

# 2024 CONQUER CANCER - JOSE BASELGA, MD, PhD, YOUNG INVESTIGATOR AWARD IN DRUG DEVELOPMENT

# REQUEST FOR PROPOSALS

Last Updated: July 1, 2023

Application Deadline: January 31, 2024

Conquer Cancer<sup>®</sup>, the ASCO Foundation 2318 Mill Road, Suite 800 Alexandria, VA 22314 grants@conquer.org

Please visit <u>asco.org/YIA</u> for the most up-to-date version of the Request for Proposals.

#### **About Conquer Cancer**

Conquer Cancer funds research for every cancer, every patient, everywhere. Since 1984, its Grants & Awards program has awarded more than \$178 million through more than 8,600 grants and awards to improve cancer care and accelerate breakthroughs in clinical and translational oncology research. Conquer Cancer donors support vital programs needed to deliver the highest quality, equitable patient care and share a vision of a world where cancer is prevented or cured, and every survivor is healthy. For more information, visit <a href="CONQUER.ORG">CONQUER.ORG</a>.

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# **Purpose**

The Conquer Cancer – Jose Baselga, MD, PhD, Young Investigator Award (YIA) in Drug Development provides funding to promising investigators to encourage and promote quality research in clinical oncology with a focus on drug development, from discovery to development of new therapeutic drugs for cancer treatment. This award is to fund young physician scientists at a critical time in their academic careers – when they transition from training to becoming independent investigators and begin to set up labs or research programs of their own under the guidance of mentors. The award provides support for the mentor to have protected time in mentoring clinician-scientists in drug development research. Applications are accepted from U.S. and international applicants.

## **Funding Available**

The total award amount is \$60,000 for one year, payable on or about July 1 and January 1 in two equal installments to the sponsoring institution. The award will consist of \$50,000 in funding to support the investigator and funding of \$10,000 to the mentor. Conquer Cancer has funding for one Jose Baselga, MD, PhD, YIA in Drug Development which will be awarded to the most meritorious application evaluated for this competition.

## **Health Equity, Diversity, and Inclusion**

Conquer Cancer will work to advance ASCO's Health Equity Policy Statement which calls for bolder, more aggressive steps to achieve equity for all individuals with cancer. This statement serves as a blueprint for the Society's activities to ensure that all patients, no matter who they are or where they live, can receive the highest quality equitable cancer care. ASCO and Conquer Cancer are committed to fostering health equity in cancer research by improving diversity and inclusion in the oncology workforce, funding research focused on health disparities and bolstering funding for investigators from underrepresented populations in medicine<sup>1</sup> and low and middle-income countries. Addressing inequities in cancer care includes improving representation of all populations who stand to benefit from the research. Every person with cancer should have an equal opportunity to participate in, be recognized for, and benefit from research across the spectrum, including clinical trials, health services research, and other types of research studies and methodologies.

# **Eligibility Criteria**

#### Applicants must meet the following criteria:

 Be a physician (MD, DO, or international equivalent) working in any country and currently in the last two years of their final oncology subspecialty training at an academic medical institution <u>and</u> within 10 years of obtaining their medical degree at the time of grant submission. Examples of subspecialty training include, but are not limited to, a hematology-

<sup>&</sup>lt;sup>1</sup> AAMC definition of underrepresented in medicine.

oncology fellowship, a surgical oncology fellowship, or a radiation oncology residency. An MD, PhD is eligible if both degrees are completed prior to the start of the grant period. If there are questions regarding whether the potential applicant is at the correct career stage, send an email to <a href="mailtogrants@conquer.org">grants@conquer.org</a> for clarification and eligibility verification and include your latest CV.

- Be planning an investigative career in clinical oncology with a focus on drug development research
- Have a valid, active medical license in the country where the research will be conducted at the time of application.
- Be working in an oncology laboratory or clinical research setting.
- Have a mentor, who is an ASCO member, in the field of drug development from the sponsoring
  institution. The mentor must assume responsibility and provide guidance for the research. If
  the mentor is not an ASCO member, a supporting letter from an ASCO member from the
  sponsoring institution must be included.
- Be an ASCO member or have submitted a membership application with the grant application.
   To apply for new membership, or to renew an existing membership, visit asco.org/membership.
- Be able to commit at least 60% of full- time effort in research (applies to total research, not
  just the proposed project) during the award period, as confirmed in an institutional Letter of
  Support.

Eligible applicants are allowed to hold only one active grant from Conquer Cancer at a time.

There are no citizenship or geographic requirements. However, by submitting an application, an applicant applying from an institution located in a country in which they are 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 they applied.

The Conquer Cancer Grants Selection Committee reserves the right to evaluate and determine an applicant's eligibility based on the information and justifications included in the application materials. Applicants who are uncertain about their eligibility are encouraged to refer to the Eligibility section of the FAQ or contact grants@conquer.org for clarification and provide their latest CV for evaluation.

Conquer Cancer has separate YIA special competitions for certain disease areas and topics. Please review the list of special competitions on the <u>YIA page</u> before starting an application. An applicant may only submit one application for a Young Investigator Award. **An applicant may only submit one application either under a special competition or the general competition.** 

#### Research Project Criteria

The YIA in Drug Development is intended to support proposals with a clinical research focus on drug development. ASCO's definition of clinical research is "hypothesis-driven research that employs measurements in whole patients or normal human subjects, in conjunction with laboratory measurements as appropriate, on the subjects of clinical biology, natural history, prevention, screening, diagnosis,

therapy, or epidemiology of neoplastic disease" (*Journal of Clinical Oncology*, Vol. 14, No. 2, 1996 pp. 666-670). In YIA proposals, preclinical *in vitro* and/or animal studies are acceptable as long as the outcome of these studies would ultimately lead to patient-oriented clinical research. **Project proposals should have measurable outcomes during the one-year grant period.** 

YIA proposals must ensure that the research reflects the needs of patients with cancer and must be developed with the participation of a patient advocate. Please refer to page 16 of this RFP for additional information about engaging a patient advocate in the YIA project.

# **Physician Payments Sunshine Act**

The Physician Payments Sunshine Act, or "Sunshine Act", is part of the Patient Protection and Affordable Care Act (health care reform) that passed in 2010. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and healthcare companies. More information about the Sunshine Act can be found at <a href="https://www.asco.org/practice-policy/policy-issues-statements/asco-in-action/physician-payment-sunshine-act-additional">https://www.asco.org/practice-policy/policy-issues-statements/asco-in-action/physician-payment-sunshine-act-additional</a>.

The Sunshine Act requires manufacturers of pharmaceutical drugs and devices, as well as group purchasing organizations, to report payments or transfers of value made to teaching hospitals and U.S. licensed physicians. (Please see the following excerpt from the Sunshine Act Final Rule that defines physician according to this law. If there are any questions regarding reportability, please talk with your institution. "As required by section 1128G(e)(11) of the Act, we proposed to define "physician" as having the meaning set forth in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the State in which they practice.") Reports are made to the Centers for Medicare and Medicaid Services (CMS), a government agency.

Conquer Cancer understands that payments made through this award are reportable under the Sunshine Act as indirect payments or transfers of value because these awards are funded by companies that are considered manufacturers of pharmaceutical drugs and devices and/or group purchasing organizations.

Conquer Cancer has entered into agreements with the supporters of this award that require that Conquer Cancer provide reportable information under the Sunshine Act. RECIPIENTS OF YOUNG INVESTIGATOR AWARDS MAY BE REPORTED ON THE CMS OPEN PAYMENTS WEBSITE AS HAVING RECEIVED PAYMENTS OR TRANSFERS OF VALUE FROM MANUFACTURERS OF PHARMACEUTICAL DRUGS AND/OR DEVICES. If there are any questions about reporting due to the Sunshine Act, please contact Gray Ladd, Associate Director, Business Operations and Compliance, at 571-483-1700 or operations@conquer.org

Disclaimer: The information on this section is not intended to provide legal advice. For legal advice concerning the Sunshine Act, the applicant must consult their institution or legal counsel.

For more information, see Terms and Conditions located in Appendix A.

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

The award of the YIA 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 and embargoes (including but not limited to those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury). Notwithstanding any other provision in this this Request for Proposals, any grant award is contingent on Conquer Cancer's ability to transfer grant funds to the sponsoring institution and/or individual(s) and support the research project to be conducted by the applicant in compliance with all applicable legal requirements. Conquer Cancer will not accept applications from, and/or make grant awards to, certain foreign sponsoring institutions or individuals if Conquer Cancer is prohibited from doing so under U.S. sanctions laws, or if Conquer Cancer would be required to obtain a license from the Office of Foreign Assets Control or the Department of Commerce to make such grants. If it is impossible or inadvisable for Conquer Cancer, in its sole and absolute discretion, to fulfill its obligations in a grant award, including but not limited to the transfer of grant funds to the sponsoring institution and/or individual(s) pursuant to applicable legal requirements, the grant will not be awarded to the sponsoring institution and/or individual. If, after payment of the first installment of a grant award, it becomes impossible or inadvisable for Conquer Cancer, in its sole and absolute discretion, to transfer grant funds to the sponsoring institution and/or individual(s) pursuant to applicable legal requirements, then Conquer Cancer shall have no obligation to pay additional installments of the grant award. It is the responsibility of the sponsoring institution and the applicant to provide Conquer Cancer with the information or lawful means that permit Conguer Cancer to transfer the grant funds in compliance with all legal requirements.

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
- <a href="http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx">http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx</a>

Additional Terms and Conditions are located in Appendix A.

#### **Peer Review of Applications**

The applications are reviewed by the Conquer Cancer Grants Selection Committee Career Development Award Panel using a multi-stage review process. Each application is assigned to at least two committee members who are leaders in their areas of expertise for independent and confidential review. Applications that reach the final review stage are also reviewed by a biostatistician and a patient advocate.

The applications are evaluated and scored by the Grants Selection Committee based on the following criteria using the 1-9 NIH scoring scale.

#### **Primary Criteria**:

- Strength of the hypothesis-driven proposal with a clinical research focus or with the goal of generating the rationale for future clinical studies. (May include pre-clinical in vitro and/or animal experiments that are designed to address a clinical question.) (~35%)
  - Significance and originality of the proposed study and hypothesis
  - Appropriateness, feasibility of the proposed project within the one-year timeframe, adequacy of the proposed experiment and methodology and overall description of the research strategy to accomplish the specific aims of the project
  - Appropriate and detailed statistical analysis plan
  - A focus on patient-oriented or translational and, ultimately, clinical research (including an appropriate and detailed plan in the patient advocate form)
- Strength of the mentor in supporting the applicant's proposal and in facilitating the applicant's career development (~30%)
  - o Quality of the mentor and the plan for mentoring interactions with the applicant

# Secondary Criteria:

- Potential for the applicant to pursue an academic clinical oncology career (~25%)
  - Potential favorable impact on career development of the applicant
  - The qualifications and experiences of the applicant. Factors considered include the quality and extent of past education, scientific training, research experience, research originality, productivity, potential for independent investigation, and commitment to a career in clinical oncology research.
- Availability of institutional resources to support the proposed project (~10%)

#### **Key Dates**

Online Applications Open: July 1, 2023

Full Applications Due: January 31, 2024 (11:59 PM ET)

Supplemental Materials Due: February 21, 2024

Notification Date: April 2024

Award Term: July 1, 2024– June 30, 2025

#### POST SUBMISSION MATERIALS ACCEPTED

Updates must be submitted by email to <a href="mailto:grants@conquer.org">grants@conquer.org</a>

# Deadline #1

(Due February 21, 2024)

Updates to publications initially submitted

IRB approval

Clinical protocol

If mentor left the institution: New mentor biosketch, letter of support, and updated mentorship plan *(required)* 

Letter/proof of receipt of drug from a company or any additional letters of collaboration

NOTE: These documents are optional, unless otherwise indicated, but are highly encouraged to be provided for inclusion in the application review.

#### **Application Changes**

The applicant must notify Conquer Cancer **immediately** by sending an email to <u>grants@conquer.org</u> if any of the following conditions apply from application submission through award notification:

- 1. <u>Withdrawal of Application</u>. Send an email to <u>grants@conquer.org</u> to inform the Conquer Cancer Grants and Awards team 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.
- 2. <u>Change of Institution or Position</u>. The applicant has a career plan change, leaves their current position in the institution, or is unable to meet the eligibility requirements of this RFP. If the applicant is selected to receive a YIA, Conquer Cancer has the right in its sole discretion to withdraw the award.
- 3. Mentor or Co-Mentor Change of Institution. If the applicant's mentor or co-mentor leaves their current position or institution, the applicant is required to identify a new mentor and submit updated documents. Please refer to post-submission materials accepted under Key Dates.
- 4. <u>Change in Proposal (Scope, Timeline, Budget, etc.)</u>. The applicant has significant changes in the submitted proposal affecting aims, research strategy, timeline, and/or budget. If Conquer Cancer is notified of the change in proposal after the applicant is notified of an award, Conquer Cancer has the right in its sole discretion to withdraw the award.

Changes in institution/position, mentor, or project scope after an award notification will require additional documents and review and approval from Conquer Cancer. Conquer Cancer has the right in its sole discretion to withdraw the award.

#### **Award Notification**

Applicants can expect to be notified in April 2024 via email from awards@mail.asco.org. To ensure receipt of notifications from the application portal, it is highly recommended to include awards@mail.asco.org to the applicant's safe sender list. All communication regarding applications, including award notifications, will be sent to the preferred email address on the applicant's membership profile. For questions, please contact <a href="mailto:grants@conquer.org">grants@conquer.org</a>.

# **Application Information Use and Sharing**

Conquer Cancer may use and process the information submitted through this application form for several purposes, including but not limited to: 1) evaluating the application, 2) communicating with you regarding your application and other opportunities that may be of interest to you, 3) publishing information regarding Conquer Cancer's grants and awards program, including through third party databases, 4) informing Conquer Cancer's grant making strategies and policies, and 5) for other legitimate purposes in keeping with Conquer Cancer's Privacy Policy and charitable mission. 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.

In addition, by submitting an application form to Conquer Cancer, the applicant grants Conquer Cancer the right to use all application information submitted, outside of the research proposal, for any purpose.

The details of research proposals submitted are considered confidential property of the applicant. Conquer Cancer is permitted to share research proposals with Conquer Cancer staff and reviewers, third party contractors, and potential supporters, and Conquer Cancer will require all to maintain the confidentiality of such proposals.

If an applicant is selected for an award, the applicant grants Conquer Cancer permission to deposit grantee information collected in any documents or communications related to the application (including but not limited to investigator name, degree(s), clinical specialty, Open Researcher and Contributor ID (ORCID), institution and institutional information, project title, abstract, grant start date and duration, and grant amount) into the Health Research Alliance (HRA) online database (HRA Analyzer) of privately funded grants, the Dimensions database, or any other similar database.

If an applicant is deemed fundable but Conquer Cancer does not have funding available, the applicant grants Conquer Cancer permission to share the full proposal to potential supporters.

#### **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 ASCO and Conquer Cancer application portal at <a href="mailto:awards.asco.org">awards.asco.org</a>. 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 January 31, 2024. No late applications will be accepted. Please note that technical assistance is only available until 5:00 PM ET on January 31.

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

#### **Application Guide**

Sections of the full application are listed below. More details about each section, including requirements and instructions, are described in the next pages.

- **1.** Applicant Information (required)
- 2. Project Information (required)
- **3.** Research Strategy (required)
- **4.** Biostatistical Plan (required)
- **5.** Cited References (required)
- **6.** Patient Advocate Form (required)
- **7.** Budget (required)
- **8.** Project Timeline Form (required)
- **9.** Resubmission Documentation (required if application is a resubmission)
- **10.** Personal Statement Form (required)
- **11.** Applicant's Biosketch (required)
- 12. Mentor & Sponsor Recommendation (required)
  - a. Mentor(s) Biosketch and Letter of Support (required)
  - **b.** Sponsor Biosketch and Letter of Support (required if mentor is not an ASCO member)
- **13.** Mentorship Plan (required)
- **14.** Institutional Letter of Support from Department Chair or Dean (required)
- **15.** Clinical Protocol (optional) strongly encouraged
- **16.** Publication Form (optional) maximum of two publications
- **17.** Additional Supporting Documentation (required)
  - **a.** Letter of biostatistical support (required)
  - **b.** Letter of support from patient advocate (required for clinical proposals)
- **18.** Institutional Approval (required)
- **19.** Review and Submit (required)

Applicants are encouraged to visit the Application Resources on asco.org and to refer to the FAQ.

- 1. <u>Applicant Information (required).</u> This section includes the following:
  - Applicant Information. This information is pulled directly from the applicant's ASCO membership
    profile. If changes need to be made to the applicant's information, visit <u>profile.asco.org</u>. Make sure
    that the applicant's profile has the most up-to-date information before beginning an application.
    Changes made to the applicant's profile are not saved in real-time but will be reflected on this form
    before submitting the full application.
    - First Name
    - Middle Name
    - Last Name
    - o Degree
    - Primary Organization Name
    - Address (including city, state, and zip code)
    - Country
    - Primary email address (all future communications about the application will be sent to this address)
    - o ORCID ID
    - ASCO Member ID
  - Additional questions and required information. Answer the following:
    - o Do you have a medical degree or international equivalent?
    - Do you have a full-time faculty appointment (this includes full-time instructor position)?
    - o Academic Rank. Select from the drop-down list.
    - Certification/Subspecialty Training. Select from the drop-down list.
    - Field of Clinical Training. Select all that apply
    - o Field of Research Training. Select all that apply.
  - After completing this form, click "Mark as Complete".
- **2.** <u>Project Information (required).</u> This section includes the following proposed project information (all are required):
  - Research Project Title (250 characters maximum): Provide a short descriptive title of the research project.
  - <u>Brief Research Project Description/Abstract (3000 characters maximum)</u>: Provide a brief abstract of the research project.
  - <u>Lay Abstract (2500 characters maximum)</u>. 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. If selected to receive an award, Conquer Cancer may use the content of
    this layperson summary on its website and/or other public facing materials.
  - Specific Aims (1000 characters maximum per aim): Select the number of aims from the drop-down list. Briefly describe the goals of each aim separately and concisely in the boxes provided. Include the following for each aim: the aim objective, hypothesis, the research approach, expected results and 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.

- <u>Subject Area</u>: Select one Subject Area from the drop-down list that best describes the research project, its objectives and proposed project outcomes. 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.
- <u>Equity, Diversity, and Inclusion:</u> Select "Yes" or "No" in response to the question "Does your research project address health disparities and inequities?"
- Research Classification: Select a category that relates to the research project. The list has six broad categories of scientific interest in cancer research.
- <u>Type of Research Study</u>: Select the type from the drop-down list to indicate if the research project is "Clinical", "Pre-clinical", or "Health Services Research".
  - o If "Clinical" is selected, indicate the clinical trial phase and clinical trial number or identifier.
- <u>Assurances:</u> IRB and IACUC approvals are not required at the time of submission but highly encouraged to provide documentation if approval is obtained by Post-Submission Materials deadlines.
  - 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.
    - If the status is Pending, please indicate the anticipated date of approval and enter any additional comments in the comment box.
  - 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.
    - If the status is Pending, please indicate the anticipated date of approval and enter any additional comments in the comment box.
- <u>Use of Drug(s)</u>: 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 "Yes" or "No" from the drop-down list to indicate if the application is a resubmission of a previous application.
- How many mentors do you have?
  - Select "1" from the drop-down list. Only one mentor is allowed.
  - o Indicate if the mentor is an ASCO member (if mentor is not an ASCO member, the applicant will be required to invite a Sponsor, who must be an ASCO member).
  - NOTE: It is important to enter the correct information, as it will affect which forms are required to be completed in the application. <u>The sponsor invite task (if applicable) will be available in the application once the Project Information task has been marked as complete.</u>
- After completing this form, click "Mark as Complete".

3. <u>Research Strategy (required).</u> The research strategy is limited to four (4) 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 4-page limit. If the document uploaded exceeds the page limit, Conquer Cancer will return the application.

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.
  - 4. Provide a strong justification for selection of therapeutic drug including its candidate targets and relevant prior work.
  - 5. Provide information about characterization of the candidate compound including feasibility regarding production and availability of the candidate compound.

#### 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.

#### iii. Approach:

- 1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- 2. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention.
- 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.
- Discuss potential problems, alternative strategies including alternate compounds in the event the compound fails to achieve proposed objectives, 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 access to an experimental therapy, or an approval letter from CTEP or a cooperative group. NOTE: Applicants may send

- supporting letters regarding feasibility (e.g., proof of receipt of drug from a company, IRB approval, etc.) to <a href="mailto:grants@conquer.org">grants@conquer.org</a>.
- 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 (i.e. writing of protocol, performing the assays, etc.).
- 9. When patients are involved, the precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained.
- 10. List and describe the facilities and resources available to conduct the study, including a description of industry support for any clinical trials and results from previous trials with proposed candidate drugs or other relevant drugs.

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

Use this file naming convention: [year and program abbreviation]\_ResearchStrategy\_[Last name] (e.g., 2024YIA ResearchStrategy Smith)

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

4. <u>Biostatistical Plan (required).</u> Applications will be reviewed and scored by a biostatistical reviewer for statistical rigor. A detailed statistical plan is required for all applications. The plan is limited to one (1) typewritten, single-spaced page with one-inch margins and 11-point Arial font type. References, if any, may be included in this section and detailed in the Cited References. If the document uploaded exceeds the page limit, Conquer Cancer will return the application.

All studies whether clinical, observational, in-vivo or laboratory-based in vitro research proposals should include the primary objective/hypothesis and endpoint of the study (with clear definition), description of experimental design and study groups that will be compared, justification of the proposed study sample size, detailed procedures for data analysis, and any other appropriate statistical details that describe the summary measures that will be used to meet the objectives of the study. An appropriate sample size justification should include all parameters and assumptions required for the computation of the sample size (including key references if novel methods used, and sufficient enough to allow replication): the effect size, power and type I error rates for each aim where applicable. If Bayesian approaches are used, prior assumptions and operating characteristics should be provided. When relevant to the project, the plan should state the median follow-up, prevalence of mutations in a given population, accrual rate, or number of events for a time-to-event outcome. The statistical analysis plan should provide details for analyzing high-throughput data including the pipelines and procedures, if the proposal involves such data. For studies using artificial intelligence and machine learning techniques, detailed statistical design and analysis plan for algorithms, training data and validation data, performance metrics, and data/software sharing must be included in the proposal.

The applicant is required to closely work with the collaborating biostatistician and or bioinformatician if applicable in developing the research strategy and during the conduct of the research project The applicant is required to upload a Letter of Support from a biostatistician and/or

bioinformatician if applicable, under the Additional Supporting Documentation section. The letter from the collaborating biostatistician should clearly state a mentoring plan to help with the design of the study, data analysis and interpretation of findings. The letter should also mention the resources that will be provided to ensure the statistical rigor and feasibility of the proposed project.

Visit the <u>Application Resources</u> on asco.org. It includes a webinar recording on "Working with a Biostatistician."

Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_BiostatisticalPlan\_[Last name] (e.g., 2024YIA\_BiostatisticalPlan\_Smith).

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

5. <u>Cited References (required).</u> Upload a bibliography of any references cited in the Research Plan. <u>The Cited References has no page limit, must be typewritten with single-space, one-inch margins and using an 11-point Arial font type.</u>

Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_CitedReferences\_[Last name] (e.g., 2024YIA CitedReferences Smith)

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

6. Patient Advocate Form (required). Applications will be reviewed and scored by a patient advocate. The patient advocate reviewer will assess how well the applicant explains how the proposed project could impact patients. The responses on this form must be written in a way that is understood by people who do not have scientific or medical backgrounds. Clinical studies must be clearly written and well-designed, must follow all ethical and Institutional Review Board regulations. Clinical studies must clearly demonstrate how they will lead to future clinical research and benefit patients.

Clinical proposals must be developed with a patient advocate. Pre-clinical studies do not require involvement of patient advocate, but applicants are strongly encouraged to engage an advocate in developing the project. Collaboration and engagement of patient advocates for the preclinical studies will help to recognize clinical implications of the proposed preclinical translational work. All studies must reflect the needs of patients with cancer to minimize patient burdens and advance clinical outcomes for improved cancer treatment.

The patient advocate should be involved early during the development of the project and the application. This will help to ensure that the proposed research is relevant to patients and addresses

their needs efficiently. A patient advocate can include but is not limited to a survivor of or person living with cancer, a family member or primary caregiver of a person living with cancer, or other individual with a strong personal connection or experience with cancer. A patient advocate should have a dedicated interest in cancer research and survivorship and be able to represent the perspective of patients with cancer/survivors/co-survivors in the development and conduct of the project.

Applicants are encouraged to work with their mentors to leverage institutional resources, such as community advisory groups or advocacy programs, to identify advocates to work with. Applicants are also encouraged to contact local cancer advocacy groups when appropriate. Applicants may interact with an advocate virtually, rather than in-person, as well if appropriate. Whenever possible, applicants are strongly recommended to work with an advocate who has experience with the cancer type to be studied in the proposed research.

Note: If your institution does not have patient advocates to help in developing your study, please visit the <u>Application Resources</u> on asco.org. It includes a webinar recording on "Working with a Patient Advocate", and article on "Patient Engagement in Cancer Research From the Patient's Perspective" and resources on patient advocates involved in cancer research.

In order to inform the reviewers of the applicant's proposed research's relevance for patients with cancer and to ensure that their research is patient-focused, applicants must answer the following questions as concisely as possible (2500 characters per question) using lay-friendly language.

- Discuss the project and identify the potential translational and clinical significance of the project from the patient perspective. How will successful completion of the project lay foundation for future translational and clinical research studies?
- Discuss how the project will affect fundamental concepts and adds to the existing body of cancer research in ways that are relevant and beneficial to patients, their families, and caregivers.
- How will your career evolve to impact outcomes important to patients?
- If the applicant is working with an advocate, please describe how a patient advocate was involved in developing the grant application and explain the role a patient advocate will have during the conduct of the research project.

Applicants submitting clinical proposals are required to upload a Letter of Support from a patient advocate under the Additional Supporting Documentation section.

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

7. <u>Budget (required).</u> The award funds will be directed to the sponsoring institution and should be used towards salary support, supplies, equipment, travel, etc. necessary for the pursuit of the applicant's research project.

The budget must be directly entered into the budget section of the online application. Budget justification for the entire period <u>must</u> be entered in the "Description of Costs" column. Enter N/A for budget categories not being requested. The direct and indirect costs will calculate automatically at the bottom of the page as entered. Do not use a comma when entering budget amounts.

The budget guidelines are as follows:

- <u>Total Award</u>: The total award amount is \$60,000 for one year, payable on or about July 1 and January 1 in two equal installments. The total requested budget must be exactly \$60,000.
- Research support: At least \$56,000 should support costs directly related to the research project such as personnel salary, supplies, equipment, 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 (including ASCO), tuition fees, and fees for academic courses and certifications are unallowable costs.
- Support for Mentor: No more than \$10,000 should be included as Personnel Costs for the Mentor.
- <u>Travel</u>: Up to \$1,500 should be allotted specifically for the applicant's travel to the Conquer Cancer
  Grants and Awards Ceremony and for any other travel essential to conducting the study.
  Attendance is **mandatory** at the Conquer Cancer Grants and Awards Ceremony, which will take
  place during the ASCO Annual Meeting in June 2024 immediately following acceptance of the
  grant. As the award term begins after the Conquer Cancer Grants and Awards Ceremony, Conquer
  Cancer approves costs incurred to attend the Ceremony as pre-award costs.
- <u>Indirect costs</u>: Up to \$2,500 may be applied to overhead or facilities and administrative costs of the applicant's institution in administering the research project.

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

8. Project Timeline Form (required, 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 during the award term. However, the timeline should be clear what outcomes will be achieved during the award period and its expected timeframe. The expected date of completion for the major milestones described in each aim of the proposal must be provided.

Download the template, then update the following:

- Enter the name of the milestone/activity
- Enter a description of the milestone/activity and the time frame it will be completed
- Enter the expected date of completion for major milestones
- Indicate whether the milestone/activity is a deliverable
- Select the appropriate status
- Do not enter any comments.
- Ensure all columns are visible on each page and set to proper print area. Upload as a PDF file.

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

Use this file naming convention: [year program abbreviation]\_Timeline\_[last name] (e.g., 2024YIA\_Timeline\_Smith)

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

**9.** Resubmission Documentation (required for resubmissions only). Applicants resubmitting a prior application are required to upload a one-page introduction to address the feedback and critiques provided during the prior application cycle.

The introduction is limited to one (1) typewritten, single-spaced page with one-inch margins and 11-point Arial font type. This introduction should discuss how the application is modified in response to previous review comments. It is advised that applicants ask their mentors to read the reviewers' critiques and the resubmission responses to confirm that the critique has been considered and appropriately addressed.

Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_ResubmissionDoc\_[Last name] (e.g., 2024YIA\_ ResubmissionDoc\_Smith).

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

- **10.** <u>Personal Statement Form (required).</u> Enter answers to the following questions. Cutting and pasting from a Word document is allowed. Each response must not exceed 2,000 characters.
  - Applicant's career plan. Provide a brief description of the applicant's career plan.
  - <u>Impact of award on applicant's career</u>. Provide a brief explanation on how receiving this award would affect the applicant's career.
  - <u>Percentage time on research activities</u>. Provide the percentage of time the applicant will spend on total research activities.
  - <u>Applicant's role</u>. Describe briefly the applicant's role versus the mentor's role in the proposed research study.
  - Sources of salary support. List the applicant's sources of salary support.
  - Collection and support of data. Briefly describe who will collect and analyze the data.
  - Other funding sources. List other funding agencies/organization where this research proposal was or will be submitted. If none, please indicate N/A.

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

11. <u>Applicant's Biosketch (required).</u> Applicants should use the NIH biosketch <u>template</u> provided with an expiration date of 01/31/2026. The biosketch must not exceed five (5) pages. To complete the biosketch, please refer to these <u>instructions</u>. If the document uploaded exceeds the page limit, Conquer Cancer will return the application.

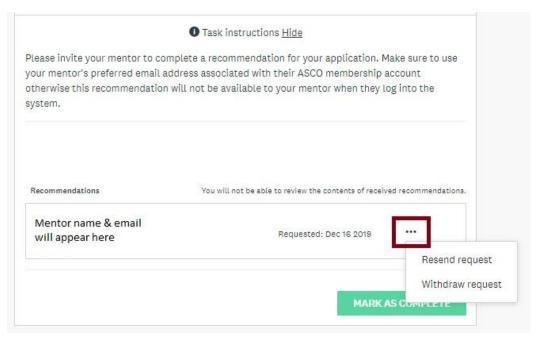
Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year program abbreviation]\_Biosketch\_[Last name] (e.g., 2024YIA\_Biosketch\_Smith)

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

#### 12. Mentor and Sponsor Recommendation (required)

- The mentor must be from the applicant's sponsoring institution. For questions about selecting a mentor, contact <a href="mailto:grants@conquer.org">grants@conquer.org</a>.
- If the application indicates that the mentor is not an ASCO member, a Sponsor Invite appears in the left navigation. The sponsor must be an ASCO member from the applicant's sponsoring institution and is only required when the mentor is not an ASCO member.
- To request a recommendation from the mentor or sponsor:
  - o Click "Request a Recommendation".
  - Enter the First name, Last name, Email address, and a brief message (optional) to the mentor or sponsor.
    - IMPORTANT: If the mentor is an ASCO member, make sure to enter the email address associated with the mentor's ASCO user account, otherwise this recommendation will not be available to the mentor when they log in the system. If an incorrect email address is used, withdraw the request and create a new request using the correct email address.
  - Click "Send Request".
  - The mentor will receive an email with an invite to complete a recommendation in the Application Portal. This includes submitting their Biosketch and their Letter of Support for the applicant.
  - If a sponsor was invited, the sponsor will receive an email with an invite to complete a recommendation in the Application Portal. This includes submitting their Biosketch and their Letter of Support for the applicant.
  - When they click "Start" they will be asked if they wish to Accept or Decline the recommendation request from the applicant. Upon accepting, the mentor and sponsor will be able to complete and submit their recommendation.
  - The applicant will be notified by email when the mentor or sponsor makes a decision to Accept or Decline the recommendation.
- To resend or withdraw the request, click the ellipsis (...) near the mentor's name and email and select the appropriate option from the drop-down list as shown below.



• **IMPORTANT**: The mentor and sponsor must complete their task and click "Submit" prior to the application deadline. The applicant will not be able to submit the application until these tasks are submitted. Once the mentor and sponsor have submitted their documents, return to this task and click "Mark as Complete".

#### **Mentor must submit the following:**

- Mentor's Biosketch The mentor should use the NIH biosketch template provided with an expiration date of 01/31/2026. The biosketch must not exceed five (5) pages. To complete the biosketch, please refer to these instructions.
- <u>Letter of Support</u>. The letter must be signed, printed on official letterhead and should include the following information:
  - Confirmation that the applicant is currently in the last two years of their final subspecialty training at an academic medical institution at the time of grant submission
  - o A critical review of both the applicant and the research proposal
  - The role of the applicant in the development of the proposal
  - The role(s) or anticipated role(s) the applicant holds (will hold) at the institution
  - The level of institutional commitment to the applicant's career development as an independent clinical investigator
  - Assurance that the applicant's sponsoring institution will provide adequate facilities and support for performance of the proposed work
  - The role the mentor will play in supporting the career development of the applicant during the grant period
  - The mentor's research and training qualifications, including experience with training early career clinician-scientists
- If there is more than one mentor, a biosketch and a letter of support is required from each mentor.

  Applicants should not have more than two mentors.

 A mentor is strongly encouraged to have no more than two mentees applying for the Young Investigator Award, Global Oncology Young Investigator Award, and/or Career Development Award for this funding cycle.

The Applicant will be notified when the mentor submits a recommendation. The mentor must click "**Submit**" at the bottom of the page to trigger the email. The applicant will not be able to view the documents submitted by the mentor.

## If there is a Sponsor, the Sponsor must submit the following:

- Sponsor's Biosketch. The Sponsor should use the NIH biosketch template with an expiration date
  of 09/30/2024. The biosketch must not exceed five (5) pages. To complete the biosketch, please
  refer to these instructions.
- <u>Letter of Support</u>. The letter must be signed, printed on official letterhead and should include the following information:
  - Confirmation that the applicant is currently in the last two years of their final subspecialty training at an academic medical institution at the time of grant submission
  - o A critical review of both the applicant and the research proposal
  - o The role(s) or anticipated role(s) the applicant holds (will hold) at the institution
  - The level of institutional commitment to the applicant's career development as an independent clinical investigator
  - Assurance that the applicant's sponsoring institution will provide adequate facilities and support for performance of the proposed work

The applicant will be notified when the sponsor submits a recommendation. The sponsor must click "**Submit**" at the bottom of the page to trigger the email. The applicant will not be able to view the documents submitted by the sponsor.

13. Mentorship Plan (required). The mentorship plan is limited to two (2) typewritten, single-spaced pages, with one-inch margins, using an 11-point Arial font type, must be jointly written and signed by the applicant and mentor. If the document uploaded exceeds the page limit, Conquer Cancer will return the application. The mentorship plan must describe a systematic professional development plan for the applicant, including intended structure of the mentor/mentee interaction, the specific details on the skills that the proposed mentor will help the applicant develop, and other academic career development activities (such as coursework, biostatistical mentoring/training, journal clubs, grantwriting, manuscript preparation and one-on-one meetings) that will occur during the proposed investigation to help the applicant develop the knowledge and skills necessary for a successful career in clinical oncology research, with a focus on drug development.

Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year program abbreviation]\_MentorshipPlan\_[last name] (e.g., 2024YIA\_MentorshipPlan\_Smith)

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

14. <u>Institutional Letter of Support from Department Chair or Dean (required).</u> 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 and that the applicant will have at least 60% protected time for research during the award period. 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.

Note: If the mentor is the Department Chair, the Institutional Letter of Support must come from the Division Head, Dean, or any member of the institution's leadership that can assure support on the performance of the proposed research. The sponsor may be the same individual writing the institutional letter of support, however, the sponsor letter of support should be written differently using the guidelines in #12.

Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_InstitutionalLOS\_[Last name] (e.g., 2024YIA\_InstitutionalLOS\_Smith).

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

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

Upload as a PDF file. Click "Attach File" and select the file to be uploaded in the application.

Use this file naming convention: [year and program abbreviation]\_ClinicalProtocol\_[Last name] (e.g., 2024YIA\_ClinicalProtocol\_Smith)

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

**16.** <u>Publications (optional).</u> Up to two prior publications that are relevant to the proposed project may be included. The publications must highlight the applicant's experience and qualifications to conduct the proposed project. The applicant must be a co-author on these publications.

To enter publications:

- Select the total number of publications from the drop-down (1 or 2).
- For each publication, enter the title, PubMed ID number, year, type, name, status, URL, and funding status.
- Upload as a PDF file. Click "Attach File" and select the file(s) to be uploaded in the
  application. Use this file naming convention: [year program abbreviation]\_Publication 1\_[last
  name] (e.g., 2024YIA\_Publication 1\_Smith)

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

17. Additional Supporting Documentation (required). 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 support for any investigational agents, a letter of collaboration from another laboratory providing expertise for this project, a letter of support for a collaboration, etc.). A letter of support from collaborating biostatistician(s) or bioinformatician is required for both preclinical and clinical studies. A letter of support from a patient advocate is required for clinical proposals only. All letters must be signed and on official letterhead. 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.

Upload as a PDF file. Click "**Attach File**" and select the file to be uploaded in the application. Repeat this step to upload multiple files.

Use this file naming convention: [year and program abbreviation]\_SupportingDoc\_[number]\_[Last name] (e.g., 2024YIA\_SupportingDoc\_1\_Smith; 2024YIA\_SupportingDoc\_2\_Smith; etc.).

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

- **18.** <u>Institution Approval (required).</u> 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.
    - o 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 their task and click "Submit" at the bottom of the page <u>prior</u> to the deadline. An email notification will be sent to the applicant confirming that the task has been completed.
  - The applicant will not be able to submit the application until this task is submitted.
  - Once the Institution Approver has submitted the task, return to this section and click "Mark as Complete".

19. <u>Review and Submit (required).</u> The applicant will not be able to navigate to this page until all required sections have been "Marked as Complete" and all tasks from the Mentor(s), Sponsor (if applicable), and Institution Approver have been submitted.

On the left navigation, click "Review" to review or "Submit" to submit the application.

<u>To download a copy of the application</u>, 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.

# **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)
Research Strategy (required)
Biostatistical Plan (required)
Cited References (required)
Patient Advocate Form (required)
Budget (required)
Project Timeline Form (required)
Resubmission Documentation (required if application is a resubmission)
Personal Statement Form (required)
Applicant's Biosketch (required)
Mentor & Sponsor Recommendation (required)
<ul> <li>Mentor(s) Biosketch and Letter of Support (required)</li> </ul>
<ul> <li>Sponsor Biosketch and Letter of Support (required if mentor is not an ASCO member)</li> </ul>
Mentorship Plan (required)
Institutional Letter of Support from Department Chair or Dean (required)
Clinical Protocol (optional) – strongly encouraged
Publication Form (optional) – maximum of two publications
Additional Supporting Documentation (required)
<ul> <li>Letter of biostatistical support (required)</li> <li>Letter of support from patient advocate (required for clinical proposals)</li> </ul>
Institutional Approval (required)
Review and Submit (required)

# **Appendix A. Terms & Conditions**

Each applicant selected to receive a YIA, and their Sponsoring Institution, must execute a separate Terms and Conditions document with Conquer Cancer in order to receive a YIA. This section of the RFP sets forth selected provisions of the Terms and Conditions that the applicants and their Sponsoring Institution should review carefully before submitting an application for a YIA. This RFP does not contain the complete Terms and Conditions document. Conquer Cancer reserves the rights to modify any of the provisions of the Terms and Conditions prior to execution by the applicant and Sponsoring Institution.

#### Responsible Conduct of Research

- (1) The Research Project will be conducted according to the highest scientific and ethical standards and in compliance with all applicable laws and regulations and with the policies of the Sponsoring Institution, including with respect to Sponsoring Institution's conflict of interest policies and procedures. To the extent policies of the Sponsoring Institution conflict with these Terms and Conditions, these Terms and Conditions will prevail.
- (2) Upon request of Conquer Cancer, the Recipient will provide copies of documentation of Institutional Review Board approval for human research subjects to Conquer Cancer prior to commencing research on human subjects, if applicable.
- (3) Upon request of Conquer Cancer, the Recipient will provide copies of documentation of Institutional Animal Care and Use Committee approval or international animal welfare board equivalent to Conquer Cancer prior to commencing research on animal subjects, if applicable.

#### **Funds: Payment and Use**

- (4) The Award total is \$60,000, paid in two installments of \$30,000, on or about July 1, 2024 and January 1, 2025 subject to compliance by Recipient and Sponsoring Institution with these Terms and Conditions. The Award funds will be paid to the Sponsoring Institution.
- (5) The Award will be used solely as detailed in the Research Project (including the grant proposal and budget).
- (6) No more than \$2,500 will be applied to overhead or indirect costs of the Sponsoring Institution in administering the Research Project. At least \$56,000 of the Award funds will be applied to research support. No more than \$1,500 per year will be used to cover the Recipient's travel expenses (including to the ASCO Annual Meeting). Direct costs include costs related to sub-grants and subcontracts. Salary limits will be equivalent to the NIH applicable limit.
- (7) Award funds will not be used for expenditures incurred prior to the first day of the Award Period (except for expenses related to travel to the Conquer Cancer Grants and Awards Ceremony) or after the last day of the Award Period. No additional expenses may be paid from Award funds after Conquer Cancer has received the Recipient's final expenditure report or after any unexpended

- funds have been returned to Conquer Cancer, which must be provided in accordance with specific paragraphs in the full Terms and Conditions.
- (8) At the end of the Award Period, any unexpended funds and any funds expended inconsistent with the Research Project will be returned to Conquer Cancer.

#### **Requests for Budget Changes or Extensions**

- (9) The Recipient may move funds of up to 5% of the total yearly budget (\$2,500) between budget categories or into new budget categories without prior written approval of Conquer Cancer. Notwithstanding the foregoing, budget limits on indirect and travel costs will be strictly followed and cannot be adjusted.
- (10) Budget changes of greater than 5% per year between budget categories will be approved in writing by Conquer Cancer before expenditure of funds. The Recipient will submit a re-budget request with a detailed justification of the proposed change through the application portal.
- (11) Any request for a no-cost extension or budget change must be made through the application portal no earlier than 90 days prior to the expiration of the Award Period. Requests received after the last day of the Award Period will not be accepted and will automatically be disapproved. No cost-extensions of up to six months may be approved by Conquer Cancer in its sole discretion. Conquer Cancer may approve up to a maximum of three no-cost extensions.
- (12) Requests for a six month no-cost extension require a no-cost-extension request submission through the application portal and a detailed explanation of why the request is being made. Requests will only be approved if they pertain to Research Project. Conquer Cancer will approve or disapprove the request at its discretion.
- (13) If a no-cost extension is granted by Conquer Cancer, the Recipient will submit additional progress reports and financial expenditure reports every six months during the extension term.

#### **Change of Personnel**

(14) Neither the Sponsoring Institution nor the Recipient is permitted to transfer the Award to a coinvestigator or any member of the research team, or a mentor. The Recipient's mentor may not be changed without the prior written approval of Conquer Cancer. Conquer Cancer will approve or disapprove the request for mentor change at its discretion.

#### Changes in Research Focus and Project Scope

(15) Changes in the specific aims of the Research Project will not be allowed without prior written consent from Conquer Cancer. Any request for changes in the specific aims of the Research Project must be made through the application portal prior to performing any changes to the Research Project. Conquer Cancer will approve or disapprove the request at its discretion.

- (16) Major changes in research design require prior written approval from Conquer Cancer. A request must be submitted by the Recipient through the application portal prior to performing any aspects of any newly designed study. Examples of a major change include, but are not limited to, studying a different patient population than originally proposed or studying a different therapeutic than originally proposed. Conquer Cancer will approve or disapprove the request at its discretion.
- (17) Minor changes in research methodology are not subject to prior approval by Conquer Cancer, but must be explained and justified by the Recipient in the mid-year or annual progress report.

# **Institution Transfer**

- (18) The Recipient must be affiliated or employed with the Sponsoring Institution throughout the Award period. If the Recipient accepts an appointment at another institution during the Award Period, and desires to have the Research Project transferred to the new institution, the Recipient will submit a request through the application portal to transfer the Award to the new institution at least 60 days before the anticipated date of transfer. Subject to Conquer Cancer's written approval and in Conquer Cancer's sole discretion, the Award may be transferred provided arrangements satisfactory to Conquer Cancer are implemented to continue the Research Project in a manner in which it was originally approved by Conquer Cancer. Any transfer must be approved in writing by Conquer Cancer before any such transfer takes place. Upon approval of a transfer of the Award to a new institution, the Sponsoring Institution will return any unexpended funds and any funds expended inconsistent with the Research Project to Conquer Cancer. The new institution will agree to comply with these Terms and Conditions. Conquer Cancer will make arrangements to provide remaining Award funds to the new institution.
- (19) If the Recipient is unable or not permitted to transfer the grant to a new institution, the Recipient and the Sponsoring Institution will relinquish the Award and any unexpended funds and funds expended inconsistent with the Research Project will be returned to Conquer Cancer.

# **Program Reporting**

- (20) Throughout the Award Period, the Recipient will submit expenditure reports and progress reports regarding the Research Project through the application portal. It is the responsibility of the Recipient to submit the reports in a timely manner. Conquer Cancer may contact appropriate persons connected to the Research Project to ensure the progress reports and expenditure reports are received as required. Recipient and Sponsoring Institution will comply with the then-current procedures of Conquer Cancer regarding submission of progress and expenditure reports.
- (21) Noncompliance with any of these Terms and Conditions, including failure to submit progress or expenditure reports, may result in the withholding of payment on this Award or other awards of Conquer Cancer in effect at the Sponsoring Institution, or on Conquer Cancer awards that may be awarded in the future, or such other action deemed appropriate by Conquer Cancer.

(22) Any unobligated balance must be returned in full to Conquer Cancer along with the final expenditure report. The check should be made payable to the "Conquer Cancer, the ASCO Foundation."

#### **Post-Award Reporting Obligation**

- (23) The Recipient will respond to Conquer Cancer's requests for information on their career progress following the Award Period and may be requested to provide their current Curriculum Vitae or update their information through the application portal using the "Career Progress" task. The information may be used for program evaluation and alumni communications. The Recipient understands that this obligation survives the Award Period and that they have an ongoing obligation to provide this information.
- (24) Conquer Cancer reserves the right to include information relating to the Award in its periodic reports, annual reports, awardee directory, publicly accessible databases of privately funded grant awards, or in any other materials issued by or on behalf of Conquer Cancer or Conquer Cancer's affiliates.

#### **Physician Payments Sunshine Act**

(25) The Physician Payments Sunshine Act, or "Sunshine Act", is part of the Patient Protection and Affordable Care Act (health care reform) that passed in 2010. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and healthcare More information about the Sunshine Act can companies. https://www.asco.org/practice-policy/policy-issues-statements/asco-in-action/physician-paymentsunshine-act-additional. The Sunshine Act requires manufacturers of pharmaceutical drugs and devices, as well as group purchasing organizations, to report payments or transfers of value made to teaching hospitals and U.S. licensed physicians. (Please see the following excerpt from the Sunshine Act Final Rule that defines physician according to this law. If there are any questions regarding reportability, please talk with your institution. "As required by section 1128G(e)(11) of the Act, we proposed to define "physician" as having the meaning set forth in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the State in which they practice.") Reports are made to the Centers for Medicare and Medicaid Services (CMS), a government agency. Conquer Cancer understands that payments made through the Conquer Cancer Young Investigator Award are reportable under the Sunshine Act as indirect payments or transfers of value because these awards are funded by companies that are considered manufacturers of pharmaceutical drugs and devices and/or group purchasing organizations. Conquer Cancer has entered into agreements with the supporters of the Conquer Cancer Young Investigator Award that require that Conquer Cancer provide reportable information under the Sunshine Act. Conquer Cancer's understanding is that payments made to the Recipient of the Conquer Cancer Young Investigator Award are reportable as research grants under the Sunshine Act.

- (26) The Sunshine Act requires that all reportable payments or transfers made starting August 1, 2013 be reported to CMS. To assist Conquer Cancer in complying with its reporting obligations to its supporters, the Recipient agrees to provide information to Conquer Cancer, including: State of License; State License Number; and, National Provider Identifier (NPI) Number. Recipient must submit the information through the application portal by the due date specified.
- (27) The information in this Terms and Conditions is not intended to provide legal advice to Recipient and Sponsoring Institution regarding the Sunshine Act. Recipient and Sponsoring institution should consult their own counsel with questions regarding the Sunshine Act.

#### **Provision of Information to Funder**

- (28) The Recipient acknowledges, agrees, and consents to Conquer Cancer providing their current and future contact information to Funder.
- (29) The Recipient acknowledges, agrees, and consents to Conquer Cancer providing progress and expenditure reports and copies of press releases relating to the Award or the Research Project to Funder.

#### Publications and Other Public Release of Results

- (30) Conquer Cancer strongly encourages Recipient to submit the results of Research Project for publication or other public release. In the event the Recipient's results are published or otherwise publicly released either during or after the Award Period, the Recipient will provide Conquer Cancer with a copy of such publication or public release. All publications and public releases will include an acknowledgment of Conquer Cancer and Funder (see Public Announcements and Acknowledgment).
- (31) Conquer Cancer supports the widest possible dissemination of funded research results. Recipient is highly encouraged to publish in scientific journals that will provide public access to the research findings no later than twelve months after the date of publication.

#### Public Announcements and Acknowledgments

- (32) Conquer Cancer will announce the Award and other recipients of the Conquer Cancer Young Investigator Award. Conquer Cancer anticipates that the Sponsoring Institution may wish to make a public announcement of this Award. The Sponsoring Institution will submit to Conquer Cancer any proposed announcement, press release, or other public statement by the Sponsoring Institution relating to the Award, prior to release, and to coordinate the release of such public announcement, press release, or statement with Conquer Cancer. A copy of any press release, announcement, or public statement must be provided to Conquer Cancer.
- (33) The Recipient and the Sponsoring Institution will acknowledge the support of Conquer Cancer and Funder in all publications and presentations of the research funded by the Award. The Recipient

understands that all abstracts, publications, and presentations resulting from research supported by the Award will contain the acknowledgment, "This work was funded by a Conquer Cancer Young Investigator Award, supported by Funder. Any opinions, findings, and conclusions expressed in this material are those of the author(s) and do not necessarily reflect those of the American Society of Clinical Oncology®, Conquer Cancer®, or the Funder."

(34) The Recipient is encouraged to use an emblem for the Conquer Cancer Young Investigator Award on posters, presentations, and similar items produced for scientific meetings and conferences. The emblem may be used with the acknowledgment language. The Recipient can request this emblem by sending an email to <a href="mailto:grants@conquer.org">grants@conquer.org</a>.

#### **Intellectual Property Rights**

(35) Conquer Cancer and Funder will have no intellectual property rights or other rights in or to data collected or scientific discoveries made through the Research Project funded by the Award. Conquer Cancer encourages its recipients and their sponsoring institutions to report to Conquer Cancer any inventions, discoveries, or intellectual properties that result from the support of the research.

# Appendix B. Helpful Tips for Using the Application Portal

#### **Getting Started**

To access the application portal, go to 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 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.
- <u>To initiate an application</u>, once logged into the application portal, click "View Programs", select the program "Young Investigator Award Special Competitions", and click "**Apply**".
- *NOTE:* Make sure that your ASCO membership profile has the most up-to-date information before beginning an application.

# **Completing the Eligibility Quiz**

You will first be asked to complete an eligibility quiz. Once you have answered each question, click "Mark as Complete" at the bottom of the page. You will then receive an email to confirm your eligibility. If you are eligible, you will automatically have access to the full application. The different application tasks will appear in the left navigation. If you have any questions regarding eligibility, contact <a href="mailto:grants@conquer.org">grants@conquer.org</a>.

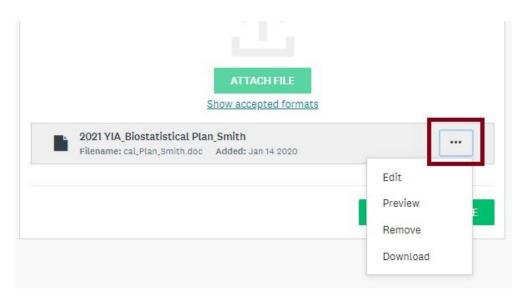
# **Navigating the Application**

- Click the task(s) in the left navigation to start working on your 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!



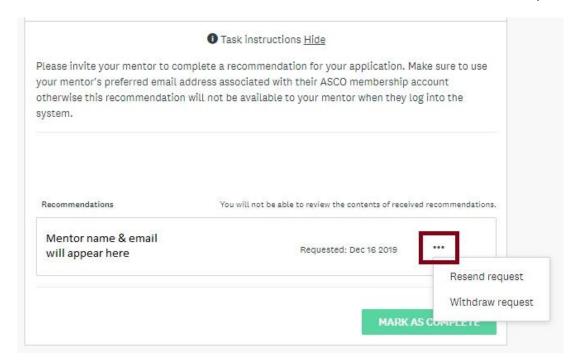
#### **Uploading a Document**

- Click "Show accepted formats" to determine the file formats accepted. Documents <u>should not be password protected.</u>
- 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 upload a document, click "Attach File" and select the file to be uploaded.
- 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". NOTE: You may need to clear your browser's cache to make sure you are able to view the re-uploaded document.



#### Requesting a Recommendation

- As part of your application process, you will need to "Request a Recommendation" from third
  parties such as a Mentor, Sponsor, and 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, you will be instantly notified.
- 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 junk/spam 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.



# **Receiving Notifications**

Add <a href="mailto:awards@mail.asco.org">awards@mail.asco.org</a> and <a href="mailto:grants@conquer.org">grants@conquer.org</a> to your safe senders list to ensure timely receipt of notifications associated with recommender task submissions, application submissions, etc. If you are not receiving notifications, check your junk/spam folders first, then contact <a href="mailto:grants@conquer.org">grants@conquer.org</a> for additional assistance.