 1/3 of the Letters of Intent received by Gateway make it through the full application process and are funded at their full grant request for 1-3 years.*

B. Full Application

If invited, the applicant will submit the full application through the same online Grant Management System used for the LOI, building upon the information already submitted to give Gateway a thorough picture of the proposed research study, which will be reviewed and scored by Gateway's convened Board of Scientific Counselors, as described below. The application will build upon the information supplied by the applicant in the LOI by asking for further documentation to demonstrate the study's readiness to begin, such as IRB approvals, the full project budget with other sources of funding, and similar information. It is Gateway's intent to provide funding for studies that would not otherwise be able to move ahead without its support, but that are ready to move ahead as soon as possible to begin testing new interventions and therapies to help patients more quickly. (Please see Attachment E for a summary of the additional application content.)

5. Funding Decisions

Gateway's Board of Scientific Counselors will evaluate all proposals and make recommendations to the Board of Directors for funding decisions at their quarterly meetings. The criteria to determine a fundable project are innovation and originality, feasibility, significance and patient impact, conformity with Gateway's mission, and reasonable budget. In addition, the grant should contribute to an independent research project and cover a substantial scientific part of the project.

6. Gateway Research Grants Contacts

For more information about the funding process, please reach out to the following Gateway Research Department contacts:

Jerian Dixon-Evans
Research Grants Specialist
e. Jerian.Dixon-Evans@gatewaycr.org
p. (847) 342-7361

Domarina Oshana, Ph.D.
Director of Research and Grants
e. Domarina.Oshana@gatewaycr.org
p. (847) 342-7443

Attachment A: Glossary of Key Terms

Biobehavioral: relating to, or involving the interaction of behavior and biological processes.

Clinical Practice Guidelines: Guidelines developed to help health care professionals and patients make decisions about screening, prevention, or treatment of a specific health condition.

Clinical Study: A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Also called clinical trial.

Clinical trial phase: A part of the clinical research process that answers specific questions about whether treatments that are being studied work and are safe. Phase I trials test the best way to give a new treatment and the best dose. Phase II trials test whether a new treatment has an effect on the disease. Phase III trials compare the results of people taking a new treatment with the results of people taking the standard treatment. Phase IV trials are done using thousands of people after a treatment has been approved and marketed, to check for side effects that were not seen in the phase III trial.

Combination Therapy: Therapy that combines more than one method of treatment. Also called multimodality therapy and multimodality treatment.

Comparative Effectiveness Research (CER): Systematic research that compares interventions and strategies to prevent, diagnose, treat, and monitor health conditions. The purpose of this research is to inform patients' providers and decision-makers, responding to their expressed needs about which interventions are most effective for which patients under specific circumstances.

Consultation with patient representative: Study incorporates consultation with patient representatives in one or more of the following ways: 1) including patient representative on your study team in a meaningful way; 2) involving patient representatives or patients in the design of the study; 3) having conducted research to determine what questions are important to the specific patient population; and 4) PI/Co-PI and/or treating physician are available to patients for questions/consultation.

Epigenetics: The study of how age and exposure to environmental factors, such as diet, exercise, drugs, and chemicals, may cause changes in the way genes are switched on and off without changing the actual DNA sequence. These changes can affect a person's risk of disease and may be passed from parents to their children.

European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): a questionnaire developed to assess the quality of life of cancer patients.
It is a copyrighted instrument, which has been translated and validated into 81 languages and is used in more than 3,000 studies worldwide. Presently QLQ-C30 Version 3.0 is the most recent version and should be used for all new studies. http://groups.eortc.be/qol/eortc-qlq-c30

FACT-G: Functional Assessment of Cancer Therapy - General (now in Version 4): a 27-item compilation of general questions divided into four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. It is considered appropriate for use with patients with any form of cancer. It can be found here: http://www.facit.org/FACITOrg/Questionnaires

Herth Hope Index: a 12-item interview containing three dimensions: temporality and future, positive readiness and expectance, and interconnectedness. Tested on family caregivers of terminally ill people and terminally ill persons, as well as in community and hospital patients and family members. Found through CAM Research Network: http://www.incamresearch.ca/content/herth-hope-index

Integrative Medicine: A form of treatment that incorporates standard treatments with complementary therapies that are intended to treat the whole person and best address an individual's unique needs and circumstances. Unlike standard treatments that go through a long and careful research process to prove they are safe and effective, less is known about complementary treatments. Complementary methods may include dietary supplements, megadose vitamins, herbal preparations, special teas, acupuncture, massage therapy, magnet therapy, spiritual healing, and meditation.

Overall Survival Rate: The percentage of people in a study or treatment group who are still alive for a certain period of time after they were diagnosed with or started treatment for a disease, such as cancer. The survival rate is often stated as a five-year survival rate, which is the percentage of people in a study or treatment group who are alive five years after their diagnosis or the start of treatment. Also called survival rate.

Patient-Centered: Per Gateway's research mission, patient-centered research "improves cancer treatment outcomes, restores cancer patients' quality of life and has potential to positively impact the lives of cancer patients at the earliest opportunity"

Personalized medicine (Precision Medicine): Treatment precisely customized to the characteristics of each individual's tumor and host. Personalized medicine may include complementary therapies, immunotherapies, genomic therapies, and patient preferences. Personalized medicine may include N-of-1 studies, but is not limited to these types of studies. In oncology, personalized medicine and precision medicine are interchangeable.

Progression-free Survival: The length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works. Also called PFS.

Quality of Life: The overall enjoyment of life. Many clinical trials assess the effects of cancer and its treatment on the quality of life. These studies measure aspects of an individual's sense of well-being and ability to carry out various activities.

Standard of care: Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.

Targeted Therapy: A type of treatment that uses drugs or other substances to identify and attack specific types of cancer cells with less harm to normal cells. Some targeted therapies block the action of certain enzymes, proteins, or other molecules involved in the growth and spread of cancer cells. Other types of targeted therapies help the immune system kill cancer cells or deliver toxic substances directly to cancer cells and kill them. Targeted therapy may have fewer side effects than other types of cancer treatment. Most targeted therapies are either small molecule drugs or monoclonal antibodies.

Translational Research: A term used to describe the process by which the results of research done in the laboratory are used to develop new ways to diagnose and treat disease. Describes efforts directed toward converting basic and clinical research discoveries into new clinical and research tools, medications and therapies.

Attachment B: Gateway Master Terms & Conditions

As used in this Research Funding Terms and Condition ("Terms and Conditions"), "Grant" means any type of funding received from Gateway for Cancer Research, Inc., an Oklahoma not- for- profit corporation ("Gateway"), including without limitation, from research grants and other awards.

1. Eligibility

The applicant seeking Gateway funding must be employed at a for-profit or non-profit organization or institution (each referred to as a "Grantee Institution") within the United States or any other foreign country where supervision of grant administration is possible. Such Grantee Institution must agree to be bound by the present Terms and Conditions by signing this document through its duly authorized representative. If the grant application is approved, Grantee Institution, except in unusual circumstances, will be the official recipient of Gateway's funding, receive such funding on behalf of the successful applicant ("Recipient"), and will be solely responsible for the handling and disbursing of such funds in support of the Recipient's research.

It is expected that the person indicated as the principal investigator in an application for a grant is the one who is personally and actively responsible for the conduct of the research and who is considered eligible by his or her Grantee Institution to apply for a research grant.

2. Award Process

Gateway uses a two phase grants application process. Letters of intent are accepted year around. If deemed relevant and of interest, applicants will be invited to submit a full grant application. Full grant applications will be reviewed quarterly by Gateway Board of Scientific Counselors ("BSC") and ranked on the basis of novelty, scientific merit, direct patient impact, relevance, and other factors as determined by Gateway. The BSC will make recommendations to Gateway Board of Directors ("BOD"), which makes the final award decisions in its sole discretion. Recipient and the Grantee Institution will be notified with an award letter of the duration and amount of the grant.

3. Disbursements

As Gateway is committed to support clinical trials that have a meaningful therapeutic impact for enrolled subjects in terms of better, less toxic treatment options and improved quality of life, a milestone driven pay-per-patient payment system is used. Gateway makes payments on approved Grants based on each new patient enrolled and treated and as reported on the Semi-Annual update form. From the total approved grant budget, after deduction of seed money and withholding for final research report and/or publication of research data in a scientific peer reviewed journal, Grantee Institution will be paid a certain amount for each subject treated in the study. All seed money provided by Gateway to the Grantee institution must be restricted for use on Gateway-funded research only, and may not be used for other purposes.

Continued disbursement is not automatic and is subject to Recipient's satisfactory progress as determined by Gateway based on semi-annual reports provided by the Recipient, and adherence to the further requirements and limitations set forth in these Terms and Conditions.

Safeguarding the rights and welfare of human subjects involved in activities supported by grants from Gateway for Cancer Research is the responsibility of the Grantee Institution. Grantee Institution hereby agrees that it shall assume full responsibility and liability for the care and treatment of the study subjects involved in the study as well as full responsibility for any study subject claims. Grantee Institution shall hold Gateway for Cancer Research harmless from any and all liability arising out of any such claims.

4. Unused Funds and Unallowable Costs

Because budgets in applications for Grants are estimates of the funds required to perform the research indicated, unexpended funds may remain at the end of each year and at the termination of the Grant. Unexpended funds remaining at the termination of the Grant must be returned to Gateway.

The following costs are not allowable under Gateway research grants programs:

(i) Institutional overhead (indirect costs)
(ii) New construction and alterations or renovations of existing facilities

(iii) Consultant fees, capital equipment, and computer hardware or software, unless specified in the original Application and approved by Gateway
(iv) Travel costs, unless approved by Gateway.

5. Public Relations

The Recipient of a Grant agrees to the announcement of such award in media chosen by Gateway, and will provide a recent photograph of himself/herself for publication on Gateway's website, or elsewhere as desired by Gateway. Recipient will also provide the name of a contact within Grantee Institution's public relations department so that Gateway can coordinate the release of PR around the issuance of the grant.

Public acknowledgement of the Gateway for Cancer Research grant award is required. For purposes of publicizing the award, Gateway expects use of the following boilerplate in any press releases acknowledging Gateway:

About Gateway for Cancer Research℠

Gateway for Cancer Research is a nonprofit 501(c)(3) organization committed to funding innovative cancer research that helps people with cancer to feel better, live longer and conquer cancer TODAY! Thanks to generous underwriting, 99 cents of every dollar Gateway receives directly funds Phase I and Phase II cancer clinical trials at leading research institutions across the country and abroad. Since 1991, Gateway has supported more than 140 clinical trials and funded millions in breakthrough research. Get involved today by visiting GatewayCR.org, like us on Facebook at facebook.com/demandcures and join the conversation on Twitter @DemandCures, #BeAGateway.

6. Conditions of Award

A. Progress Reports
Each disbursement of funding awarded pursuant to a Grant is contingent upon Recipient's demonstration of progress that is satisfactory to Gateway in its sole discretion. Recipient will be required to submit written reports to Gateway as described herein or upon request by Gateway describing progress made on research. Accordingly, Recipient will submit semi-annual updates ("Semi-annual Report") after initiation of clinical trial to report on patient accrual, health status, findings, and grant expenditures. The template Semi-annual Report will initially be made available by Gateway. Thereafter, Recipient is responsible for timely submission through the Gateway Grant Management System

After the expenditure of first-year funding, Gateway will review the semi-annual reports submitted by the Grantee to date, in order to determine whether funding should be continued for the study in the second and/or third year, as applicable. Funding continuation decisions will depend upon timely reporting and adequate progress toward meeting the milestones outlined in the approved grant application, with a specific emphasis on preliminary research results, patient impact and financial resources used thus far.

A final report is due within two months after completion of the clinical trial and must include information as to whether the funded project has achieved the specific milestones, aims, and objectives included in the approved grant application as well as a brief lay summary suitable for publication on Gateway's website. The final progress report must also include a plan for publication of results and findings within one year after the end of the grant period. At Gateway's request, Recipients will also make a presentation about the significance and progress of their work to a meeting of the BOD or other participants chosen by Gateway. Upon reasonable notice, Grantee Institution and Recipient agree to allow Gateway representatives to visit the Recipient's facilities where the research is being conducted in order to gain further knowledge to evaluate Recipient's progress. Gateway will execute an appropriate Business Associate Agreement prior to such site visit. After completion of the Gateway funded trial, Grantees agree to respond to annual Gateway brief follow-up contacts to track the longer term impact of the funded study.

B. Duplication of Support
The Recipient and Grantee Institution hereby assure Gateway that this project is not receiving, and will not receive, other funds to overlap or duplicate Gateway funding. In the event that the Recipient is currently funded, expects to be funded in the future or has applied for funding from other sources, Recipient must disclose all other sources on the "Other Funding Sources" portion of the Research Budget form as outlined in the approved grant application. After beginning the project, any funding received by the Recipient that will be used to support any research that is being supported by Gateway must be disclosed as soon as the new funding has been approved. Under any circumstances where there is or has been duplication of support, Gateway reserves the right to alter, reduce or suspend further support of all parts of the project and request repayment of duplicated funds.

C. Publication and Sharing of Research Results

Gateway expects that all Recipients will publish all meaningful results and findings of his/her work in peer-reviewed scientific journals in an expeditious manner. Future funding of Recipient by Gateway may in part be influenced by the extent to which the Recipient complies with the foregoing. All results and findings of Recipient's work that are not published or otherwise disclosed to the public within one year after the end of the grant period will be provided by Recipient to Gateway, and Gateway may publish, disclose and use such results and findings without limitation in its sole discretion. Recipient will acknowledge Gateway on any published or distributed work or audiovisual results or findings of work supported by Gateway. In addition, any publication(s) in the peer-reviewed literature that results from work supported by Gateway must be reported to Gateway and an electronic version of such publications must be sent to Gateway via email.

D. *Limited availability of research results or resources impedes the advancement of science.* Accordingly, Gateway encourages the sharing of research data, tools and other materials developed by the Recipient and Grantee Institution with Gateway support for noncommercial research purposes to other investigators, including on a non-collaborative basis at the earliest opportunity. Applicants are asked to include a description of a specific plan for sharing and distributing such information so that other researchers can benefit from these resources or state reasons why such sharing is restricted or impossible.

E. Termination of Grant

A research grant award may be terminated before the end of the project (i) if the Recipient requests in writing that the award be terminated; (ii) if the Recipient is unable to carry out the research or fails to perform the work in good faith according to these Terms and Conditions as outlined in the grant application and grant award letter; (iii) if Grantee Institution requests in writing that the Grant be terminated because of Recipient's termination of his/her academic appointments; (iv) if Recipient changes any aspect of the Grant from that which was originally approved by Gateway, including significant changes in the specific aims of the research studies, without prior notification and approval by Gateway, (v) when above mentioned semi-annual or final reports are not received from Recipient; (vi) Recipient is found by an institutional investigation to have committed scientific misconduct or fraud; or (vii) by action of Gateway's BOD.

Recipient or Grantee Institution will notify Gateway in writing immediately if any of the above condition occurs. The Recipient and the Grantee Institution agree to return unused funds upon request by Gateway. The Recipient may submit a letter of explanation and a revised grant application for reinstatement of funding which will be reviewed by Gateway and the BSC.

F. Time Limits on Grant Start-Up and Closure

Gateway seeks to bring urgency to the somewhat tedious and slow process of cancer research for those patients who are looking for treatments today and are faced with difficult decisions without good options. Therefore, Gateway expects that all Recipients will begin patient enrollment and treatment within a calendar year of the grant award letter, preferably, within the first six months or less.

Recognizing that certain innovative treatments may take longer than a calendar year to pass pharmaceutical negotiations and/or regulatory scrutiny, in rare and limited circumstances, and with prior written notification to Gateway, a Recipient may take up to a second calendar year from the date of the grant award letter to begin patient enrollment and treatment. A research grant award for which seed money has not been initiated for more than two calendar years from the date of the grant award letter will be terminated by Gateway without exception.

Within two months after completion of the clinical trial, a final report is due from Recipient to Gateway. With prior written notification to Gateway, a Recipient may take up to 10 additional months to complete the final report. A research grant award will be terminated and final impact payment withheld if Recipient fails to submit a final report within 12 months of project completion.

G. International Grants

All international Grantee Institutions will agree to submit all important documents (regulatory approvals, reports, invoices, etc.) in English and using US Dollars, so that Gateway staff members and leadership may easily complete all appropriate reviews and due diligence.

H. Institutional Transfer

If the Recipient accepts an appointment at another institution during the grant term, and desires to have the research project transferred to the new institution, the Recipient will submit a request to Gateway to transfer the award to the

new institution at least 60 days before the anticipated date of transfer. Subject to Gateway's written approval and in Gateway's sole discretion, the award may be transferred provided arrangements satisfactory to Gateway are implemented to continue the research project in a manner in which it was originally approved by Gateway. Any transfer must be approved in writing by Gateway before any such transfer takes place. Upon approval of a transfer of the award to a new institution, the Grantee Institution will return any unexpended funds and any funds expended inconsistent with the research project to Gateway. The new institution will agree to comply with these Terms and Conditions. Gateway will make arrangements to provide remaining Award funds to the new institution.

If the Recipient is unable or not permitted to transfer the grant to a new institution, the Recipient and the Grantee Institution will relinquish the award and any unexpended funds or funds expended inconsistent with the research project will be returned to Gateway.

I. Patient Voice

Gateway is keenly interested in lifting up the voice of patients and caregivers. Therefore, all Grantees are asked to actively partner with Gateway to extend Gateway-prepared written invitations to patients—before, during, or after their participation in a Gateway-funded trial—to share their experiences and questions with Gateway, so that those experiences may inform Gateway's understanding of the patient experience and future research funding directions.

J. Liability and Insurance

Gateway does not assume responsibility for activities supported by the award. Recipient and Grantee Institution acknowledge complete responsibility for all aspects of the research, investigation, funding, and administration of and in connection with the research project. To the extent permitted by law, the Grantee Institution will indemnify and hold Gateway, and its affiliates and respective officers, directors, employees, members, and harmless from and against any and all costs, losses, or expenses, including reasonable attorneys' fees, that the indemnified parties may incur by reason of the negligence, misconduct, of the Grantee Institution, the Recipient, or any part of the research team related to the research project or any third party claim arising out of or in connection with the research project. If this indemnification is prohibited by the laws that govern the Grantee Institution, then this provision will be deemed to be unenforceable and will have no force and effect.

Grantee Institution will maintain adequate liability and other insurance comparable to coverage held by institutions of similar size and nature, covering the PI, employees, officers, and agents of Grantee Institution during the grant term. Upon request, Grantee Institution will provide certificates evidencing its insurance coverage to Gateway.

K. Request for Extensions

A no-cost extension extends the project period beyond the original project end date. As the phrase "no cost" suggests, there is no additional funding. Gateway caps no-cost extension requests to two, per Recipient. Each no-cost extension request may not exceed 12 months.

Any request for a no-cost extension must be made in writing to Gateway at least 30 days prior to the expiration of the project end date. Requests received after the last day of the project end date will not be accepted and will automatically be disapproved.

Requests for a no-cost extension require a detailed explanation of why the request is being made. Gateway will approve or disapprove the request at its discretion. If a no-cost extension is granted by Gateway, the Recipient will continue to submit progress reports and financial expenditure reports every six months during the extension term.

L. Inventions, Patents and Public Access

All Grants are subject to Gateway's policies on Inventions and patents described herein. By returning an executed copy of these Terms and Conditions and if a Grant is awarded, the Recipient and the affiliated Grantee Institution agree to be bound by the following terms and conditions on inventions and patents, and further agree to bind all his/her and its employees, agents and representatives performing work in connection with the Grant by such terms and conditions.

(i) As used in these Terms and Conditions, "Invention" shall mean all inventions, products or processes, innovations, discoveries, findings and improvements (whether or not patentable), research tools and other materials discovered, conceived or first reduced to practice in the performance of research supported in whole or in part by Gateway.

(ii) Upon discovery of any Invention, Recipient must report such discovery to Gateway in the next semi-annual or final report due hereunder. Recipient must also promptly (but in no event later than 30 days thereafter) notify Gateway in writing of the filing of any patent application for an Invention and of any patent that has been issued in any jurisdiction.

(iii) Unless otherwise provided herein, the Grantee Institution will own all Inventions. Recipient or Grantee Institution is asked to notify Gateway prior to its or the Grantee Institution's execution of any license or other agreement concerning an Invention.

(iv) If results or materials generated with Gateway funding (in whole or in part) lead to patent issuance, licensing, commercialization, or otherwise generate revenues for the Recipient or Grantee Institution, the Recipient or Grantee Institution, as the case may be, will pay royalties to Gateway in accordance with terms to be negotiated in good faith between the parties. The parties agree that their goal in establishing the rate of royalties shall be at a minimum to enable Gateway to recoup its contribution. Such royalties shall reasonably reflect the proportion of the total funding for research provided by Gateway. In the event that there are other sources of funding, the Recipient, the Grantee Institution and such other funding sources shall negotiate the appropriate royalties to be paid to Gateway subject to the aforementioned guidelines.

(v) Neither Grantee Institution nor Recipient will enter into any agreement that conflicts with their respective obligations under the Terms and Conditions and each shall ensure that its employees, agents and representatives do not enter into any such agreement. If Recipient or Grantee Institution licenses or otherwise grants rights to an Invention to any party, it will require a written agreement that requires such party to; *(i)* include provisions in the agreement obligating the other party to commercialize the Invention in a diligent manner to ensure its Practical Application (as described below); *(ii)* include appropriate diligence requirements and milestones; and *(iii)* monitor the performance of the other party.

(vi) An objective of Gateway in awarding Grants is to bring inventions to Practical Application to benefit the general public as expeditiously as possible. In furtherance of this objective, if Recipient or Grantee Institution (or any of its licensees) has not, within two years of notifying Gateway of an Invention as required herein, taken effective steps to bring the Invention to Practical Application or has discontinued efforts to bring the Invention to Practical Application, at Gateway's request, the Recipient and Grantee Institution will: *(i)* assign said Invention and all associated patents and other intellectual property rights to Gateway; *(ii)* cancel any outstanding exclusive and non-exclusive licenses; *(iii)* grant exclusive or non- exclusive licenses to said Invention, as directed by Gateway; or *(iv)* make any other reasonable disposition of the Invention, as directed by Gateway. As used herein, the term "Practical Application" means to utilize and commercialize an Invention in such manner as to ensure that its benefits are, to the extent permitted by law or government regulations, widely available to the public on reasonable terms.

(vii) GATEWAY MAY CEASE FUNDING ANY PROJECT AT ANYTIME. GATEWAY SHALL HAVE NO LEGAL OR CONTRACTUAL OBLIGATION TO FUND ANY GRANT OR PROJECT, EVEN AFTER APPROVAL. THIS DOCUMENT DOES NOT CONSTITUTE CONSIDERATION FOR ANY OBLIGATION OF GATEWAY, AND GATEWAY SHALL NOT BE LIABLE TO GRANTEE INSTITUION NOR RECIPIENT UNDER ANY THEORY. NEITHER GRANTEE INSTITUTION NOR RECIPIENT SHALL ASSERT A CLAIM AGAINST GATEWAY BASED ON "PROMISSORY ESTOPPEL", "DETRIMENTAL RELIANCE" OR SIMILAR LEGAL THEORIES IN THE EVENT THAT GATEWAY CEASES FUNDING OF A GRANT OR FAILS TO FUND A GRANT.

Attachment C: Gateway Reporting Requirements

All Gateway-funded grantees will be required to submit semi-annual outcome and financial reports via Gateway's online Grants Management System by January 31st and July 31st each year, in addition to a final study report due within 2 months of completion that captures the overall results of the study in its entirety (including all of the questions below), as well as key findings, plan for publication/sharing of results, anticipated next steps for the study, a financial report, and anticipated next steps for the study. The specific questions to be included in the semi-annual report are listed below.

1. Basic Information:
   - Name of PI, institution and contact information
   - Title of study & date Gateway approved the grant award
   - Date seed funding issued/paid and expected end date

2. Enrollment/Accrual:
   - # total patients expected to enroll
   - # new patients enrolled this period
   - Please upload a de-identified list of the patients enrolled period, including start and end dates.
   - # of patients enrolled in trial to date
   - # still expected to be enrolled

3. Treatment:
   - # of patients who have completed treatment
   - # currently being treated
   - # who have dropped from the study
   - Why did these patients drop from the study?

4. Quality of Life:
   - # Patients reporting stable or improved quality of life over course of study, if applicable.
   - # Patients reporting gains in hope for the future over the course of the study, if applicable.
   - # Patients reporting a reduction in interference with life (or "burden of treatment") as a result of support or services provided during the course of the treatment, if applicable.

5. Patient Voice
   - How are your patients connecting with the PI to ask questions, discuss their treatment?
   - How have you systematically distributed Gateway's invitation to patients and caregivers[8] who may be interested in sharing their stories, recognizing someone important to them, submitting a research question?
   - Comments by patients regarding improved quality of life changes:

6. Developments:
   - Any modifications made to approved/funded protocol
   - Any new insights to share
   - Unanticipated obstacles/challenges and how you are addressing
   - Changes to personnel on this study

7. Financial/semi-annual invoice:
   - Total original grant, spending for period, total spending since grant start
   - Request for funding (based upon accrual rate in grant terms and conditions/contract)

[8] For this purpose, Gateway will provide the researcher copies of a "Quick Card" or similar materials designed to engage patients and caregivers to share their story and/or become involved with Gateway in other ways.

Attachment D: Letter of Intent Content

All applicants should include clear, concise answers to the following questions through the Gateway online grant management system. Please note that this information should be complete and compelling, since it will be used by Gateway Research Grants Staff and members of Gateway's Board of Scientific Counselors to determine if the research project is a good fit with Gateway's intended impact, scientific merit, and other funding guidelines.

1. Provide contact, team member, and grant information.
2. Answer basic questions about proposal (request amount, phase of research, duration of study).
3. Identify the type of cancer studied and therapies proposed.
4. Articulate the problem statement, overall research objectives, and the significance of these objectives.
5. Summarize your proposed methods and strategies to achieve these research objectives.
6. Describe briefly, in non-scientific language, how your project relates to cancer in general and how it specifically addresses the mission of Gateway.
7. How many patients do you expect to enroll in the proposed Gateway study?
8. Provide a clear and focused patient impact statement. Why do you expect your treatments to work for the patients in your study? Explain how your research fits Gateway's mission and will make a difference in the lives of patients right now.
9. Enter the funding amount (by study year) that you are requesting from Gateway (in US Dollars)[9], including total request, standard of care costs, and additional study costs. Note: You will be asked to enter the budget in detail if invited to apply.
10. Budget justification: Please provide an estimate of what the funds will be spent on as well as a brief rationale for the proposed costs.
11. Do you have the appropriate IRB and/or IND approval[10] for your protocol?
12. If your proposed treatment requires use of pharmaceutical and/or biotechnology compounds (including monoclonal antibodies), have you secured the manufacturer's underwriting for the supply of these compound(s)?
13. Provide 2-3 names of leading researchers in the area of research that is the focus of your proposed study. These experts should not be affiliated with your study in any way, as they may be asked to perform an ad hoc reviewer role for Gateway.

[9] Gateway's usual grant range is between $200,000-$800,000 for a 1-3 year grant term.
[10] Gateway prefers studies to have regulatory approvals (IRB/IND) and clinical protocols ready so that if funding is awarded the clinical trial can start right away.

Attachment E: Application Content

If invited to the application stage, all applicants will be asked to submit answers to the following questions, attaching documentation as requested within Gateway's online Grant Management System.

1. Provide additional detailed contact, team member, and grant information.
2. Please provide a brief scientific description or abstract of your project.
3. Using lay language, briefly summarize your overall study plan in 1-2 paragraphs, capturing what the study will do, how it will be done, and why it is being done.
4. Please upload your entire, detailed clinical protocol. The protocol must be designed according to accepted professional and ethical standards, clearly answering at least the following elements: 1) study overview or summary; 2) background information/significance; 3) objectives/rationale/research question; 4) clinical study design; 5) patient accrual/enrollment plan (i.e. recruitment, inclusion/exclusion criteria for subjects, communication plan, informed consent process and forms); 6) adverse event reporting; 7) assessment of safety and efficacy; 8) treatment of subjects; 9) data collection plan; 10) statistical methods including power; 11) conflict of interest; 12) publication or presentation plans; 13) timeline; 14) references; and 15) attachments.
5. If you intend to use equipment or machinery in your study, please provide the make, model, and year of this equipment.
6. Please verify the number of patients you expect to enroll/accrue in the proposed Gateway study.
7. How will you ensure that patient and caregiver voices are heard in the design and implementation of your study (choices provided and narrative box)?
8. Are you prepared to included and report upon robust patient-centered quality of life outcomes in your study? Yes/No check box
    a. If yes, what validated tool(s) do you intend to use to track patient-reported outcomes across quality of life domains (Physical, Social/Family Well-Being, Emotional, & Functional)?
    b. If yes, will you include validated tools that measure patients' hope for the future, such as the Herth Hope Index?
    c. If yes, will you measure and address any burdens of treatment or interference with patients' lives?
9. Provide further information about IRB/IND approvals, if applicable.
10. Acknowledgement of the terms and conditions of the grant (after reviewing all terms).
11. Provide a summary timeline for your proposed study in Gateway-provided format, addressing the duration of clinical trial from start to finish, as well as major milestones, estimated patient enrollment by period, start and end dates.
12. Submit detailed research study budget (in Gateway-provided format).