



# **GATEWAY DISCOVERY GRANT TO ADDRESS CANCER DISPARITIES IN CLINICAL TRIALS**

## **PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS**

[www.asco.org/gateway](http://www.asco.org/gateway)

Last Updated: October 30, 2020

Letter of Intent Due: March 15, 2021

*For LOIs that are approved, Full Application Due: August 16, 2021*

Application portal: [awards.asco.org](http://awards.asco.org)

ADMINISTERED BY

**CONQUER** CANCER®  
THE ASCO FOUNDATION

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## **GATEWAY DISCOVERY GRANT PROGRAM**

Launched in 2019, the Gateway Discovery Grant Program 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 to five years will be provided to support innovative cancer researchers poised to advance clinical practice standards in areas of unmet need. A grant is offered every two years and addresses a different area of research each time. The first grant was awarded in 2020 and focused on immunotherapy research.

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

## **PARTNERS**

### ABOUT GATEWAY FOR CANCER RESEARCH

Gateway for Cancer Research<sup>SM</sup> is a nonprofit 501C(3) organization committed to funding practice-changing discoveries in cancer care by awarding grants to clinician-scientists advancing early stage clinical trials for cancers of all types, bringing breakthroughs to the bedside for patients facing a cancer diagnosis. 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 around the world. Since 1991, Gateway has supported more than 180 clinical trials and funded over \$90 million in transformational cancer research. Get involved today by visiting [www.GatewayCR.org](http://www.GatewayCR.org), like us on Facebook at [facebook.com/demandcures](https://facebook.com/demandcures) and join the conversation on Twitter and Instagram at [@DemandCures](https://twitter.com/DemandCures), [@DemandCures](https://www.instagram.com/DemandCures), #BeAGateway.

### ABOUT CONQUER CANCER

Conquer Cancer<sup>®</sup>, the ASCO Foundation, funds research for every cancer, 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, we support groundbreaking research and education so both doctors and patients have the resources they need. For more information, visit [www.CONQUER.ORG](http://www.CONQUER.ORG).

## **2022 GATEWAY DISCOVERY GRANT TO ADDRESS CANCER DISPARITIES IN CLINICAL TRIALS**

### **PURPOSE**

Gateway for Cancer Research is dedicated to funding practice-changing discoveries in cancer care by harnessing the unrelenting passion of the research community and empowering informed patients to triumph over their disease. Gateway awards grants to clinician-scientists that advance Phase I and Phase II clinical trials for cancers of all types at leading research institutions around the world, bringing breakthroughs to the bedside on behalf of all patients facing a cancer diagnosis.

The Gateway Discovery Grant to Address Cancer Disparities in Clinical Trials is designed to provide funding to catalyze innovative clinical research with a strong potential impact on mitigating cancer health disparities and improving equitable access to cancer clinical trials. The grant will provide up to \$1.5 million in funding for the direct costs of the research over a three- to five-year project period.

This grant encourages submissions implemented by a multi-institutional team to facilitate collaboration and increase patient recruitment.

### **AREAS OF INTEREST**

The intent of this grant is to support proposals focused on reducing disparities in minority and health disparity populations and improving equitable access to care for all people facing cancer.

Historically underserved populations include:

- Blacks/African Americans
- Hispanics/Latinx
- American Indians/Alaska Natives
- Asian Americans
- Native Hawaiians and other Pacific Islanders
- socioeconomically disadvantaged populations
- underserved rural populations
- sexual and gender minorities

This Request for Proposals (RFP) is not specific to one cancer type. Proposals should identify and address system-level barriers and factors contributing to disparities in clinical trials and the delivery of care for all people with cancer.

The American Society of Clinical Oncology (ASCO) [Policy Statement on Cancer Disparities and Health Equity](#) and the 2017 AACR-ACS-ASCO-NCI [Position Statement Charting the Future of Cancer Health Disparities](#) outline several recommendations for improving the cancer research infrastructure to better address inequities in cancer care and outcomes.

Projects are expected to use an approach that encompasses one or multiple themes. Examples include, but not limited to:

- Inclusion of more members of minority investigators in study design and/or research teams
- Support for low-resourced institutions to recruit participants to trials

- Trial design that fosters recruitment of underrepresented populations
- Trials that are conducted at sites with diverse patient populations
- Required collection and reporting of research data within the treatment trial known to influence outcomes such as race/ethnicity, sexual orientation and gender identity, nativity, ability status, socioeconomic status, age, and immigration status.
- Multisector partnerships and collaborations to improve equitable participation and access to research
- Interinstitutional collaboration to build research capacity for reducing health disparities

Potential projects include, but are not limited to:

- Use of telehealth and/or local facilities for certain services to increase access to trials for those in geographically rural areas or where transportation is otherwise a barrier to participation (e.g. allowing remote administration of treatment, patient assessments and imaging at local centers/laboratories, remote/virtual consent)
- Use of patient navigation, community health workers and/or other community-based partners to increase awareness of and recruitment to trials
- Recruitment strategies to ensure adequate representation of key groups at risk of disparate toxicity or mortality outcomes for treatment of interest
- Robust data collection of factors that impact disparities in cancer care and patient outcomes, including a patient's social status and demographics, community and lifestyle factors, and biology and genetics to support further disparities research.
- Self-management training for patients with low health literacy to improve retention and adherence
- Collection and analysis of trial related dataset. For example, analyzing tissues/biological samples collected during the trial to understand disparity related effects.
- Use of models/technologies that will help with clinical trials during the COVID-19 pandemic to address health disparity questions.

## FUNDING AVAILABLE

One grant will be awarded in 2022. The grant will provide up to \$1.5 million in funding for direct costs of the research over a three- to five-year project period.

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, Gateway reviews all current grants for progress, and makes decisions at the appropriate time whether to continue funding for subsequent years.

## KEY DATES

Letter of Intent Opens:	<b>October 30, 2020</b>
Letter of Intent Due:	<b>March 15, 2021 by 11:59 PM ET</b>
Letter of Intent Notifications:	<b>On a rolling basis until March 15, 2021 by 11:59 PM ET</b>
Full Application Due:	<b>August 16, 2021</b>
Anticipated Notification of Award:	<b>March 2022</b>
Anticipated Grant Term:	<b>July 1, 2022 – June 30, 2027</b> (project can span up to 5 years)

## **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 health disparities 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, 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.
- Must 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.

Applicants who are uncertain about their eligibility are encouraged to contact [grants@conquer.org](mailto:grants@conquer.org) before starting 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 multiphase process. Members of the Committee are jointly appointed by Conquer Cancer and Gateway. Each application is reviewed by committee members with scientific expertise in the field as well as biostatisticians and patient advocates.

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

- Overall impact
- Strength of the hypothesis-driven proposal
  - 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
- Diversity in the clinical research team
- Patient-centeredness and engagement
- Qualifications, experience and productivity of the Principal Investigator and Co-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**

After merit review, the Gateway Discovery Grant Selection Committee will submit its recommendations to the Gateway Board of Scientific Counselors. Conquer Cancer and Gateway for Cancer Research anticipate notifying the applicant under consideration in March 2022. A formal notification of award will be provided to the applicant and Sponsor Institution upon acceptance of Gateway's Terms and Conditions.

## **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 Terms and Conditions document with Gateway for Cancer Research 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 applying. This RFP does not contain the complete Terms and Conditions document. Gateway reserves the right 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 INFORMATION USE AND SHARING**

Conquer Cancer may use and process the information submitted through the application form for several purposes, including but not limited to: 1) providing all information about the application Gateway for Cancer Research and the joint reviewers, 2) evaluating the application, 3) communicating with you regarding your application and other opportunities that may be of interest to you, 4) publishing information regarding Conquer Cancer's grants and awards program on an anonymous basis, and 5) informing Conquer Cancer's grant making strategies and policies. Information submitted through this application form will be kept on secure servers accessible to Conquer Cancer personnel and third parties authorized by Conquer Cancer to perform functions on Conquer Cancer's behalf.

Research proposals submitted are considered confidential property of the Applicant. Conquer Cancer is permitted to share these research proposals with Gateway for Cancer Research, Conquer Cancer staff and reviewers, third party contractors, and potential supporters, and Conquer Cancer will require all to maintain appropriate standards of confidentiality.

By submitting an application to Conquer Cancer, the Applicant grants Conquer Cancer the right to use all application information submitted, outside of the research proposal, in aggregate and de-identified form, for any purpose.

## APPLICATION PROCEDURES

Please review this Request for Proposals (RFP) carefully before applying. Applicants are encouraged to start their application early due to the complexity of the online application process.

All application materials must be in English and must be submitted online through the Conquer Cancer application portal at [awards.asco.org](https://awards.asco.org). No paper applications sent by mail, e-mail, or fax will be accepted.

The application portal pulls the applicant's profile information from [profile.asco.org](https://profile.asco.org). The applicant's profile must be up to date before initiating an application. If the applicant does not have an ASCO account, he/she must [create an account](#). ASCO membership is not required to create an account.

The Gateway Discovery Grant contains two phases: Letter of Intent (LOI) phase and Full Application phase.

LOIs will be approved or denied on a rolling basis **until March 15, 2021**. Once an LOI is approved after administrative review, application materials will be readily accessible in the application portal to begin the full application submission. **Only applicants who have received an approval for their LOI will be eligible to submit a full application.** Full applications are due on **August 16, 2021**.

## APPLICATION CHANGES

The Applicant must notify Conquer Cancer immediately by sending an email to [grants@conquer.org](mailto:grants@conquer.org) if any of the following conditions apply at any time from LOI and Full Application submission through award notification:

1. Withdrawal of Application. Send an email to [grants@conquer.org](mailto:grants@conquer.org) to inform Conquer Cancer 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.
2. 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 RFP.
3. Change in Proposal (Scope, Timeline, Budget, etc.). The Applicant has significant changes in the submitted proposal affecting aims, research strategy, timeline, and/or budget.

Helpful Tips for Using the Application Portal are included in Appendix B.

## **PHASE 1: LETTER OF INTENT SUBMISSION**

### **Letter of Intent Components**

Sections of the LOI are listed below. More details about each section, including requirements and instructions, are described in the succeeding pages:

1. Applicant Information (required)
2. Project Information (required)
3. Biosketch of Lead Principal Investigator (required)
4. Additional Information (required)
5. Review and Submit (required)

1. **Applicant Information (required)**. This section includes the following:
  - **Application Information**. This information is pulled directly from the applicant's ASCO account profile. If the applicant needs to make any changes to his/her information, visit [profile.asco.org](https://profile.asco.org). The profile must be up to date before submitting the full application.
    - First Name
    - Middle Name
    - Last Name
    - Designation
    - Primary Organization Name
    - Address (including city, state, and zip code)
    - Country
    - Primary email address  
(*Important:* Please confirm that the email in the ASCO account profile is the most current before initiating an application. This email will be associated with the application in this portal. All future communications about the application will be sent to this address)
    - ORCID ID (optional)
    - ASCO Member ID (only applies to ASCO members; ASCO membership is not required to apply for this grant)
  - **Additional questions and required information**. Answer the following:
    - Do you have a medical degree or the international equivalent?
    - Do you have a full-time faculty appointment?  
(An Instructor position is considered as a faculty appointment).
    - Field of Clinical Training. Select all that apply.
    - Field of Research Training. Select all that apply.
  - After completing this form, click "**Mark as Complete**".
2. **Project Information (required)**. Enter general information about the research project being proposed:
  - **Research Project Title (250 characters maximum)**: Provide a short descriptive title of the research project.
  - **Brief Research Project Description/Abstract (3000 characters maximum)**: Provide a brief abstract of the research project.
  - **Lay Abstract (2500 characters maximum)**. Provide a layperson summary of the project. Describe the work in a way that it will be understood by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms when possible. It should not include confidential information.
  - **Specific Aims (1000 characters maximum per aim)**: Select the number of aims from the drop-down list. Briefly describe each aim separately and concisely in the boxes provided. Include the following for each aim: the aim objective (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), goals, and summarize the expected outcomes. At least one specific aim is required. Details (e.g., background, rationale for each aim and alternative strategy) for respective aims can be included in the Research Strategy section.
  - **Subject Area**: Select one Subject Area from the drop-down list that best describes the research project. If "Other" is selected, provide information in the text field.

- Focus Area(s): Select all that apply. If "Other" is selected, provide information in the text field.
  - Research Classification: Select a category that relates to the research project. The list has six broad categories of scientific interest in cancer research.
  - Type of Research Study: Select the type from the drop-down list to indicate if the research project is "Clinical", "Pre-clinical", or "Health Services Research".
    - If "Clinical" is selected, indicate the clinical trial phase and clinical trial number or identifier.
  - Assurances:
    - Animal Use. Indicate whether animals will be used in the research. If yes, select the appropriate status.
      - If the status is Approved, enter the IACUC Approval Date, Expiration Date, and Number.
      - If the status is Exempt, enter the Exemption Number.
    - Human Subjects. Indicate whether human subjects will be involved in the research. If yes, select the appropriate status.
      - If the status is Approved, enter the IRB Approval Date, IRB Expiration Date, and Assurance Number.
      - If the status is Exempt, enter the Exemption Number.
  - Use of Drug(s): Indicate if the research involves the use of drug(s). If yes, enter the name of the drug(s) and the drug manufacturer(s). It is highly encouraged to include a letter from the manufacturer(s) or supplier(s) that they will provide the drug in the Supporting Documentation section of the application.
  - Resubmission: Select "No" from the drop-down list.
  - Acknowledgment: Check the box to confirm that the applicant has read and understood the Terms and Conditions of Gateway for Cancer Research indicated in this RFP (see Appendix A).
  - After completing this form, click "**Mark as Complete**".
3. **Applicant's Biosketch (required)**. Applicants should use the NIH biosketch template provided with an expiration date of 02/28/2023. The biosketch must not exceed more than five (5) pages. To complete the biosketch, please refer to these [instructions](#). **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.**
- Click "**Attach File**" and select the file to be uploaded in the application.
  - Use this file naming convention: *2022Gateway\_PIBiosketch\_Last Name*
  - After completing this form, click "**Mark as Complete**".
4. **Additional Information (required)**. In up to 5 pages, applicants should answer the following questions succinctly. **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.**
- a. Describe the primary audience(s) targeted for this project.
  - b. Describe how the proposal uniquely contributes to addressing disparities in clinical trial participation.
  - c. How many patients do you expect to enroll in the proposed study?
  - d. Provide the anticipated length of the project including projected start/end dates. The project timeline can span three to five years. If the LOI is approved a project timeline will be required in the Full Application.

- e. Describe key members of the project team and respective roles, including collaborating partners / institutions.
- f. Do you have the appropriate IRB and/or IND approval for your protocol?

- Click “**Attach File**” and select the file to be uploaded in the application.
- Use this file naming convention: *2022Gateway\_AdditionalInfo\_Last Name*
- After completing this form, click “**Mark as Complete**”.

**5. Review and Submit (required).**

The applicant will not be able to navigate to this page until all required sections have been “**Marked as Complete**”.

On the left navigation, click “**Review**” to review or “**Submit**” to submit the application.

To download a copy of the application, click “**My Applications**”. Click the ellipsis (...) on the specific application and click “**Download**”.

On the next screen, select the desired options and click “**Download**”.

A new tab will open. Once the download is ready, click “**Download**”. The application will be downloaded as a zip file.

Please note that technical assistance is only available until 5:00 PM ET on the due date. Email [grants@conquer.org](mailto:grants@conquer.org) if you have any questions.

**LOI Review Criteria and Notification**

LOIs will be administratively and programmatically reviewed by Conquer Cancer based on the following criteria:

- Completeness of information and adherence to instructions
- Eligibility
- Alignment with the grant purpose and guidelines
- Appropriateness of scientific topic

The LOIs will be approved or denied on a rolling basis **until March 15, 2021** (11:59 PM ET). Once an LOI is approved after administrative review, application materials will be readily accessible in the Application Portal to begin the full application preparation. **Only applicants who have received an approval for their LOI will be eligible to submit a full application.**

## **PHASE 2: FULL APPLICATION**

**Only applicants who have received an approval for their LOI will be eligible to submit a full application.** The full application must be submitted on or before **August 16, 2021 by 11:59 PM ET.**

### **Full Application Components**

Sections of the full application are listed below. More details about each section, including requirements and instructions, are described in the next pages. Some information may carry over from the LOI phase.

1. Applicant Information (required)
2. Project Information (required)
3. Project Timeline (required)
4. Budget (required)
5. Publications (optional) – maximum of two publications.
6. Biosketch of Lead Principal Investigator (required)
7. Co-Investigator Biosketches and Commitment Letters (required)
8. Collaborators and Project Team Members (required)
9. Research Strategy (required)
10. Biostatistical Plan (required)
11. Cited References (required)
12. Patient Advocate Form (required)
13. Institutional Letter of Support from Department Chair or Dean (required)
14. Clinical Protocol (optional) – strongly encouraged
15. Additional Supporting Documentation (optional)
16. Institutional Approval (required)
17. Review and Submit (required)

**NOTE:** The applicant may add other individuals (such as a grants manager, assistant, co-investigator, collaborator, etc.) as a “Collaborator” to his/her application to complete specific sections of the application.

1. **Applicant Information (required)**. This section includes the following:
  - **Application Information**. This information is pulled directly from the applicant’s ASCO account profile. If the applicant needs to make any changes to his/her information, visit [profile.asco.org](https://profile.asco.org). The profile should be up to date before submitting the full application.
    - First Name
    - Middle Name
    - Last Name
    - Designation
    - Primary Organization Name
    - Address (including city, state, and zip code)
    - Country
    - Primary email address  
(*Important:* Please confirm that the email in the ASCO account profile is the most current before initiating an application. This email will be associated with the application in this portal. All future communications about the application will be sent to this address)
    - ORCID ID (optional)
    - ASCO Member ID (only applies to ASCO members; ASCO membership is not required to apply for this grant)
  - **Additional questions and required information**. Answer the following:
    - Do you have a medical degree or the international equivalent?
    - Do you have a full-time faculty appointment?  
(An Instructor position is considered as a faculty appointment).
    - Field of Clinical Training. Select all that apply.
    - Field of Research Training. Select all that apply.
  - After completing this form, click “**Mark as Complete**”.
2. **Project Information (required)**. Enter general information about the research project being proposed:
  - **Research Project Title (250 characters maximum)**: Provide a short descriptive title of the research project.
  - **Brief Research Project Description/Abstract (3000 characters maximum)**: Provide a brief abstract of the research project.
  - **Lay Abstract (2500 characters maximum)**. Provide a layperson summary of the project. Describe the work in a way that it will be understood by people who do not have scientific or medical backgrounds. Be clear and avoid technical and scientific terms when possible. It should not include confidential information.
  - **Specific Aims (1000 characters maximum per aim)**: Select the number of aims from the drop-down list. Briefly describe each aim separately and concisely in the boxes provided. Include the following for each aim: the aim objective (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), goals, and summarize the expected outcomes. At least one specific aim is required. Details (e.g., background, rationale for each aim and alternative strategy) for respective aims can be included in the Research Strategy section.

- **Subject Area**: Select one Subject Area from the drop-down list that best describes the research project. If "Other" is selected, provide information in the text field.
  - **Focus Area(s)**: Select all that apply. If "Other" is selected, provide information in the text field.
  - **Research Classification**: Select a category that relates to the research project. The list has six broad categories of scientific interest in cancer research.
  - **Type of Research Study**: Select the type from the drop-down list to indicate if the research project is "Clinical", "Pre-clinical", or "Health Services Research".
    - If "Clinical" is selected, indicate the clinical trial phase and clinical trial number or identifier.
  - **Assurances**:
    - **Animal Use**. Indicate whether animals will be used in the research. If yes, select the appropriate status.
      - If the status is Approved, enter the IACUC Approval Date, Expiration Date, and Number.
      - If the status is Exempt, enter the Exemption Number.
    - **Human Subjects**. Indicate whether human subjects will be involved in the research. If yes, select the appropriate status.
      - If the status is Approved, enter the IRB Approval Date, IRB Expiration Date, and Assurance Number.
      - If the status is Exempt, enter the Exemption Number.
  - **Use of Drug(s)**: Indicate if the research involves the use of drug(s). If yes, enter the name of the drug(s) and the drug manufacturer(s). It is highly encouraged to include a letter from the manufacturer(s) or supplier(s) that they will provide the drug in the Supporting Documentation section of the application.
  - **Resubmission**: Select "No" from the drop-down list.
  - **Acknowledgment**: Check the box to confirm that the applicant has read and understood the Terms and Conditions of Gateway for Cancer Research indicated in this RFP (see Appendix A).
  - After completing this form, click "**Mark as Complete**".
3. **Project Timeline Form (required, use template provided)**. Enter each major project milestone/activity, a brief description, the expected completion date, the status and if it 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 period.

Download the template, then complete the following:

- Enter the name of the milestone/activity
- Enter a description of the milestone/activity
- Enter the expected date of completion
- Indicate whether the milestone/activity is a deliverable
- Select the appropriate status
- Do not enter any comments.

Use this file naming convention: *2022Gateway\_Timeline\_Last Name*

After completing the template, upload it, and click “**Mark as Complete**”.

4. **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. *Do not use commas when entering budget amounts.* Budget justification for the entire period must be entered in the “Description of Costs” column. The costs will calculate automatically at the bottom of the page as entered.

Budget Guidelines:

- **Total Award**: The total award amount is up to \$1.5 million; the project period can span three to five 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 2020.
- **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 (see Appendix A, section 5):

- 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.

After completing this form, click “**Mark as Complete**”.

5. **Publications (optional)**. Up to two prior publications that highlight the Applicant’s experience and qualifications may be included. The Applicant must be a co-author on these publications.

To enter the publications:

- Select the total number of publications from the drop-down list (1 or 2).
- For each publication, enter the title, PubMed ID number, year, type (from the drop-down list), name, status (from the drop-down list), URL, and funding status (from the drop-down list).

- Upload a copy of the publication. Use this file naming convention:  
*2022Gateway\_Publication1\_ Last Name; 2022Gateway\_Publication2\_ Last Name*

After completing this form, click “**Mark as Complete**”.

6. **Biosketch of Lead Principal Investigator (required)**. Use the NIH biosketch template with an expiration date of 02/28/2023. The biosketch must not exceed five (5) pages. To complete the biosketch, refer to these [instructions](#). **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.**

Use this file naming convention: *2022Gateway\_PIBiosketch\_ Last Name*

After completing this form, click “**Mark as Complete**”.

7. **Co-Investigator Biosketches and Commitment Letters (required)**. Select from the drop down list the number of co-investigators involved in the research project. Provide the following for each co-investigator.
- First Name
  - Last Name
  - Degree
  - Institution

**Biosketch**: Use the NIH biosketch template with an expiration date of 02/28/2020. The biosketch must not exceed five (5) pages. To complete the biosketch, refer to these [instructions](#). **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.** Use this file naming convention: *2022Gateway\_CoInvBiosketch\_ Co-I Last Name*

**Commitment Letter**: The letter must include a statement confirming the scope of the Co-Investigator’s involvement in the proposed research. This letter must be signed by the Co-Investigator and on official letterhead. **If the letter is not signed and not printed on official letterhead, Conquer Cancer will return the application.** Use this file naming convention: *2022Gateway\_CommitmentLetter\_ CoInv Last Name*

After completing this form, click “**Mark as Complete**”.

8. **List of Collaborators and Project Team Members (required)**. List all team members and their names that will work on the project and briefly describe the pertinent qualifications and role of each research team member. Team members and collaborators are permitted to be from other countries, including high-income countries. It is not required to have team members outside of the applicant’s home country.

This should be no more than four (4) typewritten, single-spaced pages, with one-inch margins and using an 11-point Arial font type. This should include list of (1) the researchers the applicant plans to collaborate with on the proposed research project, including co-Investigators; (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. **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.**

Click "**Attach File**" and select the file to be uploaded in the application.

Use this file naming convention: *2022Gateway\_Collaborators\_Last Name*

After completing this form, click "**Mark as Complete**".

9. **Research Strategy (required)**. The research strategy is limited to ten (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. **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.**

The Research Strategy must contain the following information:

a. Significance and Background:

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

b. Innovation:

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

c. Approach:

- i. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- ii. Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- iii. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- iv. 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.

- v. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- vi. 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.
- vii. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- viii. Clearly state the applicant's role in the project.
- ix. The precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained.
- x. Explain how patient-reported outcomes, including health-related quality of life, will be measured.
- xi. List and describe the facilities and resources available to conduct the study, including a description of industry support for any clinical trials.

**10. Biostatistical Plan (required). Applications will be reviewed by a biostatistician.** A detailed statistical plan is required for all applications. The plan is limited to two (2) typewritten, single-spaced page with one-inch margins and 11-point Arial font type. **If the document uploaded exceeds the page limit, Conquer Cancer will return the application.**

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.

The applicant should work with a biostatistician to develop the application. If statistics are not applicable to the project, the applicant should upload a document stating that "Biostatistics are not applicable", and the reviewers will evaluate.

- Use this file naming convention: *2022Gateway\_BiostatisticalPlan\_ Last Name*

- After completing this form, click “**Mark as Complete**”.

**11. Cited References (required).** Upload a bibliography of any references cited in the Research Plan.

- Use this file naming convention: *2022Gateway\_CitedReferences\_Last Name*
- After completing this form, click “**Mark as Complete**”.

**12. Patient Advocate Form (required).** Applications will be evaluated by a patient advocate based on how well the applicant explains the potential impact of the proposal. Write a response in a way that it will be understood by people who do not have scientific or medical backgrounds. It is required that the applicant work with a patient advocate to develop the application. The applicant must seek to ensure that their clinical studies are well-designed and ethical, minimizing patient burdens.

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. Answer these questions in the text boxes provided (1300 characters maximum):

- a. Describe the clinical problem being addressed, its scope, and the impact your research could potentially have on this patient population.
- b. 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.
- c. How do you plan to engage patient advocates and relevant stakeholders in the design/implementation of your study and dissemination of the results?
- d. How will the results of this study improve a patient’s quality of life?
- e. What burdens will the trial impose on patients? What have you done in designing the study to minimize the burden to patients?

After completing this form, click “**Mark as Complete**”.

**13. Institutional Letter of Support from Department Chair or Dean (required).** A letter from the Department Chair or Dean from the applicant’s sponsoring institution where the 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.

This letter must be signed and on official letterhead. **If the letter is not signed and not printed on official letterhead, Conquer Cancer will return the application.**

Use this file naming convention: *2022Gateway\_InstitutionalLOS\_Last Name*

After completing this form, click “**Mark as Complete**”.

**14. Clinical Protocol (optional, strongly encouraged).** If the research project involves a clinical protocol, it is strongly encouraged to upload a copy of the protocol.

- Use this file naming convention: *2022Gateway\_ClinicalProtocol\_Last Name*
- After completing this form, click “**Mark as Complete**”.

**15. 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.

- Use this file naming convention for each document you upload:  
*[2022Gateway\_SupportingDoc1\_Last Name; 2022Gateway\_SupportingDoc2\_Last Name; etc.]*.
- After completing this form, click “**Mark as Complete**”.

**16. Institution Approval (required).** The Authorized Official representing the sponsoring institution must approve the completed application (both the project proposal and the budget) before submission by completing the “Institution Approval” task. This individual is typically from the institution’s Office of Sponsored Research.

- To request a recommendation from the Institution Approver:
  - Click “Request a Recommendation”.
  - Enter the First name, Last name, Email address, and write a message (optional) to the Institution Approver.
  - Click “Send Request”. The Institution Approver will receive an email notification with the message.
  - If the Institution Approver accepts or decline the recommendation request, the Applicant will receive an email notification.
- To resend or withdraw the request, click the ellipsis (...) near the Institution Approver’s name and email and select the appropriate option from the drop-down list.
- **IMPORTANT:** The Institution Approver must complete his/her task and click “Submit” at the bottom of the page **prior** to the deadline. An email notification will be sent to the applicant confirming that the task has been completed. Once the Institution Approver has submitted the task, return to this section and click “**Mark as Complete**”.

**17. Review and Submit (required).** The **applicant** will not be able to navigate to this page until all required sections have been “**Marked as Complete**”.

On the left navigation, click “Review” to review or click “**Submit**” to submit the application.

To download a copy of the application, click “**My Applications**”. Click the ellipsis (...) on the specific application and click “**Download**”.

On the next screen, select the desired options and click “**Download**”.

A new tab will open. Once the download is ready, click “**Download**”. The application will be downloaded as a zip file.

Please note that technical assistance is only available until 5:00 PM ET on the due date. Email [grants@conquer.org](mailto:grants@conquer.org) if you have any questions.

**FULL APPLICATION SUBMISSION CHECKLIST**

All required and optional (if filled out) sections must be marked as complete and uploaded documents must follow the prescribed file naming convention.

- Applicant Information (required)
- Project Information (required)
- Project Timeline Form (required)
- Budget (required)
- Publication Form (optional) – maximum of two publications
- Biosketch of Lead Principal Investigator (required)
- Co-Investigator Biosketches and Commitment Letters (required)
- Collaborators and Project Team Members (required)
- Research Strategy (required)
- Biostatistical Plan (required)
- Cited References (required)
- Patient Advocate Form (required)
- Institutional Letter of Support from Department Chair or Dean (required)
- Clinical Protocol (optional) – strongly encouraged
- Supporting Documentation (optional)
- Institution Approval (required)
- Review and Submit (required)

## **Appendix A. Gateway Research Funding Terms & Conditions**

### **1. Eligibility**

Applicants seeking Grants from Gateway must be employed by 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 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 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. Award Process**

Gateway uses a two-phase grant application process. Letters of intent are accepted year-round. If a letter of intent is deemed relevant and of interest to Gateway, applicants will be invited to submit a full grant application. Full grant applications will be reviewed quarterly by the Gateway Research and Grants Committee and ranked on the basis of novelty, scientific merit, direct patient impact, relevance, and such other factors as determined by Gateway. The Research and Grants Committee will make recommendations to the Gateway Board of Directors (“**BOD**”), which makes the final Grant decisions in its sole discretion. If selected for a Grant, Recipient and the Grantee Institution will be notified with an award letter setting forth the duration and amount of the Grant.

### **3. 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.

#### **4. 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 Recipient, and adherence to the further requirements and limitations set forth in these Terms and Conditions.

#### **5. 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.

#### **6. Public Relations**

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<sup>SM</sup>**

Gateway for Cancer Research<sup>SM</sup> is a nonprofit 501C(3) organization committed to funding practice-changing discoveries in cancer care by awarding grants to clinician-scientists advancing early stage clinical trials for cancers of all types, bringing breakthroughs to the bedside for patients facing a cancer diagnosis. 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 around the world. Since 1991, Gateway has supported more than 180 clinical trials and funded over \$90 million in transformational cancer research. Get involved today by visiting [www.GatewayCR.org](http://www.GatewayCR.org), like us on Facebook at [facebook.com/demandcures](https://facebook.com/demandcures) and join the conversation on Twitter and Instagram at [@DemandCures](https://twitter.com/DemandCures), #BeAGateway.

## **7. 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 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*

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 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 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 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 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 Recipient requests in writing that the Grant be terminated; (ii) if 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. Recipient and the Grantee Institution agree to return any unused funds upon request by Gateway. 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 Research and Grants Committee.

#### *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 Recipient accepts an appointment at another institution during the Grant term, and desires to have the Research Project transferred to the new institution, 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 Recipient is unable or not permitted to transfer the Grant to a new institution, 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, 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 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, 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 the terms and conditions set forth in this Section 7(M). Recipient and the Grantee Institution agree to be bound by and comply with such terms and conditions, and the Grantee Institution shall cause all Grantee Personnel to be bound by and comply with such terms and conditions. As used herein, “**Grantee Personnel**” means Recipient and all other employees, medical staff, contractors, agents and representatives of the Grantee Institution performing any of the obligations of the Grantee Institution and/or Recipient, and/or exercising any rights thereof hereunder, including without limitation in connection with any Grant.

- (i) As used in these Terms and Conditions, “**Inventions**” means all inventions, processes, protocols, innovations, discoveries, findings, improvements, modifications, enhancements, strategies, methods, devices, compounds, formulas, algorithms, computer programs (including source code, object code, routines and macros), prototypes, specifications, specimens, products, services, research tools, technical information, designs, drawings, schematics, materials, and other work product, technologies and intellectual property, whether or not patentable or registrable under copyright or similar laws, created, discovered, conceived, first reduced to

practice, or further developed by any Grantee Personnel in the performance of any research and/or clinical trials supported in whole or in part by Gateway, including but not limited to under any Grant.

- (ii) Except as otherwise provided herein, as between Gateway and the Grantee Institution (and all Grantee Personnel), the Grantee Institution will own all rights, title and interest in and to all Inventions in any and all media, languages, territories and jurisdictions throughout the world, now known or hereafter devised, including, but not limited to, any and all intellectual property rights, and the right to prosecute and recover monetary damages for any infringements and other violations thereof.
- (iii) Following creation, discovery, conception, reduction to practice or development (collectively, "**Creation**") of any Invention, Recipient shall report such Invention to Gateway by including in the next Semi-annual Report or final report due hereunder a brief description of the Invention. Recipient shall also provide promptly to Gateway any and all information relating to the Invention, and the Creation, validity, and enforceability thereof as Gateway may reasonably request. In addition, Recipient shall notify Gateway of (a) each patent application and other application for registration in any jurisdiction claiming or otherwise relating to any Invention or relating to any product or service based on any Invention, promptly (and in any event within thirty (30) days) after filing such application, and (b) any patent and other registration issued thereon in any jurisdiction, promptly (and in any event within thirty (30) days) after the issuance of such patent or other registration.
- (iv) The Grantee Institution and Recipient acknowledge and agree that a key objective of Gateway in awarding Grants is to facilitate the Creation, utilization and commercialization of Inventions in such manner as to ensure that the benefits of each Invention are, to the extent permitted by applicable laws and regulations, made widely available to the public as expeditiously as possible on reasonable terms for the purpose of curing, diagnosing and/or treating cancer ("**Practical Application**"). Accordingly, following Creation of each Invention, the Grantee Institution shall use diligent efforts, at its sole expense, to develop products and/or services comprising or otherwise based on each Invention or to otherwise commercialize such Invention in a timely manner to achieve such Practical Application. The Grantee Institution shall prepare and maintain complete and accurate records regarding all such development and commercialization activities, and shall deliver to Gateway at such intervals as Gateway reasonably requests (a) a summary of the Grantee Institution's plans and progress with respect to such initiatives and (b) accurate and complete copies of any and all agreements and other documentation related to such activities, including but not limited to any manufacturing agreements and agreements memorializing any Transactions (as defined below).
- (v) The Grantee Institution shall pay to Gateway a royalty ("**Royalty**") equal to **[15%]** of all revenues and other consideration of any nature whatsoever received at any time (whether prior to, on or after the effective date of termination of the Grant) by the Grantee Institution or any Grantee Personnel in connection with any and all sales, licenses and other transactions with third parties with respect to any Invention and/or any products or services comprising or otherwise based upon such Invention (each, a "**Transaction**"), after deducting, to the extent applicable, any reasonable, out of pocket costs incurred directly by the Grantee Institution in connection with the negotiation of such Transaction (collectively, "**Net Income**"). ***[Other potential deductions include (a) all taxes, costs of insurance, freight and transportation and similar charges,***

***and all customs duties, surcharges and other charges incurred in connection with the importation or exportation of licensed Inventions or related products/services, (b) all discounts, rebates, credits and returns relating thereto, (c) all claims and deductions made by a customer when remitting payment, (d) costs of development of the Invention or related products/services, and (e) costs of filing for, prosecuting and maintaining any patents or other registrations for the applicable Invention or products/services based thereon.]*** The Grantee Institution shall pay all such Royalties in respect of any calendar quarter during and after termination of the Grant and/or these Terms and Conditions by no later than the end of the following calendar quarter, and shall provide to Gateway with each such payment financial information adequate to establish and document the amount of Net Income and the calculation of Gateway's share. Gateway shall have the right, upon reasonable written notice to the Grantee Institution to inspect and audit all books and records and other documentation of the Grantee Institution to verify the Net Income and such calculation.

- (vi) Neither the Grantee Institution nor Recipient will enter into any agreement that conflicts with their respective obligations under these Terms and Conditions, and the Grantee Institution shall ensure that no Grantee Personnel enter into any such agreement. Moreover, the Grantee Institution agrees that to the extent it or any Grantee Personnel license(s) or otherwise grant(s) to any third party any rights to any Invention, the Grantee Institution shall ensure that such arrangement is consistent with the goal of expeditiously striving for Practical Application, as described herein, and shall monitor the performance of such other party to facilitate achievement of such goal.
- (vii) In furtherance of the Practical Application objective, if, within two (2) years of notifying Gateway of an Invention as required herein, neither the Grantee Institution nor Recipient has taken effective steps to bring the Invention (or products or services based on the Invention) to Practical Application, or the Grantee Institution and Recipient have discontinued efforts to bring the Invention to Practical Application, then the Grantee Institution and, to the extent applicable, Recipient, will make any reasonable disposition of the Invention as Gateway may direct, including (a) assigning to Gateway such Invention, together with all patent applications, patents and other intellectual property rights therein and the right to prosecute and recover monetary damages for all past, present and future infringements and other violations thereof; (b) cancelling any outstanding exclusive and non-exclusive licenses thereof; and (c) granting exclusive or non-exclusive licenses to said Invention.

## **8. 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.

## **Appendix B. Helpful Tips for Using the Application Portal**

### **Getting Started**

To access the application portal, go to [awards.asco.org](https://awards.asco.org)

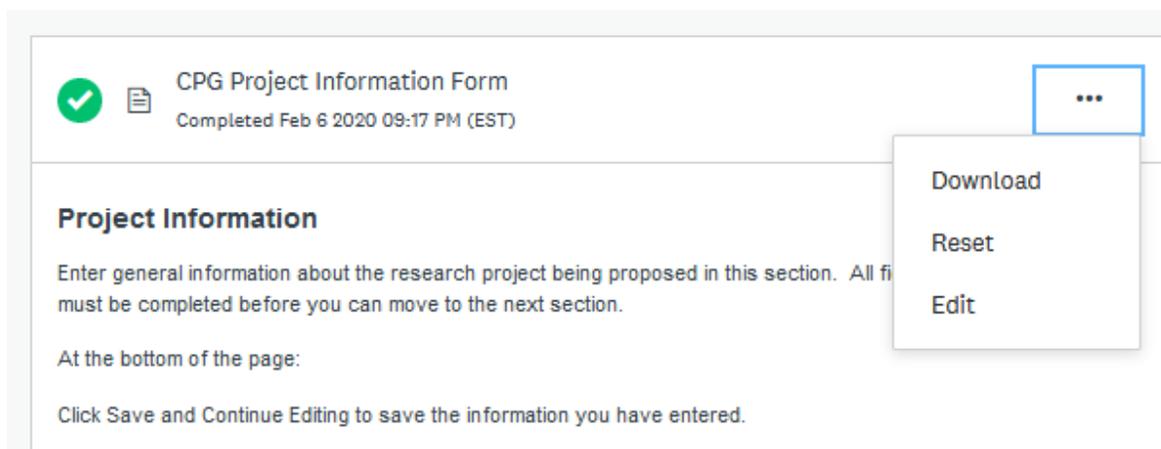
- *If you have an existing ASCO account*, use your ASCO credentials to log into the application portal. If you are having issues logging in, click the “Need Help?” link in the “Log-in” page.
- *If you do not have an ASCO account*, go to [awards.asco.org](https://awards.asco.org) and click “Log-in” in the top right corner of the screen. On the next screen, click “Create Account” and follow the prompts to complete your account setup and create a password. After your account is set up, you will be returned to the application portal.
- *To initiate an application*, once logged into the application portal, click “View Programs”, select the program “Gateway Discovery Grant”, and click “Apply”.

### **Eligibility Quiz**

You will first be asked to complete an eligibility quiz. Once you have answered each question, click “**Mark as Complete**”. If you are eligible, you will automatically have access to the full application and you will see the different sections of the application along the left navigation (e.g., Applicant Information). Select any section to begin working on your application. If you have any questions regarding eligibility, contact [grants@conquer.org](mailto:grants@conquer.org).

### **Navigating the Application**

- Click “Save and Continue Editing” at the bottom of the page as you go through the application.
- When finished with a particular task (e.g., Project Information), click “Mark as Complete” at the bottom of the page to validate task completion.
- If you need to edit a task after it has been Marked as Complete, click the ellipsis (...) on the top right corner of the task as shown below. Select “Edit” to reopen the form.
  - **IMPORTANT!** Do NOT click “Reset” as this will delete previously entered data!

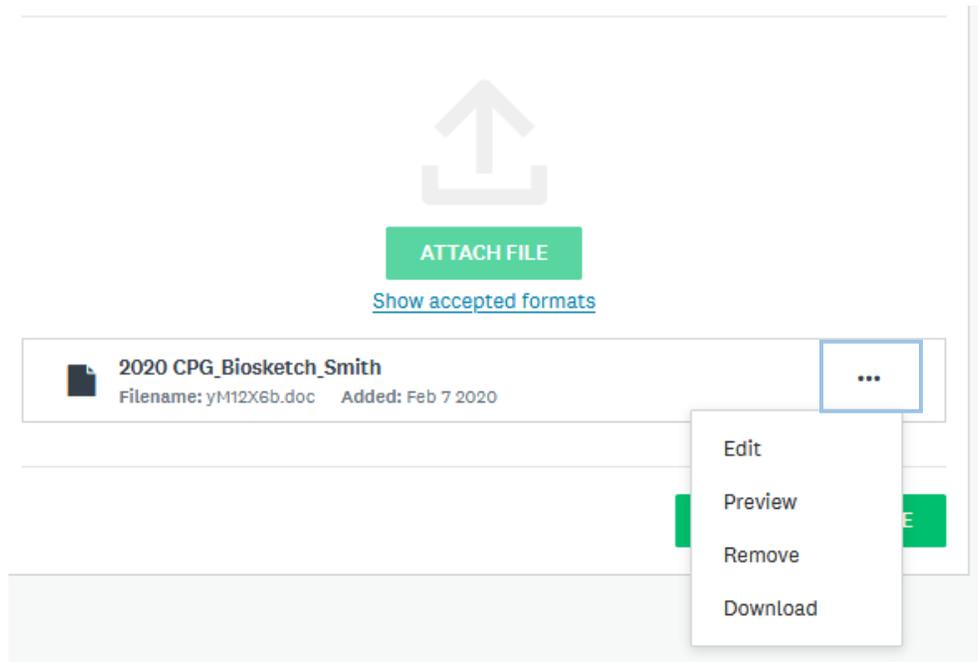


## Receiving Notifications

Applicants should add [grants@conquer.org](mailto:grants@conquer.org) to their safe senders list to ensure they receive timely notifications associated with recommender task submissions, application submissions, etc. If Applicants are not receiving notifications, they should check their junk/spam folders first, then contact [grants@conquer.org](mailto:grants@conquer.org) for additional assistance.

## Uploading a Document

- Click “Show accepted formats” to determine the file formats accepted. Documents should not be password protected.
- Documents must follow the file naming convention and requirements for page limits, margins, and fonts (see individual application sections for details). **If any document you uploaded does not meet the specific criteria, Conquer Cancer will return your application.**
- To edit a file name, click the ellipsis (...) next to the file name as shown below. Select “Edit” and enter the new file name based on the file naming convention.
- To remove or replace an uploaded document, click the ellipsis (...) next to the file name as shown below. Select “Remove” then click “Attach File”.



## **Requesting a Recommendation**

- As part of your application process, you will need to “request a recommendation” from third-parties such as the Institution Approver. Click on the task and fill in the details of the Recommender including the First Name, Last Name, Email, and a brief message (optional) to send the recommender. Once the information is submitted, an automated email will be sent to the recommender letting them know that they’ve been asked to provide a recommendation. When the recommendation is submitted, the Applicant will be instantly notified.

**Task instructions** [Hide](#)

Please invite your mentor to complete a recommendation for your application. Make sure to use your mentor's preferred email address associated with their ASCO membership account otherwise this recommendation will not be available to your mentor when they log into the system.

Recommendations You will not be able to review the contents of received recommendations.

Mentor name & email will appear here	Requested: Dec 16 2019	...
--------------------------------------	------------------------	-----

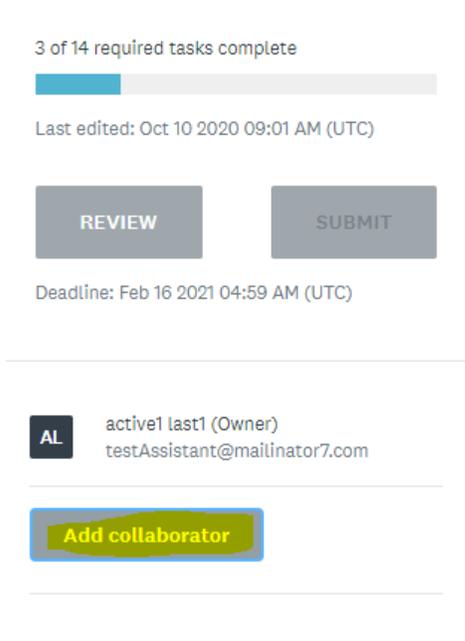
Resend request  
Withdraw request

**MARK AS COMPLETE**

- If the Recommender didn't receive an email invite, confirm that you sent the invite to the correct email address and there are no spelling errors, ask the Recommender to check their Spam/Junk Folder, or resend the Invitation.
- To resend or withdraw the request, click the ellipsis (...) near the Recommender's name and email and select the appropriate option from the drop-down list as shown below.

## Adding a Collaborator

- Other individuals (such as a grants manager, assistant, co-investigator, collaborator, etc.) may be added as a “Collaborator” to the application to complete specific sections. On your task list page, click **Add collaborator**.



3 of 14 required tasks complete

Last edited: Oct 10 2020 09:01 AM (UTC)

REVIEW SUBMIT

Deadline: Feb 16 2021 04:59 AM (UTC)

AL active1 last1 (Owner)  
testAssistant@mailinator7.com

Add collaborator

- On the next window, enter your collaborator(s) email address, select the type of access, and add an optional message.
- Click **Send Invite** to trigger a notification email to your collaborator(s).

Collaborators ×

Add collaborators to view or contribute to your application.

Email address of collaborators Separate addresses by commas

Type of access

View & edit  View only

Message (optional)

**SEND INVITE**