GATEWAY DISCOVERY GRANT IN IMMUNOTHERAPY RESEARCH

PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS

www.asco.org/gateway

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ADMINISTERED BY

CONQUER CANCER®
THE ASCO FOUNDATION

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GATEWAY DISCOVERY GRANT PROGRAM

This initiative is designed to identify compelling areas of inquiry in the field of cancer research and to fund the talented clinician-scientists best positioned to pursue the studies. Grant funding of up to $1.5 million over three years will be provided to support innovative cancer researchers poised to advance clinical practice standards in areas of unmet need. The program is offered every two years with the inaugural grant awarded in 2020. The focus area of each grant will differ every two years.

Conquer Cancer is the scientific partner for the Gateway Discovery Grant Program and will provide scientific expertise and peer review. Gateway for Cancer Research is the grantor and provider of funding for the research grant. Gateway will provide grant administration and the grant recipient must agree to bound to the Terms and Conditions of Gateway.

PARTNERS

ABOUT GATEWAY FOR CANCER RESEARCH

Gateway for Cancer Research℠ is a nonprofit 501c(3) organization committed to funding innovative cancer research that helps people living 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 treatment based investigator initiated clinical trials at leading research institutions across the country and abroad. Since 1991, Gateway has supported more than 170 clinical trials and funded over $85 million in breakthrough cancer research. To learn more, visit www.GatewayCR.org.

ABOUT CONCER CANCER

Conquer Cancer®, the ASCO Foundation, funds research into every facet of cancer to benefit every patient, everywhere. In 1964, seven oncologists created the American Society of Clinical Oncology (ASCO), now a global network of nearly 45,000 cancer professionals. As ASCO's foundation, Conquer Cancer helps turn science into a sigh of relief for patients around the world by supporting groundbreaking research and education across cancer's full continuum. For more information, visit www.CONQUER.ORG.

2020 GATEWAY DISCOVERY GRANT IN IMMUNOTHERAPY RESEARCH

PURPOSE

The focus of the inaugural Gateway Discovery Grant is immunotherapy, a compelling area of cancer research. The grant will provide funding for a Phase I or Phase II treatment based clinical trial that has the potential to make an impact on patient care and advance clinical practice standards for today's cancer patients.

This project encourages submissions implemented by a multi-institutional team to facilitate collaboration and increase patient recruitment. Gateway for Cancer Research is committed to advance therapeutic care options in patient-centered research. The grant will provide up to $1.5 million in funding for the direct costs of the research over a 3-year grant term.

RESEARCH PROJECT CRITERIA

Cancer immunotherapy encompasses a broad range of medicines and treatment approaches that stimulate the immune system including vaccines, immune checkpoint inhibitors, and most recently, cellular therapies. These interventions have improved the outlook for multiple cancers, producing long-lasting remissions that can last for years in some patients. At present, however, long-term disease control occurs in just a minority of patients. In addition, immunotherapies can cause substantial adverse effects that can be life-threatening and, in some cases, permanent. Methods to identify patients most likely to benefit from immunotherapy and those at high risk for severe adverse events are urgently needed. The ability to adequately assess benefits and risks of immunotherapy for each individual will lead to better outcomes for patients. The importance of immunotherapy was highlighted by ASCO in its inaugural list of *Research Priorities to Accelerate Progress Against Cancer*.

Prioritized areas of interest may include:

- Identifying factors that predict response, long-term disease control, prolonged survival, treatment resistance, and adverse events for all types of immunotherapies.
- Developing blood- and tissue-based biomarkers and novel immune-response signatures that predict treatment benefit.
- Developing predictive models and algorithms that assign risk of severe immune-related toxicities based on readily available patient data.

Proposals will be accepted for new ideas that better predict response to immunotherapies. A new indication for an existing therapy will be considered only if particularly compelling evidence is provided in the submission. Proposed research should include a phase 1 or 2 treatment based investigator initiated clinical trial.

FUNDING AVAILABLE

The grant will provide up to $1.5 million in funding for direct costs of the research over a 3-year grant term. One grant will be awarded in 2020.The recipient will be announced on February 1, 2020. The grant term is July 1, 2020 – June 30, 2023.

Gateway uses a "pay-per-patient" method for grant payments based upon patient enrollment in the study. In order to facilitate start-up, Gateway provides 20% of the grant as seed money at the beginning of the trial. After that, payments are based on patient enrollment and demonstrated impact through semi-annual reports. Moreover, on an annual basis, in the fall, Gateway reviews all current grants for progress, and makes decisions at that time whether to continue funding for subsequent years.

KEY DATES

Online Applications Open:	**July 1, 2019**
Full Applications Due:	**September 27, 2019 (by 11:59 PM Eastern Time)**
Notification of Award:	**February 1, 2020**
Grant Term:	**July 1, 2020 – June 30, 2023**

ELIGIBILITY

Eligible Organizations

Applications may be submitted by entities that engage in cancer research including:

- Higher Education Institutions
- University Medical Centers
- Nonprofits Other Than Institutions of Higher Education
- Government Organizations (may include medical centers and hospitals that have access to resources and infrastructure to support a research project)
- Foreign Institutions are eligible to apply.

The sponsor institution must have a track record in scientific leadership and collaboration, and demonstrate depth and breadth in its research. The institution must assure support for the proposed research project. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and resources that can contribute to the planning process and implementation of the project. The sponsor institution must assure to provide protected time to the Principal Investigator.

Eligible Individuals

Multi-institutional collaboration is encouraged for this grant. The person indicated as the Lead Principal Investigator (Lead PI) in the grant application is the one who is personally and actively responsible for the conduct and oversight of the research and who is considered eligible by the sponsor institution to apply as PI for a grant.

Principal Investigators (PIs)

- Must have a doctoral degree (including MD, PhD, MD/PhD, DO, DC, ND, DDS, DVM, ScD, DNS, PharmD, or equivalent doctoral degree) in the biomedical sciences or in a field applicable to immunotherapy research.
- Must be a full-time employee of the sponsor institution.
- Has individual experience serving as PI, Co-PI or collaborator on human research protocols

- Has demonstrated ability to carry out the responsibilities of PI, including administrative management of protocols.
- Physicians must have a valid, active medical license in the country where the research will be conducted at the time of application and during the entire period of the grant.
- Be able to commit sufficient time and effort to assure successful progress of the clinical trial (applies to total research, not just the proposed project) during the award period.
- Only one application per Lead PI will be accepted for the Gateway Discovery Grant in Immunotherapy Research, although individuals may serve as a co-PI or contribute to more than one application.
- Postdoctoral or clinical research fellows or the equivalent who are working under the auspices of a scientific mentor are not eligible to apply.
- There are no citizenship or geographic requirements. However, by submitting an application, an applicant applying from an institution located in a country in which he/she is not a citizen or a permanent resident assures that the visa status will provide sufficient time to complete the project and grant term at the institution from which he/she applied.

Members of the Project Team

- Gateway funded trials must involve patient advocates: Investigators are required to consult with patient representatives and advocates to gather their input into the trial design.
- The Team should include at least one young investigator (e.g., clinical research fellow; junior faculty member) that should play a key role in the project.
- Other collaborators

The Gateway Discovery Grant Selection Committee reserves the right to evaluate and determine applicants' eligibility based on the information and justifications included in the application materials. Applicants who are uncertain about their eligibility are encouraged to contact grants@conquer.org before submitting an application.

Members of the Gateway Discovery Grant Selection Committee are not eligible to apply as a Principal Investigator or Co-Investigator on the grant.

PEER REVIEW OF APPLICATIONS

Applications are peer-reviewed by the Gateway Discovery Grant Selection Committee using a multi-stage review process. Each application is reviewed by committee members with expertise in the field as well as biostatisticians and patient advocates.

Applications are peer-reviewed by a Scientific Review Committee comprised of senior researchers and physician-scientists respected for their own accomplishments and are viewed as leaders in the field.

The Committee will consider the following criteria when reviewing applications and determining funding decisions:

- Strength of the hypothesis-driven proposal with a focus on immunotherapy research
    - Significance and originality of the proposed study and hypothesis

  - Appropriateness, feasibility, and adequacy of the proposed experiment and methodology
  - Appropriate and detailed statistical analysis plan
- Access to patient population sufficient to demonstrate high potential for enrollment success
- Meaningful involvement of patient representatives and advocates
- Qualifications, experience and productivity of the Principal Investigators
- Ability to conduct the clinical trial in compliance with all applicable regulatory requirements
- Availability of institutional resources to support the proposed project

AWARD PROCESS AND AWARD NOTIFICATION

The Gateway Discovery Grant Selection Committee will make recommendations to the Gateway Board of Scientific Counselors. If selected for a grant, the successful applicant will be notified by Conquer Cancer and Gateway. The official award announcement will be made by Gateway on February 1, 2020.

TERMS AND CONDITIONS

Gateway for Cancer Research is the grantor and provider of funding for the Gateway Discovery Grant program. The successful applicant and his or her Sponsor Institution must execute a separate Terms and Conditions document with Gateway for Cancer Research in order to receive a Gateway grant. The Terms and Conditions in **Appendix A** sets forth selected provisions of the Gateway Terms and Conditions that the applicant and Sponsor Institution should review carefully before submitting an application. This RFP does not contain the complete Terms and Conditions document. Gateway reserves the rights to modify any of the provisions of the Terms and Conditions prior to execution by the applicant and Sponsor Institution.

Compliance with Applicable Legal Requirements (Applies to Non-U.S. Institutions and Entities)

The award of the grant is subject to applicable financial and legal requirements, including but not limited to United States laws addressing foreign corrupt practices and economic and trade sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury).

Among the resources available to evaluate compliance with requirements administered by the Office of Foreign Assets Control are:

- http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx
- http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx
- http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx

APPLICATION PROCEDURES

All applications must be submitted in accordance with the requirements and instructions of this Request for Proposals (RFP). All application materials must be in English and must be submitted online through the Conquer Cancer grants portal at https://grants.conquer.org. No paper applications sent by mail, e-mail, or fax will be accepted.

Applicants are encouraged to start their application early due to the complexity of the online application process. The full application must be submitted by **11:59 PM ET on September 27, 2019**. No late applications will be accepted. Please note that technical assistance is only available until 5:00 PM ET on September 27th.

Getting Started on the Conquer Cancer Grants Portal
If you are a new user, click the "New User?" link on the homepage and complete the registration process.

If you are an existing user, use your email address as your log in ID. If your email address has changed, send an email to grants@conquer.org to update your login ID. **Do not register for a new account with a new email address to avoid duplicate records.** For password help, click the "Forgot Password?" link on the homepage. If you have previously applied for a Conquer Cancer grant or have participated on a Conquer Cancer review committee, your login information should be the same.

To initiate an application, click **Apply for Funding** on your homepage, once logged in to the grants portal, and select the "2020 Gateway Discovery Grant in Immunotherapy Research."

APPLICATION CHANGES

The applicant must notify Conquer Cancer immediately by sending an email to grants@conquer.org if any of the following condition applies from application submission through award notification:

1. Change of Institution or Position. The applicant has a career plan change, leaves his/her current position in the institution, or is unable to meet the eligibility requirements of this grant.

2. Change in Proposal (Scope, Timeline, Budget, etc.). The applicant has significant changes in the submitted proposal affecting aims, research strategy, timeline, and/or budget.

3. Application Withdrawal. Send an email to grants@conquer.org to inform the Conquer Cancer of the reason(s) for withdrawing the application. The email should include the applicant's name, the title of the proposal, and the reason for withdrawing the application.

APPLICATION GUIDE

1. Applicant (required)
2. Organization (required)
3. Project Information (required)
4. Classification (required)
5. Assurances (required)
6. Project Timeline (required)
7. Budget (required)
8. Contacts
9. Publications (optional) – maximum of two publications.
10. Uploads
    a. Biosketch of Lead Principal Investigator (required)
    b. Biosketches of Co-Investigators (required)
    c. Collaborators and Project Team Members (required)
    d. Research Strategy (required)
    e. Biostatistical Plan (required)
    f. Cited References (required)
    g. Advancing Patient-Focused Research (required)
    h. Institutional Letter of Support (required)
    i. Co-PI Commitment Letter (required)
    j. Clinical Protocol (optional) – strongly encouraged
    k. Publications (optional)
    l. Supporting Documentation (optional)
11. Review and Submit

1. **Applicant (required).** This section includes the following applicant information:
   - Contact Section – Click Edit to update the following:
     - Prefix
     - Name (add any Suffix to the last name field)
     - Degree
     - ASCO Member ID (optional) – ASCO members may enter their Member ID. If not an ASCO member, enter "NA_YourLastName".
   - Institution Affiliations – Click Add to enter a new affiliation or Edit to update an existing affiliation.
   - Email (at least one, checked as primary) – Click Add to enter a new email or Edit to update an existing email.
   - Address (at least one, checked as primary) – Click Add to enter a new address or Edit to update an existing address.
   - Phone (at least one, checked as primary) – Click Add to enter a new phone number or Edit to update an existing number.
   - Degrees – Click Add to enter your degree information, one degree at a time.
   - Website – This section is optional.

2. **Organization (required)**
   - Under Grant Administration Organizations, click Add to enter the applicant institution(s). More than one institution may be added if the applicant is affiliated with another institution other than the applicant institution. A primary institution must be designated.
   - The system may have filled in information previously entered. Click Edit to update as needed.
   - Do not enter information in the Performance Sites section.

3. **Project Information (required).** This section includes the following proposed project information:
   - Research Project Title (250 characters maximum): Provide a short descriptive title of the proposed research project.
   - Brief Research Project Description/Abstract (3000 characters maximum): Provide a brief abstract of the proposed research project.
   - Specific Aims: List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology). The specific aims should state concisely and realistically what the research intends to accomplish and/or what hypothesis is to be tested, and should list measurable objectives.
   - Clinical Trial Phase: Indicate the phase of the clinical trial.

4. **Classification (required)**
   - Subject Area: Select one Subject Area from the drop-down list that best describes your research grant project. If "Other" is selected, provide information in the text field.
   - Focus Area(s): Scroll through the list to find research areas that may apply to your research project, then click the "Add" button to select each subject. You may add several research areas, but at least one focus area is required. If "Other" is selected, provide information in the text field.

5. **Assurances (required)**
   - Assurances for use of human and/or animal subjects in the research proposal
   - Biohazard Use is not required.

6. **Project Timeline (required).** Enter major project milestones, the expected completion date, and if there is an associated deliverable. A deliverable is something that can be included in a progress report, such as a publication or an approval letter. The applicant is not required to have deliverables. However, the timeline should make it clear what outcomes will be achieved during the grant award period. Your IRB expiration date, if applicable, should also be included in this section.

7. **Budget (required).** The award funds will be directed to the sponsor institution and should be used towards salary support, supplies, equipment, travel, etc. necessary for the pursuit of the research project.

   The budget must be directly entered into the budget section of the online application. Budget justification for the entire period must be entered by clicking on the "Notes" icon. Clicking "Save" will automatically populate the total costs. Click "Save and Continue" when the entire budget has been entered.

   Budget Guidelines:
   - Total Award: The total award amount is up to $1,500,000 million over three years.
   - Research support: Research costs should be directly related to the research project such as personnel salary* (research, analytics and patient care), supplies (research and patient care), patient outreach materials, patient travel if needed (i.e, taxi, bus, train or parking), equipment, IRB Approval, contracted services (patient care, laboratory or analytics) and other expenses. Budgeted items must be consistent with available institutional facilities and resources. Patient care costs that are reimbursable by a third-party payor, professional membership dues, tuition fees, and fees for academic courses are unallowable costs.
     *Personnel salary must follow the NIH salary cap FY 2019.
   - Travel: Patient travel costs as listed above are allowed, investigator or other resource travel costs are not allowed.
   - Indirect costs: Gateway will not pay for indirect costs applied as a percentage of the research cost to the project.

The following costs are not allowable under Gateway research grants:
- Institutional overhead (indirect costs);
- New construction and alterations or renovations of existing facilities;
- Consultant fees, capital equipment, and computer hardware or software, unless specified in the original Application and approved by Gateway; or
- Travel costs, unless approved by Gateway.

8. **Contacts (required).** The applicant should identify the specific individuals related to their project:

IMPORTANT NOTES:

- The Institutional Approver must complete the task and click "Submit" on the Review and Submit page **prior** to the deadline. The applicant will not be able to submit the application until this task is submitted and complete.
- If the individual is NOT an ASCO member, type 'N/A (Last Name of Contact)' in the "Member ID" field, to bypass the field.

Contacts–Personnel

Use this section to add the following individuals:

- Grants Administrator - will be directly involved in the pre- award and post-award activities of the grant (optional, encouraged)
- Assistant – this is the applicant's assistant (if applicable)
- Principal – the applicant is the primary person by default.

Click "Add". On the next page, select the appropriate role. Do not select the "Primary Person" checkbox for any individuals other than the primary contact (i.e., applicant). Click "Select" to search for the individual. If the individual is not in the system, click "Add New Person" and complete all fields marked by an asterisk (*).

Click "Save and Close" to save the individual and return to the previous screen.

Contacts-Other

Use this section to add the following individuals:

- An Institutional Approver (required).

Click "Add". On the next page, select the appropriate role. Click "Select" to search for the individual. If the individual is not in the system, click "Add New Person" and complete all fields marked by an asterisk (*).

After the individuals have been entered, click the "Create and Notify" button. When the "Create and Notify" button is clicked, an email will be sent to the individual with instructions for accessing the grants portal to upload the following required documents. Do not click the "Create and Notify" button if you have not completed all required sections of the application.

For Institutional Approvers:

The Authorized Official representing the institution of the applicant must approve the completed application (both the project proposal and the budget) before submission by completing the "Institutional Approval Face Sheet" (template provided in the task). This individual is typically from the institution's Office of Sponsored Research.

Upon logging in to the grants portal, the Institutional Approver will have access to the completed application in PDF format. If the application is approved, the Institutional Approver must upload the completed and signed Institutional Approval Face Sheet. The template of the Institutional Approval Face Sheet is downloadable from the Institutional Approver's online task. However, if the application

is not approved, the Institutional Approver should contact the applicant directly to correct any issues in the application prior to approval.

Upon submission of the completed and signed Institutional Approval Face Sheet, an email will be sent to the applicant confirming that this task has been completed The Institutional Approver must click "Submit" on the **Review and Submit** page after uploading the face sheet to trigger the email. Subsequently, the applicant must login and submit the completed and approved application. No changes should be made to the application upon obtaining institutional approval.

9. **Publications (optional).** Up to two prior publications may be included. The applicant must be a co-author on these publications. Please enter the publication information in this section including the title, the year published, the type of publication, publication status, and funding. Upload a copy of the actual publication in the Uploads section. Do not upload the publication in this section.

10. **Uploads** (the following components must be uploaded in the "Uploads" section).

Important Instructions about Uploads. To ensure proper conversion, uploads can be in PDF, MS Word, or MS Excel formats, although PDF format is preferred, and must be in accordance with document page limits. Uploaded documents should not be password protected or they may not convert properly.

To add a document, select the upload type from the dropdown menu, click "Add Files", and search the document from your local drive. Then click "Start" to upload the file individually or click "Start Upload" to upload the files in bulk. To ensure that the files successfully converted, refresh the page.

a. **Biosketch of Lead Principal Investigator (required).** Applicants should use the recently revised NIH biosketch template, which is provided on the grants portal for download. The NIH biosketch template has been updated to reflect an expiration date of 03/31/2020. The biosketch must have no more than five (5) pages. To complete the biosketch, please refer to these instructions.

b. **Biosketches of Co-Investigators (required).** Applicants should use the recently revised NIH biosketch template, which is provided on the grants portal for download. The NIH biosketch template has been updated to reflect an expiration date of 03/31/2020. The biosketch must have no more than five (5) pages. To complete the biosketch, please refer to these instructions.

c. **Collaborators and Project Team Members (required).** No more than 4 pages. This should include list of (1) the researchers the applicant plans to collaborate with on the proposed research project; (2) the young investigator/s; (3) patient advocate; (4) a brief description of each individual's role and duties in the project, and (5) a description of the communications and coordination plan among the investigators and members of the project team.

d. **Research Strategy (required).** The research strategy should be limited to 10 typewritten, single-spaced pages, with one-inch margins and using an 11-point Arial font type. ALL pertinent tables, pictures, and graphs MUST be included within the 10-page limit.

The Research Strategy must contain the following information:

i. Significance and Background:
   1. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   2. Explain how the proposed project will improve scientific knowledge, technical capability, and/or critical practice in one or more broad fields.
   3. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will change if the proposed aims are achieved.

ii. Innovation:
   1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   2. Describe any novel theoretical concepts, approached or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
   3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

iii. Approach:
   1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   2. Describe any novel theoretical concepts, approached or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
   3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
   4. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
   5. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
   6. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Appropriate detail and/or documentation in the Supporting Documentation section must be included to assure a reviewer that the applicant's project is feasible in the timeframe of the grant. Examples include: a letter confirming you will have access to an experimental therapy, or an approval letter from CTEP or a cooperative group.
   7. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
   8. Clearly state the applicant's role in the project.
   9. The precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained.

10. Explain how patient-reported outcomes, including health-related quality of life, will be measured.
11. List and describe the facilities and resources available to conduct the study, including a description of industry support for any clinical trials.

e. **Biostatistical Plan (required).** A detailed statistical plan is required for all applications. The plan should not be more than two (2) typewritten, single-spaced pages with one-inch margins and 11-point Arial font type. For clinical and in-vivo studies, this section should include the objectives/hypotheses and primary endpoint(s) of the study, description of experimental design and study groups that will be compared (if applicable), justification of the proposed study sample size, detailed procedures for data analysis, and any additional appropriate statistical considerations, such as stratification factors, definitions of evaluability, approaches for loss to follow-up or missing data. For studies involving hypothesis testing, an appropriate sample size justification will include all parameters required for the computation of the sample size: the effect size, power and type I error rates, and standard deviation (if relevant). When necessary, sample size justifications will include additional information to complete the calculation such as length of follow-up, prevalence of mutations in a given population, and accrual rate, for example. Phase I trials should use standard approaches for demonstrating trial design operating characteristics (e.g. likelihood of selecting the correct dose).

Laboratory-based in vitro research proposals should also include the primary objective/hypothesis and primary endpoints of studies, procedures for data analysis, and appropriate statistical details that describe the summary measures that will be used to meet the objectives of the study.

Applications will be reviewed by a biostatistician. Applicants should work with a biostatistician to develop the application and include appropriate funding for biostatistics support of the project.

f. **Cited References (required**). A list of cited references in the Research Strategy should be uploaded as a separate document in the Uploads section.

g. **Advancing Patient-Focused Research (required)**. A research advocate should be involved during the development of the research project. This section will be reviewed by a Patient Advocate Reviewer as part of the application review process. Applicants must seek to ensure that their clinical studies are well-designed and ethical, minimizing patient burdens. In order to inform the reviewers of the applicant's proposed research's relevance for cancer patients and to ensure that the proposed research is patient-focused, the applicant must answer the following questions in plain language and as concisely as possible (two pages maximum):

i. Please describe the clinical problem being addressed, its scope, and the impact your research could potentially have on this patient population.
ii. If the study is successful what will be the next steps in moving your research into clinical practice. Describe the potential barriers to accrual and/or retention.
iii. How do you plan to engage patient advocates and relevant stakeholders in the design/implementation of your study and dissemination of the results?

iv. How will the results of this study improve a patient's quality of life?
v. What burdens will the trial impose on patients? What have you done in designing the study to minimize the burden to patients?

h. Institutional Letter of Support (required). A letter from the Department Chair or Dean at the sponsor institution where the applicant's research project will be conducted must be provided. This letter must include a statement of institutional support that will enable the applicant to perform the proposed research.

i. Co-PI Commitment Letter (required). A letter of commitment from each Co-PI must be provided. This letter must include a statement confirming the scope of the Co-PI's involvement in the proposed research.

j. Clinical Protocol (optional, strongly encouraged). If the applicant's project involves a clinical protocol, it is highly encouraged to upload a copy of the protocol in the Uploads section.

k. Publications (optional). Up to two prior publications may be included. The applicant must be a co-author on these publications. Please upload a copy of each publication and complete the Publications section).

l. Supporting Documentation (optional). This section may be used to upload any necessary additional information required to properly review the application (e.g., letters documenting the feasibility of the project, a letter from a drug company that they will provide the investigational drug, a letter of collaboration from another laboratory providing expertise for this project, a letter of support for a collaboration, etc.). Applicants are encouraged to provide a letter of support for any investigational agents and letters of support from collaborating biostatisticians. Due to the limited time given to the reviewers, upload of any documents that are not critical to the review of the proposal or any additional publications is not allowable.

11. Review and Submit (required).

This page will indicate any incomplete sections. Once all sections are complete, select "View PDF" to view and save a PDF version of the application.

Click "Submit" to submit your application. Note: The Submit button will not appear until all required sections have been completed including receipt of the institutional approval face sheet.

Appendix A. Gateway Research Funding Terms & Conditions

1. Eligibility

Applicants seeking Grants from Gateway 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 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 agreement through its duly authorized representative. Unless otherwise indicated, the Grantee Institution will be the official recipient of the Grant, receive such Grant 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 project (the "Research Project").

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 and oversight of the research and who is considered eligible by his or her Grantee Institution to apply for a Grant.

2. Grantee Institution Representations and Warranties

The Grantee Institution represents and warrants the following:

(i) It will comply with all laws and regulations applicable to the Research Project.

(ii) It will obtain, as applicable, all necessary Institutional Review Board ("IRB") approvals for human subjects' research, Institutional Animal Care and Use Committee ("IACUC") approval for animal research, and Institutional Biosafety Committee ("IBC") approval for recombinant DNA research. Additionally,
   a. Copies of these approvals will be provided to Gateway prior to initiating the research,
   b. Any changes to the documentation will be submitted to Gateway as approved,
   c. In the event the IRB has determined a study is exempt, the documentation demonstrating the exempt status will be submitted to Gateway, and
   d. For research requiring an informed consent document, a copy of the IRB-approved informed consent form template will be provided to Gateway upon request.

(iii) It is in compliance with all laws, statutes, and regulations restricting work with individuals, entities, or groups subject to Office of Foreign Assets Control (OFAC) sanctions.

(iv) It will not export or re-export any U.S. origin technology or products received from Gateway, or the direct products of that technology or those products, in violation of the United States export-control or customs laws and regulations as outlined by the Bureau of Industry and Security of the U.S. Department of Commerce. This obligation survives termination of this Grant.

(v) It has established policies about, and safeguards against, conflicts of interest that prevent it and its employees, or consultants/subcontractors from using their positions for personal gain (for themselves, or for other individuals, friends, business associates, family members, or others), financially or via gifts, favors, or other similar actions.

3. Disbursements

As Gateway is committed to supporting 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 for 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, the Grantee Institution will be paid a certain amount for each subject treated in the Research Project. 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 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.

4. Unused Funds, Unallowable Costs, and Request for Repayment

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 Grant 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; or
(iv) Travel costs, unless approved by Gateway.

If Recipient fails to comply with any material terms of these Terms and Conditions, Gateway reserves the right to request immediate repayment of any Grant funds.

5. Public Relations

The Recipient and the Grantee Institution agree to the announcement of the Grant in media chosen by Gateway, and Recipient 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 the 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 Grant from Gateway is required. For purposes of publicizing the Grant, the following language must be used acknowledging Gateway's support in any press releases and other publications:

About Gateway for Cancer Research℠

Gateway for Cancer Research is a section 501(c)(3) charitable and scientific 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 150 clinical trials and funded millions of dollars 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 (each a "Semi-annual Report") after initiation of the clinical trial to report on patient accrual, health status, findings, and grant expenditures. Gateway will provide Recipient with an initial template Semi-annual Report. Thereafter, Recipient is responsible for timely submission of the Semi-annual Reports through the Gateway Grant Management System.

After the expenditure of first-year funding, Gateway will review the Semi-annual Reports submitted by the Grantee in order to determine whether Grant funding should be continued for the Research Project in the second and/or third year, as applicable. Grant 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 Research 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, the 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. If necessary, 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 brief annual Gateway follow-up communications in order to track the longer term impact of the funded Research Project.

B. Duplication of Support

The Recipient and the Grantee Institution hereby assure Gateway that this Research 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 Research 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 Research Project and request repayment of duplicated funds.

C. Publication and Sharing of Research Results

Gateway expects that Recipient 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, including the Research Project, must be reported to Gateway and an electronic version of such publications must be sent to Gateway via email within five (5) business days of such publication.

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 the Grantee Institution with the Grant 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 Grant may be terminated before the end of the Research Project: (i) if the Recipient requests in writing that the Grant 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 the 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) upon the failure of Recipient to deliver the semi-annual or final reports required under these Terms and Conditions; (vi) if Recipient is found by an institutional investigation to have committed scientific misconduct or fraud; or (vii) in Gateway's sole discretion.

Recipient or the Grantee Institution will notify Gateway in writing immediately if any of the conditions in (i), (ii), or (iii) listed above occur. Gateway shall give Recipient and Grantee Institution thirty (30) days' notice in the event it elects to terminate the Grant pursuant to (iv), (v), (vi) or (vii) above and shall pay Grantee Institution for any milestones completed prior to the termination date within sixty (60) days of the termination date. The Recipient and the Grantee Institution agree to return any unused funds upon request by Gateway. The Recipient may submit a letter of explanation and a revised grant application for reinstatement of Grant 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 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, all Recipients are expected to begin patient enrollment and treatment within a calendar year of receipt of the grant award letter, and preferably within the first six months.

Since 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 Grant 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 Grant will be terminated and the final impact payment withheld if Recipient fails to submit a final report within 12 months of the Research Project's completion.

G. International Grants

International Grantee Institutions shall submit all documentation (regulatory approvals, reports, invoices, etc.) in English and use US Dollars in all calculations, 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 Grant 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 Grant 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 Grant 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 Grant 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 Grant and any unexpended funds and/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. Funding Provider and Not Sponsor

The Grantee Institution acknowledges that Gateway is solely a provider of funding for the research performed under this Grant and is not a sponsor of the research. The Grantee Institution agrees that it will not make any statement, written or oral, that Gateway is a sponsor of the research under this grant.

K. Liability, Indemnification and Insurance

Gateway does not assume responsibility for activities supported by the Grant. Recipient and the Grantee Institution acknowledge complete responsibility for all aspects of the research, investigation, funding, and administration of the Research Project, including but not limited to safeguarding the rights and welfare of human subjects involved in activities supported by the Grant. The Grantee Institution hereby agrees that it shall assume full responsibility and liability for the care and treatment of the study subjects involved in the Research Project as well as full responsibility for any study subject claims.

The Grantee Institution will indemnify and hold Gateway, and its affiliates and respective officers, directors, employees, and members (the "Indemnified Parties"), 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 or 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. This obligation survives termination of this Grant.

The 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 the Grantee Institution during the term of the Grant. Upon request, the Grantee Institution will provide certificates evidencing its insurance coverage to Gateway.

L. Request for Extensions

A no-cost extension, under which no additional Grant funding is provided to the Recipient and the Grantee Institution, extends the Research Project period beyond the original Research Project end date. Gateway caps no-cost extension requests to two (2) per Recipient. Each no-cost extension request is limited to a maximum of twelve (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 Research Project end date. Requests received after the last day of the Research Project end date will not be accepted.

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.

M. 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, 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, first reduced to practice, or further developed 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. The Grantee Institution shall use diligent efforts, at its sole expense, to commercialize an Invention in a timely fashion, either itself or through one or more licensees in the field of curing, diagnosing, and/or treating cancer. The Grantee Institution shall prepare and maintain complete and accurate records regarding the development and commercialization of products claiming an Invention. Prior to executing any license or other agreement concerning an Invention with any third party for commercial or other purposes, Recipient or the Grantee Institution shall notify Gateway of its intention to do so.

(iv) In acknowledgement and consideration of Gateway’s provision of the Grant, the Grantee Institution shall pay to Gateway a share of Net Royalty Income received by the Grantee Institution for the option,

license or other transfer of an Invention (collectively, a "Transfer") determined by multiplying Net Royalty Income by a fraction, the numerator of which is the amount of Gateway's total Grant to the Grantee Institution for the Research Project (whether in this agreement or in prior or subsequent agreements for similar purposes), and the denominator of which is the total direct cost of the Invention (including unreimbursed patent costs and costs incurred by the Grantee Institution for the Invention, provided that, in no event shall the calculation of the foregoing result in Gateway receiving less than ten percent (10%), or more than fifty percent (50%), of Net Royalty Income. Net Royalty Income means the total amount of all payments, revenues, fees, royalties and other considerations attributable to the Transfer of the Invention (including the value of property or the portion of capital stock) received by the Grantee Institution, whether at the time the Transfer occurs or subsequently, less the following: (i) for unreimbursed patent cost, (ii) transaction costs incurred by Grantee in connection with the Transfer; and the amount the Grantee Institution is required to pay to the Inventor[s] of the Invention in accordance with its published policies.

The Grantee Institution shall make all such payments to Gateway within ninety (90) days after Net Royalty Income is received by the Grantee Institution. The Grantee Institution shall provide to Gateway with each such payment financial information adequate to establish and document the amount of Net Royalty Income and the calculation of Gateway's share. Gateway shall have the right to audit the Grantee Institution's records in order to verify the Net Royalty Income and such share. The Grantee Institution's obligation to pay royalties to Gateway shall survive after the Grant has terminated.

(v) Neither the 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.

(vi) If Recipient or the 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.

(vii)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 the 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 the 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. This obligation survives termination of this Grant.

(viii) In the event that Grant funds will be used to test, evaluate, improve or develop an Invention that is owned by a third party ("Third Party Beneficiary"), or that the Research Project will benefit a Third Party Beneficiary or an Invention owned by a Third Party Beneficiary, Grantee Institution shall notify Gateway of such Third Party Beneficiary and Gateway shall enter into an agreement with such Third Party Beneficiary before any Grant funding is disbursed for the Research Project.

7. Governing Law

These Terms and Conditions will be governed by the laws of the State of Illinois, without reference to its conflicts of laws principles. Notwithstanding the foregoing provisions, nothing in these Terms and Conditions is intended to, or should be construed to, conflict with Federal law governing the Grantee Institution, including any Bayh-Dole or NIH obligations that may arise with respect to Inventions resulting from research funded by both Gateway and the federal government.