



# 2022 CONQUER CANCER – MELANOMA RESEARCH FOUNDATION: ASCO REGISTRY MELANOMA RESEARCH GRANT

## **REQUEST FOR PROPOSALS (RFP)**

Last Updated: 3/15//22

Application Deadline: May 9th, 2022 (11:59 PM ET)

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

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

#### About Conquer Cancer

Conquer Cancer, 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 <u>CONQUER.ORG</u>.

#### About the Melanoma Research Foundation

The Melanoma Research Foundation (MRF) is the largest independent organization devoted to melanoma. Since 1998, the MRF has funded over \$20.4 million in melanoma research, transforming the landscape of treatment development. Committed to the support of medical research in finding effective treatments and eventually a cure for melanoma, the MRF also educates patients and physicians about prevention, diagnosis and the treatment of melanoma. The MRF is a committed advocate for the melanoma community, helping to raise awareness of the disease and the need for a cure. The MRF's website is the premier source for melanoma information seekers. More information is available at <a href="https://www.melanoma.org">https://www.melanoma.org</a>. Find the MRF on Facebook, Twitter, LinkedIn and Instagram.

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#### THE OPPORTUNITY

With support from the Melanoma Research Foundation (MRF), Conquer Cancer, the ASCO Foundation, has established a new grants program to foster research that uses data derived from the American Society of Clinical Oncology (ASCO) Survey on COVID-19 in Oncology Registry (the "ASCO Registry") to inform the cancer community about the patterns of symptoms and severity of COVID-19 among patients with cancer, as well as how COVID-19 is impacting the delivery of cancer care and patient outcomes. The grant award will provide funding and access to deidentified ASCO Registry data for melanoma focused research.

The award provides funding to qualified clinical oncology, health services, or data science researchers to support the rapid analysis of ASCO Registry data for melanoma focused research, manuscript development, and the dissemination of findings into high-impact scientific, peer-reviewed manuscripts. Rapid discovery and translation of data into knowledge, as well as the dissemination and potential for implementation of evidence are key to these efforts as the pandemic continues to impact patients with cancer.

The COVID-19 pandemic presents a unique opportunity to capture information on how a disease outbreak affects delivery of high-quality cancer care. While other entities have launched COVID-19 cancer registries, a majority of patients entered into the ASCO Registry are being treated at oncology practices that are independently operated or part of hospitals or health systems, rather than academic practices. ASCO's registry collects information about patients undergoing treatment for cancer and with confirmed COVID-19 infection based on a positive test. As of March 7, 2022, the ASCO Registry has over 5,700 patients from 67 practices, with 82 patients with melanoma (see dashboard for a summary of the ASCO Registry population characteristics, including demographic and clinical factors at the time of patient enrollment to the ASCO Registry).

#### ASCO Registry Melanoma Research Grant

Applicants are invited to submit research proposals consistent with ASCO's mission with research queries that can potentially be addressed with ASCO Registry data.

#### Research supported by the ASCO Registry:

The ASCO Registry collects follow-up information on both COVID-19 disease and cancer outcomes at 30day intervals for the first 90 days, 90-day intervals for the first year, and 6 month intervals thereafter up to two years after COVID-19 diagnosis. The overarching goals of the ASCO Registry are to conduct analyses and to create a dataset that can be translated into evidence to be used to improve outcomes of cancer patients with COVID-19.

A detailed dataset description (which also includes the ASCO Registry study schema and data capture forms) is provided in Appendix A: ASCO Registry Dataset Documentation. For a summary of the ASCO

Registry population characteristics, including demographic and clinical factors at the time of patient enrollment to the ASCO Registry please visit <u>here</u>.

Because of ASCO's extensive relationships with the entire cancer care community, all types of oncology practices are participating, including private practices, practices part of health systems or hospitals, and academic practices. The ASCO Registry was designed to capture COVID-19 treatments and outcomes as well as cancer treatment and outcomes, including long-term effects for those who recover from COVID-19. The data in the ASCO Registry is a "limited data set," meaning it includes a limited number of patient identifiers to enable connection of longitudinally collected data on individual patient's COVID-19 and cancer treatment and outcomes.

Note: Applicable data will be exported from the ASCO Registry on or around April 1 and no additional updates to the data will be provided; these data will be minimally cleaned and packaged for the recipient of the grant. The recipient institution must sign a Data Use Agreement before data is provided.

#### Types of outcomes and research foci that applicants may consider with the ASCO Registry dataset:

- Evaluation of SARS-CoV-2 viral infection outcomes (hospitalizations (with or without ICU); need for ventilator; short and long-term symptoms; recovery; death related to COVID-19 disease complications) and cancer outcomes (disease progression, response to treatment, delays and discontinuations of cancer treatments, and death due to cancer).
- Changes in patient care and outcomes over the course of the pandemic, including differences in COVID-19 interventions, differences in patterns of anti-cancer treatment, differences in patient outcomes.
- Comparisons of select cancer patient subgroups to COVID-19 infection, more severe cases of COVID-19 (e.g., as defined by need for hospitalization, ICU care, or ventilation), cancer outcomes, or access to COVID-19 or cancer care. Subgroups may be defined by demographic characteristics (e.g., age, gender, race/ethnicity), geographic characteristics (e.g. US Census Region, rurality, social determinants of health (SDOH)), clinical characteristics (e.g., treatment type at the time of diagnosis, cancer type, cancer stage), or interventions or care patterns related to COVID-19 (e.g., anti-COVID-19 treatments, use of telehealth).
- Analyses that will inform future infectious disease outbreaks to minimize future disruptions in the provision of high-quality cancer care.
- MRF centers could also develop a proposal to use ASCO Registry data as well as their own data to extend numbers and types of analyses.

Note: A respondent may also develop a novel research question in any area not listed above if it is consistent with the ASCO Registry Study Schema and ASCO's mission, and can be addressed with the ASCO Registry data. The ASCO Registry Study Schema and all data capture forms are available on the ASCO website at <u>www.asco.org/asco-coronavirus-information/coronavirus-registry</u>. A copy of the ASCO Registry data dictionary is available upon request.

#### Funding Available

The total award amount is \$30,000, payable on or about September 15<sup>th</sup>, 2022.

#### Eligibility Criteria

All of the following criteria must be met in order to qualify for the ASCO Registry Melanoma Research Grant.

#### Research Team:

- 1. Includes at least one oncology clinician who currently treats patients with melanoma AND at least one data scientist/biostatistician. (Involvement of an infectious disease clinician or scientist, while optional, is encouraged.)
- 2. The Principal Investigator (PI) must hold a doctoral degree (including but not limited to MD, DO, PharmD, or PhD) at the time of grant submission and may be an oncology clinician or data scientist/biostatistician as listed above.
- 3. The PI must 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, go to <a href="http://www.asco.org/membership">http://www.asco.org/membership</a>.).
- 4. All members of the Research Team must be physically located in the U.S.
- 5. All members of the Research Team must be able to comply with the conditions of the Data Use Agreement.

#### Sponsoring Institution\*:

- 1. The Sponsoring Institution will administer the grant funds for the sole purpose of the project.
- 2. Applications may be submitted from the following entities:
  - Higher Education Institutions
  - Research Organizations
  - Government Organizations (may include medical centers and hospitals that have access to resources and infrastructure to support a research project)
  - Non-profit Organizations (includes medical societies or associations, advocacy organizations, foundations, hospitals)
  - Non-Governmental Organizations.
- 3. The Sponsoring Institution must be based in the U.S.
- 4. The Sponsoring Institution must be able to comply with the conditions of the Data Use Agreement.

\*Pharmaceutical companies and medical device manufacturers, their affiliates, and related foundations, are not eligible.

The Conquer Cancer ASCO Registry Research Grant Review Committee reserves the right to evaluate and determine an applicant's eligibility based on the application materials. Applicants with questions or who are uncertain about their eligibility are encouraged to contact <u>grants@conquer.org</u> for clarification.

#### Peer Review of Applications

The applications are reviewed by the Conquer Cancer ASCO Registry Research Grant Review Committee using a multi-stage review process. Each application is assigned to at least two scientific reviewers with subject matter and biostatistical expertise for independent and confidential review.

The Conquer Cancer ASCO Registry Research Grant Review Committee will select the recipient based on the following criteria:

Criterion 1:

- Strength of the hypothesis-driven melanoma research proposal with a clinical, health services, and/or data science research focus with the goal of generating knowledge that can be translated into evidence to better understand outcomes of cancer patients with COVID-19.
  - 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

#### Criterion 2:

- Potential for the proposed research to impact high-quality oncology care and inform future pandemic response.
  - Potential favorable impact on high-quality oncology care by the proposed research; and/or, impact to inform future pandemic response in the provision of high-quality oncology care
  - The qualifications and experiences of the PI and other members of the Research Team.
     Factors considered include the quality and extent of past education, scientific training, clinical and/or research experience, research originality, and demonstration of previous productivity in oncology research

#### Key Dates

Full Applications Due: Anticipated Notification Date: Anticipated Award Term: May 9<sup>th</sup>, 2022 (11:59 PM ET) Mid-July 2022 September 1, 2022 – August 31, 2023

#### Application Changes

The PI 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 PI's name, the title of the proposal, and the reason for withdrawing the application.
- 2. <u>Change of Institution or Position</u>. The PI has a career change, leaves their current position in an institution/organization, or is unable to meet the eligibility requirements of this RFP. If the applicant is selected to receive an award, Conquer Cancer has the right in its sole discretion to withdraw the award.

3. <u>Change in Proposal (Scope, Timeline, Budget, etc.)</u>. The PI has significant changes in the submitted proposal affecting aims, research strategy, and/or timeline. If Conquer Cancer is notified of the change in proposal after the PI is notified of an award, Conquer Cancer has the right in its sole discretion to withdraw the award.

#### Award Notification

Applicants can expect to be notified Mid-July 2022 via email. All communication regarding applications, including award notifications, will be sent to the preferred email address on file. For questions, please email <u>grants@conquer.org</u>.

#### 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 <u>Physician Payment Sunshine Act: Additional Details about Final Rule | ASCO</u>.

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. <u>RECIPIENTS OF THE ASCO REGISTRY</u> <u>RESEARCH GRANT MAY BE REPORTED ON THE CMS OPEN PAYMENTS WEBSITE AS HAVING</u> <u>RECEIVED PAYMENTS OR TRANSFERS OF VALUE FROM MANUFACTURERS OF</u> <u>PHARMACEUTICAL DRUGS AND/OR DEVICES</u>. If there are any questions about reporting due to the Sunshine Act, please contact Gray Ladd, Associate Director, Business Operations & Compliance, at 571-483-1700 or <u>operations@conquer.org</u>.

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.

#### Application Information Use and Sharing

Conquer Cancer and its affiliates 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 the specific research queries present in the research proposals submitted are considered confidential property of the applicant. Conquer Cancer is permitted to share research proposals with Conquer Cancer and affiliates' staff and reviewers, third party contractors, and potential supporters, and Conquer Cancer will require all to maintain the confidentiality of such research queries.

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 and proposal (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 <u>awards.asco.org</u>. 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 May 9<sup>th</sup>**, **2022**. No late applications will be accepted. Please note that technical assistance is only available during normal business hours, and specifically until 5:00 PM ET on the due date.

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

#### 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. Project Timeline Form (required)
- 4. List of Research Team Members (required)
- 5. Budget (required)
- 6. Primary Applicant Biosketch (required)
- 7. Research Team Biosketches (required)
- 8. Research Strategy (required)
- 9. Biostatistical Plan (required)
- 10. Cited References (required)
- 11. Clinical Protocol (optional, strongly encouraged)
- 12. Supporting Documentation (optional)
- 13. Institutional Approval (required)
- 14. Review and Submit (required)
- 1. <u>Applicant Information (required).</u> This section includes the following:
  - <u>Applicant Information</u>. *This information is pulled directly from the applicant's ASCO account 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. 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
    - o Middle Name
    - o Last Name
    - Degree(s)
    - Sponsoring Institution Name
    - o Name
    - Address (including city, state, and zip code)
    - Country
    - Primary email address (all future communications about the application will be sent to this address)
    - ORCID ID
    - o ASCO Member ID
  - 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):
    - <u>Research Project Title (250 characters maximum)</u>: 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.

- <u>Specific Aims (1000 characters (not including spaces) maximum per aim)</u>: Select the number of aims from the drop-drown list (maximum of 5 aims). Use a separate text box for each aim. Briefly describe each aim separately and concisely and include the following for each aim: the aim objective (e.g., to evaluate a stated hypothesis, assess a clinical practice approach, address a critical barrier to progress in the field, or describe outcomes for a particular group of patients), 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.
- Focus Area(s): Select all that apply. If "Other" is selected, provide information in the text field.
- <u>IRB Status</u>. Western IRB reviewed the ASCO Registry and determined that it is "exempt from IRB review because it does not meet the definition of human subject as defined in 45 CFR 46.102."
  - IRB review may be required by the Principal Investigator's Sponsoring Institution.
     Does your Sponsoring Institution require IRB review? Y/N
    - If yes, enter the IRB Approval Date, IRB Expiration Date, and Assurance Number. If the protocol is currently submitted, but not reviewed, please select "Pending"
  - o If the status is Exempt, enter the Exemption Number.
- After completing this form, click "Mark as Complete".
- 3. 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 PI is required to have at least two manuscripts submitted to a peer-reviewed journal as deliverables, the first no later than 12/31/22 and the second no later than 4/30/23. There is no limit on the number of manuscripts submitted; however, each planned manuscript submission should be included in the project timeline. The grant term ends 8/31/23 and all manuscripts should be submitted by that date. The timeline should make it clear what outcomes will be achieved during the grant award period.

Download the template, then update 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.

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., 2022<u>ASCORegistry\_Timeline\_Smith</u>) • After completing this form, click "Mark as Complete".

#### 4. List of Research Team Members (required).

List all members of the Research Team (full name, institution, email) and briefly describe the pertinent qualifications and role of each Research Team member. The Research Team must include at least one oncology clinician who currently treats patients with melanoma AND at least one data scientist/biostatistician. If there are multiple investigators and data scientists on the team, please indicate who is the primary.

This should be no more than two (2) typewritten, single-spaced pages, with one-inch margins and using an 11-point Arial font type. 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: [year program abbreviation]\_ResearchTeam (e.g., 2022ASCORegistry\_ResearchTeam)

- After completing this form, click "Mark as Complete".
- 5. <u>Budget (required).</u> The award funds will be directed to the Sponsoring Institution and should be used towards salary support, supplies, 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. Do NOT use a comma when entering budget amounts. 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.

- The budget guidelines include:
- <u>Total Award</u>: The total award amount is \$30,000 for one year, payable on or about September 15<sup>th</sup>, 2022. The total requested budget must be exactly \$30,000.
- <u>Indirect costs</u>: Up to \$1,500 (or 5% of the total award amount) may be applied to overhead or facilities and administrative costs of the Sponsoring Institution in administering the research project.
- <u>Personnel Support</u>: Award funds in this category can only be budgeted for salary support for the Principal Investigator and/or research team members. Any salary support budgeted must be directly related to work on the research project and be based upon acceptable remuneration. The role of the personnel and the reason for their salary support must be well described in the "Descriptions of Costs".
- <u>Travel</u>: No funds should be allocated to travel.
- <u>Subcontracts</u>: Subcontracts to other organizations are not allowed.
- <u>Unallowable Expenses</u>: Funds may **NOT** be used to pay for: ASCO Membership Fees; fees for courses or classes; costs for proposal development for additional funding; travel to the ASCO Annual Meeting or other international congresses or conferences; political campaigns; direct

donations, grants, or scholarships to individuals; lobbying; bribery; illegal activity; or any costs that are not directly related to the research project.

- After completing this form, click "Mark as Complete".
- 6. <u>Principal Investigator Biosketch (required).</u> The PI should use the NIH biosketch template provided with an expiration date of 02/28/2023. 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. Click "Attach File" and select the file to be uploaded in the application. Please tailor the personal statement section in the biosketch for this project.
- 7. <u>Research Team Biosketch(es) (required).</u> A biosketch must be submitted for the other member(s) of the Research Team. In addition to the PI, a biosketch for the other required team member(s) (an oncology clinician who currently treats patients with cancer and/or data scientist/biostatistician) must be uploaded here. Regardless of which required position on the Research Team the PI is fulfilling, the PI does not need to upload a duplicate biosketch. Applicants should use the NIH biosketch template provided with an expiration date of 02/28/2023. Biosketches must not exceed five (5) pages. Please tailor the personal statement section of the biosketch for this project. 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: [year program abbreviation]\_Biosketch\_[Last name] (e.g., 2022ASCORegistry\_Biosketch\_Smith)

- After completing this form, click "Mark as Complete".
- 8. <u>Research Strategy (required).</u> The research strategy is limited to three (3) 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 3-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 and how the proposed project will improve scientific knowledge, technical capability, research efforts and/or clinical practice for patients with melanoma cancer and COVID-19.
  - 2. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions for patients with COVID-19 and melanoma cancer will change if the proposed aims are achieved.
- ii. Innovation:
  - 1. Explain how the application seeks to generate new evidence for research or clinical practice paradigms for patients with melanoma cancer and COVID-19.

2. Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions and any advantage over existing methods, evidence or guidance/guidelines.

#### iii. Approach:

- 1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- 2. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be transformed, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- 3. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 4. 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.
- 5. Describe approach for data handling, access, and storage.
- 6. Clearly state the role of the primary clinical investigator and the primary biostatistician/data scientist in the project
- 7. List and describe the facilities and resources available to conduct the study.

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., 2022ASCORegistry\_ResearchStrategy\_Smith)

- After completing this form, click "Mark as Complete".
- 9. <u>Biostatistical Plan (required).</u> 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 pages with one-inch margins and 11-point Arial font type. If the document uploaded exceeds the page limit, Conquer Cancer will return the application.
  - This section should include the primary objective/hypothesis and primary endpoints of the study, description of experimental design and study groups that will be compared, justification that sample size of the ASCO Registry (for the proposed analyses) is sufficient to achieve the objectives, detailed procedures for data analysis including analytic methods employed (e.g., regression models, hypothesis tests), and any other appropriate statistical considerations.

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

Use this file naming convention: [year and program abbreviation]\_Biostatistical Plan\_[Last name] (e.g., 2022ASCORegistry\_BiostatisticalPlan\_Smith).

- After completing this form, click "Mark as Complete".
- 10. <u>Cited References (required).</u> Upload a bibliography of any references cited in the Research Strategy.

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., 2022ASCORegistry\_CitedReferences\_Smith)

- After completing this form, click "Mark as Complete".
- 11. <u>Clinical Protocol (optional, strongly encouraged).</u> If a protocol has been developed for this project, and has been or will be submitted to the applicant's IRB, Conquer Cancer encourages applicant to upload a copy of the protocol.

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., 2022ASCORegistry\_ClinicalProtocol\_Smith)

- After completing this form, click "Mark as Complete".
- 12. <u>Supporting Documentation (optional)</u>. 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 of support for a collaboration, etc.).-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.

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., 2022ASCORegistry\_SupportingDoc\_1\_Smith; 2022ASCORegistry\_SupportingDoc\_2\_Smith; etc.).

- After completing this form, click "Mark as Complete".
- **13.** <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 Sponsoring Institution's Office of Sponsored Research. The task will not be available until all the required application tasks have been completed.
  - 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 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".
- 14. <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)
- □ Project Timeline Form (required)
- □ List of Research Team Members (required)
- □ Budget (required)
- Primary Applicant Biosketch (required)
- □ Research Team Biosketches (required)
- □ Research Strategy (required)
- Biostatistical Plan (required)
- □ Cited References (required)
- □ Clinical Protocol (optional) strongly encouraged
- □ Supporting Documentation (optional)
- □ Institution Approval (required)
- □ Review and Submit (required)

#### Appendix A. ASCO Registry Dataset Documentation

#### Description of ASCO Registry Datasets March 2022

This document describes the data collected in the ASCO Registry and the de-identified datasets provided to the awardee of this opportunity.

#### **Overview of the ASCO Registry**

ASCO is collaborating with oncology practices to gather data for the ASCO Registry. Because of ASCO's extensive relationships with the entire cancer care community, all types of oncology practices are participating, including private practices, practices part of health systems or hospitals, and academic practices. The ASCO Registry was designed to capture COVID-19 treatments and outcomes as well as cancer treatment and outcomes, including long-term effects for those who recover from COVID-19. The data in the ASCO Registry is a "limited data set," meaning it includes a limited number of patient identifiers to enable the connection of longitudinally collected data on individual patient's COVID-19 and cancer treatment and outcomes.

The ASCO Registry launched in March 2020 and has collected data on over 5,700 patients with COVID-19 and cancer. The number of patients has increased over time as the number of participating practices has grown, and the pandemic has spread throughout the US. Most of the patients were undergoing drug-based therapy at the time of COVID-19 diagnosis.

Patients included in the Registry meet the following TWO criteria:

- 1. Have a confirmed SARS-CoV-2 infection (requires testing verification, but does not capture test information); and,
- 2. At the time of confirmed COVID-19 diagnosis, be in one of the following four categories:
  - a. Patient with a new cancer diagnosis and in the process of cancer staging and/or receipt of initial cancer therapy
  - b. Patient with clinically evident cancer receiving anti-cancer treatment
  - c. Patient who is cancer-free and receiving any type of adjuvant therapy (including hormonal treatments) within 1 year following surgical resection (i.e., patient is less than one year from having active cancer)
  - d. Patient with clinically evident cancer receiving supportive care only

 Table 1 below shows the expected form submission times.

Visit the ASCO Registry Dashboard (<u>https://www.asco.org/asco-coronavirus-information/coronavirus-registry/covid-19-registry-data-dashboard</u>) for current information about the distribution of selected baseline clinical and demographic factors of patients, including age, cancer type, cancer extent, and key comorbidities. Note that the dashboard data is updated weekly; actual numbers in the dataset received for analysis will depend on the patients in the Registry at the time of the data export for this award. There will be no updates to the data export provided to research teams selected for the grant.

Phase	Initial Entry	6	Short term Follow-up		Long-term Follow-up
	Initial at time of COVID-19 diagnosis <sup>1</sup>	1 month after COVID-19 diagnosis	2 months after COVID-19 diagnosis	3 months after COVID-19 diagnosis	6, 9 and 12 months after COVID-19 diagnosis
Initial Entry: At time of COVID- 19 diagnosis					
Initial Clinical and Demographic Information	•				
COVID-19 Diagnosis Symptoms, and Treatment	•				
Cancer Diagnosis, Status, and Treatment	•				
Short Term Follow-up					
COVID-19 Status Update		•	•	•	
Cancer Status Update		•	•	•	
Long Term Follow-up					
COVID-19 Long-term Update					•
Cancer Long-term Update					•

Table 1: Calendar of data collection elements for the ASCO Registry.

<sup>1</sup> If patient is deceased at the time of initial form submission or leaves practice prior to 30 days, a practice should complete a patient update form at any time and receive payment for the case in that month.

#### Description of Data Collection Process for the ASCO Registry

When the ASCO Registry launched in March 2020, questions regarding cancer treatments and timing of delays of treatment were somewhat limited. Specifically, the registry forms asked about drug treatments by category and not the specific drug name, and whether there were treatment delays without specification of length and start and stop dates. At the recommendation of the ASCO COVID-19 Research and Analysis Steering Group (COVID-19 SG), a major form change was initiated in October 2020 which revised the **"Cancer Diagnosis, Status, and Treatment"** form, and the **"Cancer Status Update"** form (which applies to both the **Short-Term** and **Long-Term Follow-up** time points; Table 1). At that point, the following changes were implemented:

- 1. All newly enrolled patients had data entered using the new forms.
- 2. Patients who had data entered prior to October 24, 2020 were highly encouraged to have a "retroactive" form completed to capture the name(s) of the drug treatment(s) (where relevant) and dates of treatment. This was necessary to ensure that all patients had consistency in the cancer treatment information for all patients in the Registry.

In early January 2021, questions related to COVID-19 vaccine receipt were added to the "COVID-19 Diagnosis, Symptoms, and Treatment" form and the acute and longterm "COVID-19 Status Update" forms.

#### **Data Collection Methods**

Data are collected in a web-based REDCap survey project hosted on a secure server owned and operated by ASCO/CancerLinQ. The project includes a series of queued forms, the first of which (titled "ASCO Registry Form Selection") requires information to be entered on the patient, in order to connect the longitudinal data collected on patients (zip code and patient's date of birth), and which form is to be filled out. Note that patient zip codes are **not** provided in the de-identified dataset for awardee and dates are shifted to the Sunday of the week in which the event occurred, and intervals for certain event times are provided (see De-identification of ASCO Registry Dataset section below for more details). In addition, practices submitting data to the ASCO Registry may not report all of the patients at their practice who meet ASCO Registry inclusion criteria and thus the ASCO Registry data may not be representative of the patients with COVID-19 in their practice.

A brief description of each form and its contents is described below.

- <u>ASCO Registry Form Selection</u>: When the practice goes to the registry survey link to enter data, this is the first form to be completed. As a result, regardless of what visit and information is being submitted, this form is completed each time data is entered on a patient.
- <u>Patient's Baseline Demographic, COVID-19 and Cancer Information:</u> This form is filled out once for each patient and comprehensively details patient information in three areas, as shown in Table 1:
  - o **Clinical and Demographic information** Patient's age at COVID-19 diagnosis, gender, race, cancer type, clinical factors (e.g., smoking history, height, and weight), and select comorbidities (e.g., hypertension).

o **COVID-19 diagnosis, symptoms, and treatments** - COVID-19 symptoms, COVID-19 interventions, COVID-19 sequelae, ECOG performance status, death (including death date if the patient has died) that have occurred between COVID-19 diagnosis and the time of initial data entry.

o **Cancer diagnosis, status, and treatment** - Cancer extent, time since cancer diagnosis, cancer treatment modalities and anti-cancer agents at the time of COVID-19 diagnosis, start and stop dates of cancer treatments.

- <u>Acute COVID-19 Follow-Up:</u> COVID-19 symptoms, COVID-19 interventions, COVID-19 sequelae, ECOG performance status, and death (including death date if the patient has died) after initial data entry, through 3 months from COVID-19 diagnosis. If the initial data entry for a patient occurs more than 3 months after COVID-19 diagnosis, a patient may have no entries of this form. In addition, if the practice has no additional information on the patient between the time of initial data entry and the 3-month follow-up time point, they may not submit this form.
- Long-Term COVID-19 Follow-Up: Long-term COVID-19 symptoms, sequelae such as fatigue, headaches, shortness of breath and other syndromes that have been reported as "long-haul" symptoms in COVID-19 patients, ECOG performance status, and death (including death date if the patient has died).
- <u>Cancer Treatment and Status Follow-Up</u>: Cancer response to treatment, anti-cancer treatments started or stopped since previous form submission.

Note that the forms included as pdf files do not show the branching logic (i.e., skip patterns). For an understanding of the branching logic of the data collection in REDCap, please visit the following weblink <a href="https://redcap.link/j18x5d6k">https://redcap.link/j18x5d6k</a> which is a copy of the ASCO Registry. You will need to enter the pin '1234' to gain entry to data submission. You are free to enter data to explore the data collection process; the data entered is not included in the Registry as this REDCap database was created for the sole purpose of demonstrating of the Registry data collection process.

There are two approaches for practices to contribute patient data.

- 1. Most practices are provided with a weblink to the survey project and a practice-specific PIN that allows the practice to gain access to submit data. Data are abstracted from patient EHRs by clinical/research staff at practices.
- 2. The remaining practices (fewer than 5 total) collect the data in a local database and send it as batches to be merged with the rest of the Registry data. In these cases, practices use queries against their electronic health record (EHR) systems to identify candidates, and abstractors enter the data retrospectively.

#### **Timing of Data Collection**

The ASCO Registry is a limited dataset, which does not include direct identifiers such as name, address, phone number, or social security number. Because the ASCO Registry uses data in the form of limited datasets, and due to the nature of the Registry, an IRB has determined that patient consent is not required. **Because the study is observational in nature, ASCO does not direct practices to capture any information not already recorded in the patients' EHR data – except COVID-19 treatment and inpatient information (where relevant). Common elements collected in clinical trials are sometimes recorded in patient EHRs, but researchers should expect missingness on variables that are inconsistently collected in patient records. For example, ECOG performance status was recorded in about 75% of patients at initial data entry, with the remaining 25% being unknown. In addition, if patients have infrequent visits or interactions with their oncology practice (e.g., every 4 months), or switching practices, forms may not be entered due to lack of additional data.** 

Some patients are enrolled (i.e., their initial data is entered) soon after their COVID-19 diagnosis, whereas other patients are enrolled months after their COVID-19 diagnosis, and sometimes after the patient has died. This timing depends on several factors, including (a) when the practice joined the Registry, (b) practice workflow for data entry to the Registry, and (c) frequency of patient's clinical encounters with the oncology practice. As a result, unlike a clinical trial, which has a precise study calendar that requires certain data elements to be collected at predefined time points, the Registry calendar defines times for data abstraction from the patient EHR, but for some patients, no new data has been accumulated since the last visit. The majority of patients in the ASCO Registry, however, have metastatic (solid tumor) cancer or a hematologic malignancy, and, as a result, are in frequent contact with their oncology care team.

When the Registry first launched in March 2020, the data collection calendar specified weekly updates for COVID-19 status and monthly updates for cancer status. Based on feedback from practices and the COVID-19 SG, this schedule was deemed unnecessarily frequent, and the collection calendar shown in Table 1 reflects the current data collection schedule. As a result, patients with data entered early in the pandemic may have more frequent updates compared to patients with data entered later in the pandemic.

#### **Calculation and Availability of Key Variables of Interest**

The data collection forms for cancer drugs and cancer diagnoses utilize the BioPortal Ontology Service within REDCap. Cancer drugs are collected using the NCI Thesaurus (<u>https://ncithesaurus.nci.nih.gov/</u>), and cancer types are collected using ICD-10CM codes. ICD-10 codes are mapped to cancer types, such as melanoma, lung cancer, breast cancer, multiple myeloma.

#### **De-identification of ASCO Registry Dataset**

It is of utmost importance that patient privacy is maintained. As a result, datasets provided to the awardee will be de-identified, which will remove or transform certain data elements that are collected in the ASCO Registry forms.

All HIPAA Safe-Harbor identifiers will be removed from the data set, except for certain elements of dates. The following modifications to dates and other variables in the dataset are proposed to de-identify the dataset:

**Dates**: Dates will be shifted to the first day of the week (i.e., all dates provided will reflect the Sunday of the week of the event). These include COVID-19 diagnosis date, date of cancer diagnosis, dates of cancer treatments, dates of clinical evaluations, date of admission to the hospital, date of initiation of supplemental oxygen, etc. Dates of certain events will not be provided (see "Intervals" below for description).

**Intervals**: Date of death, date of discharge from hospital, date of discharge from ICU, date supplemental oxygen is stopped, and date ventilation is stopped will not be provided due to the need for more specificity for the duration related to these dates. Instead, intervals will be provided as follows:

- Overall survival:
  - o Date of death will <u>not</u> be included in dataset.
  - o Number of days from actual date of COVID-19 positive test to actual date of death will be included in dataset.
  - o Date of COVID-19 diagnosis will be included as per "Dates" above (i.e., shifted to Sunday of the week of positive test result).
- Hospitalization:
  - o Date of discharge from hospital will not be included in dataset.
  - o Number of days in the hospital (from actual date of admittance to actual date of discharge) will be included in dataset.
  - o Date of hospital admission will be included as per "Dates" above (i.e., shifted to Sunday of the week of hospital admission).
- ICU: report number of days in the ICU (from actual ICU admittance date to actual ICU discharge date)
  - o Date of discharge from the ICU will not be included in dataset.
  - o Number of days in the ICU (from actual date of admittance to actual date of discharge) will be included in dataset.
  - o Date of ICU admission will be included as per "Dates" above (i.e., shifted to Sunday of the week of hospital admission).
- Supplemental oxygen: number of days on supplemental oxygen
  - o Date the supplemental oxygen was discontinued will not be included in dataset.
  - o Number of days on supplemental oxygen will be included in the dataset.
  - o Date of supplemental oxygen was started will be included as per "Dates" above (i.e., shifted to Sunday of the week of supplemental oxygen started).
- Ventilation: number of days on ventilator
  - o Date the patient came off ventilator will not be included in dataset.
  - o Number of days on a ventilator will be included in the dataset.
  - o Date of patient was put on a ventilator will be included as per "Dates" above (i.e., shifted to Sunday of the week ventilation started).

**Geographic location and area-based measures:** US Census Region in which the patient lives and of practice location will be provided. A rurality index (divided into categories of rurality) will also be provided. Rurality is estimated by matching patient and practice zip codes to the US Department of Agriculture's Rural-Urban Commuting Area (RUCA) schema (last updated on the <u>USDA website</u> on 8/17/2020). For deidentification reasons, the RUCA codes were collapsed into the following three categories using this <u>guidance</u> (see Categorization B):

- "Small and Isolated Small Rural Town" (RUCA codes: 7.0, 7.2, 7.3, 7.4, 8.0, 8.2, 8.3, 8.4, 9.0, 9.1, 9.2, 10.0, 10.2, 10.3, 10.4, 10.5, 10.6)
- "Large Rural City/Town" (RUCA codes: 4.0, 4.2, 5.0, 5.2, 6.0, 6.1)
- "Urban" (RUCA codes: 1.0, 1.1, 2.0, 2.1, 3.0, 4.1, 5.1, 7.1, 8.1, 10.1)

ASCO will also provide five area-level Social Determinants of Health (SDOH) variables based on a patient's zip code of residence. The variables come from the Agency of Healthcare Quality's Social Determinants of Health Database, specifically zip code-level data derived from the Census Bureau's American Community Survey (ACS) 5-year estimates (available <u>online</u>; includes 2014-2018 estimates from time of download). To prevent reidentification of Registry patients by way of their residential area, the SDOH variables were segmented into quartiles across all US zip codes (excluding territories) and assessed for uniqueness in combination with US Region and rural category. If a zip code has a population of fewer than 20,000 residents and a unique combination of region/rural category/quartiles of SDOH variables, SDOH quartiles are suppressed for patients residing in that zip. Suppression affects SDOH data for fewer than 60 patients in the Registry. The variables are:

- Median household income (in dollars, inflation-adjusted to 2018; ACS source table B19013) Categories: <\$43,125, \$43,125 - \$54,047, \$54,048 - \$68,446, ≥\$68,446.5
- Percentage of population reporting White race (ACS source table B02001) Categories: <77.3%, 77.4% - 92.1%, 92.2% - 97.4%, ≥97.5%
- Percentage of population reporting Hispanic ethnicity (ACS source table B03003) Categories: <0.7%, 0.8% - 3.1%, 3.2% - 9.5%, ≥9.5%
- Percentage of population with only high school diploma (ages 25 and over; ACS source table B15003)
  - Categories: <25.5%, 25.5% 33.7%, 33.8% 41.2%, ≥41.3%
- Percentage of population with no health insurance (ages 64 and under; ACS source table B27010)

Categories: <4.8%, 4.8% - 8.8%, 8.9% - 14.7%, ≥14.8%

**Age:** Age at COVID-19 dx date will be provided using the following categories: <18, 18-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, >89

**Height and weight:** Height (cm) and weight (kg) will be provided for all patients over age 17 with an exception for extreme values. Extreme values identified and flagged using the following rules:

Males over 17 years old:

- Height ≤1.53 meters or ≥1.98 meters
- Weight ≤45.36 kg or ≥181.43 kg

Females over 17 years old:

- Height ≤1.42 meters or ≥1.82 meters
- Weight ≤40.83 kg or ≥158.75 kg

Race: White, Black, Other, Unknown categories will be provided.

Ethnicity: Hispanic, Not Hispanic, and Unknown categories will be provided.

**Cancer type:** We will provide ICD-10 codes and cancer types (e.g., all head and neck ICD-10 codes will be lumped into a head and neck cancer type category)

**Patient ID:** Unique patient codes will be provided to link data from the same patient. These IDs are randomly generated and cannot be used for re-identification.

**Practice ID:** Unique practice codes will be provided to identify which patients were treated at the same practice. These will be randomly generated and have no information regarding patient or practice identifiers, and no relation to geography.

**Patients with COVID-19 in the early phase of the pandemic**: No patients with COVID-19 diagnosed prior to April 1, 2020 will be included in the registry dataset. This will remove fewer than 80 patients from the Registry.

#### Other minor changes from forms:

- The free text field that refers to 'Other' when "Where was the SARS-CoV-2 test performed" will be suppressed as it may contain location specific information
- The date for "Scheduled date for SURGERY if known:" will be suppressed for future surgery dates.

#### Approach for transfer, environment and team handling the data

The applicant selected to receive the ASCO Registry Melanoma Research Grant ("Award Recipient"), and his or her Sponsoring Institution, must execute a separate Data Access and Use Agreement in order to receive an ASCO Registry Melanoma Grant and access to the COVID-19 Registry data set. The Sponsoring Institution and Awardee will sign the data use agreement affirming limited access to identified key personnel on the grant. This also includes the provisions included in the HIPAA Downstream Data Use Addendum included in the data use agreement.

Dataset will be sent from ASCO to Awardee (or designee from research team) using secure transfer via Citrix ShareFile.

The Awardee and their Sponsoring Institution will be required to have completed a security and compliance assessment that satisfies ASCO's standards to demonstrate a secure environment for data storage and analysis in advance of data reception.

All key personnel will need to complete PHI/HIPAA training and submit certification or provide proof of a suitable substitute to ASCO/CENTRA.

Data Recipient may not use the Registry Data to identify or contact any Individual who is the subject of the fully-identifiable Protected Health Information from which the Registry Data was created.

#### Approach for publication, dissemination

All abstracts, posters, presentations, manuscripts, and other reports intended for distribution beyond the Awardee research team must be reviewed and approved by the ASCO CENTRA staff prior to submission,

presentation, or dissemination. ASCO consent will be required prior to Awardee depositing any supporting data into any data repository or third-party system.

#### Navigating the Analytic Data Files

The Data Dictionary specifies all variables available to researchers, organized by analytic dataset. For each variable, the Data Dictionary includes the following information:

- Variable Name name as it appears in the analytic dataset
- Variable Label a short description of the form question and/or data included
- Variable type whether the variable is:
  - o text
  - o date (format YYYY-MM-DD)
  - o numeric
  - o yesno (yes= "TRUE" | no= "FALSE")
  - o radio (one response)
  - o dropdown (one response)

o checkbox (multiple response) – options of multiple response questions are stored as separate variables. See the Variable Value/Label column for information on the number and interpretation of those variables, as well as the REDCap codebook for details. For example, type\_of\_smoking is listed in one row of the Data Dictionary, but there are 5 variables in the Risk Factors dataset ranging from type\_of\_smoking\_\_1 = "Cigarette" to type\_of\_smoking\_\_5 = "Unknown"

- Variable Value, Label categorical values and labels, as appropriate
- Analysis Table where within the six datasets the variable resides
- **Transformation** what, if any, transformation the data has undergone to satisfy deidentification
- Original Variable Name can be used to compare to Codebook for information on how the data
  was collected in the survey. Where the data has been transformed for deidentification, the
  Original Variable Name will differ from Variable Name.
- Original Form Name in which form the data was collected
- **Branching Logic –** is response of the question conditional on a prior question?
- **Required field –** whether the question was a required question in the collection form

For details on the instructions provided to practices for completing forms and the exact wording of questions, please consult the enclosed REDCap-generated Codebook.

Missing values in the data exist for several reasons:

- Data was not entered by respondent
- Field was skipped over due to survey skip logic (see Branching Logic field from the Data Dictionary and REDCap codebook for information on skip logic)
- Data was suppressed due to deidentification rules, specifically related to a patient's height, weight, and/or BMI. Additional flag variables have been added to distinguish between missing and suppressed data in these instances.
- Geographic and area-based measures could be missing due to suppression, due to missing values in the ancillary data, or due to the original entry of zip code not corresponding to ancillary data.
- Data collected prior to the implementation of survey changes is missing for the affected questions. See the *Description of Data Collection Process for the ASCO Registry* section above. Data collected prior to October 24, 2020 will have missing cancer treatment information if the

practice did not fill out a "retroactive" cancer form. Data collected prior to January 2021 will not have values for COVID-19 vaccine-related questions.

If you have questions regarding availability or formatting of certain data elements, please contact <u>CENTRA@asco.org</u>.

#### Appendix B. Sample Data Use Agreement

In addition to the Terms and Conditions document, the applicant selected to receive the ASCO Registry Melanoma Research Grant, and their Sponsoring Institution, must execute a separate Data Access and Use Agreement in order to receive the ASCO Registry Melanoma Research Grant. This section of the RFP sets forth an example of the Data Access and Use Agreement template that the PI their Sponsoring Institution should review carefully before submitting an application for the ASCO Registry Melanoma Research Grant. This is strictly an example to be used for informational purposes in the ASCO Registry Melanoma Research Grant application process. Conquer Cancer and ASCO each reserve the rights to modify any of the provisions of the Data Access and Use Agreement prior to execution by the PI and Sponsoring Institution.

#### DATA ACCESS AND USE AGREEMENT

This **Data Access and Use Agreement** ("**Agreement**") is made as of the last date signed below ("**Effective Date**") by and between [Data Recipient Entity Name] ("**Data Recipient**") and the American Society of Clinical Oncology, Inc.,

("**ASCO**"). Data Recipient and ASCO may also be referred to individually as a "**Party**" or collectively as the "**Parties**."

WHEREAS, ASCO receives access to certain data in connection with the conduct of a research study to develop and maintain a research registry comprising data regarding patients with confirmed SARS-CoV-2 infection undergoing treatment at cancer practices or institutions (such data, "**Registry Data**" and such study, the "**Study**");

WHEREAS, ASCO receives Registry Data pursuant to a Registry Participation and Data Use Agreement ("**Participation Agreement**") between ASCO and each practice or institution participating in the Study (each, a "**Registry Participant**");

WHEREAS, Data Recipient desires to access certain Registry Data to perform certain research work; ASCO is willing to provide Data Recipient with access to certain Registry Data; and Data Recipient is willing to receive from ASCO such Registry Data;

WHEREAS, the data exchange and the research contemplated under this Agreement are consistent with the educational, instructional, scholarship, charitable, or research objectives of the Parties;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, Data Recipient and ASCO agree as follows:

 This Agreement governs the terms on which Data Recipient will be granted access to the certain Registry Data generated or made available by ASCO. In signing this Agreement, the Parties agree to be bound by the terms and conditions of access set out in this Agreement.

- 2. Definitions:
  - a. "Research Data" means all and any certain data or information created by ASCO for its own purposes and assembled at the request of Data Recipient for the purposes of performing the research under this Agreement. This Research Data does not include and shall not include fully-identifiable "Protected Health Information" ("PHI") as defined in 45 C.F.R. Section 160.103, but may contain a "Limited Data Set" as defined in 45 C.F.R. Section 164.514(e).
  - b. "Data Provider" means ASCO.
  - c. "**Publications**" means public disclosures of findings including, without limitation, articles published in print journals, electronic journals, reviews, books, abstracts, posters and other written and verbal presentations, publications, or disclosures of research.
- 3. The Data Recipient agrees to use the Research Data only for the specified purpose described in <u>Exhibit A</u> ("Project Design"). If the Data Recipient desires to use the Research Data for research other than the Project Design, the Data Recipient must obtain written consent from the Data Provider, either by an amendment to this Agreement or a new agreement, before any such research is undertaken. For clarity, the Parties agree that <u>Exhibit B</u> accurately describes the Research Data provided by ASCO to Data Recipient and fulfills this data request in its entirety.
- 4. The Data Provider explicitly retains ownership of Research Data it provides to the Data Recipient under the proposed Project Design. The Data Recipient will own all rights, title and interest in Project Design results made by its researchers, staff, employees, consultants, and/or students in the course of the Project Design. Project Design results created by both Parties will be jointly owned. The Data Recipient agrees not to use the Research Data or any part thereof for the creation of products for sale or for any commercial purpose, unless the Parties have executed a separate agreement for that purpose.

- 5. The Data Recipient agrees to preserve, at all times, the confidentiality of information and the Research Data marked as Confidential. Data Recipient agrees not to re-identify or attempt to re-identify Research Data as to any individual person or provider. Further, to the extent the Research Data constitutes a Limited Data Set as defined under 45 C.F.R. Section 164.514(e), the terms of Exhibit C shall apply to Data Recipient's use, disclosure, transmission and maintenance of such Limited Data Set.
- 6. Data Recipient agrees to acknowledge ASCO in any work based in whole or part on the Research Data, Publications from which the Research Data derives, the version of the Research Data, and the role of each Party and the organizations that provided funding for the research. Data Recipient shall have first right to publish its Project Design results from the use of the Research Data, and ASCO shall have right to publish other material that may include or be derived in whole or part from the Research Data (if applicable). Data Recipient agrees to provide any proposed Publications to Data Provider thirty (30) days before submission for review, comment, and approval. Data Recipient will incorporate comments reasonable provided by Data Provider. Data Provider can request a delay of up to thirty (30) additional days in order to request the deletion of Data Provider's confidential information. Data Recipient will remove any confidential information identified by Data Provider from the Publication. Consent of Data Provider will be required prior to Data Recipient depositing any Research Data in any data repository or third-party system.
- 7. The Data Recipient understands and acknowledges that the Research Data may be protected by copyright and other intellectual property rights, if any, and that duplication, (except as reasonably required to carry out the Data Recipient's research with the Research Data), or sale of all or part of the Research Data on any media is not permitted.
- The Parties recognize that nothing in this Agreement shall operate to transfer to the Data Recipient any intellectual property rights relating to

the Research Data. The Data Recipient has the right to develop intellectual property based on comparisons with its own data. Nothing in this Agreement prevents a Data Provider from sharing its Research Data with others.

- 9. Either Party may terminate this Agreement at any time upon prior written notice, in which case, the Data Recipient will discontinue use of the Research Data and will return or destroy the Research Data at the request of the terminating Data Provider. The Parties accept that this Agreement will terminate immediately upon any material breach of this Agreement by a Party and if the breaching Party is the Data Recipient, that Party will be required to destroy any Research Data held.
- 10. The Parties agree that, upon reasonable request, a report of the Project Design results will be prepared and sent to the requesting Party on completion of the agreed purpose. Subject to Data Recipient prior approval, which will not be unreasonably withheld, ASCO will have the right to share such report with a limited ASCO volunteer committee, each of whose members is under a written confidentiality and non-disclosure agreement.
- 11. The Research Data or Project Design results are provided to the Data Recipient AS IS and WITH ALL FAULTS. ASCO HEREBY DISCLAIMS ANY AND ALL GUARANTEES OR WARRANTIES OF ANY KIND, EXPRESS, IMPLIED OR STATUTORY, RELATING TO OR ARISING IN ANY WAY OUT OF THIS AGREEMENT. Among other things, each Party disclaims any express or implied warranty: (a) of merchantability, of fitness for a particular purpose, (b) of non-infringement or (c) arising out of any course of dealing.
- 12. In no event will the Data Provider or Data Provider's trustees, officers, agents, and employees be liable for any claim, liability, cost, expense, damage, deficiency, loss or obligation, of any kind or nature, that may arise from the use, handling, storage, or disposition of the Research Data, except to the extent of Data Provider's gross negligence or willful misconduct. The Data

#### 2022 ASCO Registry Melanoma Research Grant Request for Proposals

Recipient assumes responsibility for, and agrees to indemnify and hold harmless the Data Provider and Data Provider's trustees, officers, agents, and employees from any liability, loss, or damage they may suffer as a result of any claims, demands, costs, or judgments against them arising out of the use, handling, storage, or disposal of the Material by Recipient, except to the extent that such claims, demands, costs, or judgments arise from Data Provider's gross negligence or willful misconduct. Paragraphs 3, 4, 5, 6, 8, 9, 10, 13, and 14 will survive termination of the Agreement.

13. Any notices to be given under this Agreement to a party shall be made via U.S. Mail or express courier to such party's address set forth below:

#### If to ASCO:

American Society of Clinical Oncology 2318 Mill Road, Suite 800 Alexandria, VA 22314 Attn: Chief Executive Officer

A copy of any notice shall be sent to the attention of the Chief Operating Officer of ASCO at the same address.

If to Data Recipient<mark>: [Please include notice address]</mark>

- 14. Neither party shall assign nor transfer any interest in this Agreement without the prior written consent of the other party. This Agreement shall be binding upon and inure to the benefit of the parties, their successors and permitted assigns.
- 15. This Agreement, with its attachments, constitutes the entire agreement between the parties regarding the subject matter hereof and supersedes any other written or oral understanding of the parties. This Agreement may not be modified except by written instrument executed by both parties and signed by the authorizing authority representing each party.
- 16. The Parties agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. This Agreement

may be executed separately or independently in any number of counterparts, each and all of which together shall be deemed to have been executed simultaneously and for all purposes to be one Agreement. The Parties further waive any right to challenge the admissibility or authenticity of this Agreement in a court of law based solely on the absence of an original signature.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

#### 

#### <u>Exhibit A</u> Project Plan

[To be completed with details regarding the design of the research project.]



DATA	FORMAT



#### Exhibit C HIPAA Downstream Data Use Addendum

#### I. GENERAL PROVISIONS

**Section 1.1** <u>Data Recipient Status Regarding Registry Data</u>. Data Recipient agrees to limit its use of Registry Data and protect the Registry Data according to the terms of this Addendum and the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act and their implementing regulations as amended from time to time (collectively, "HIPAA").

**Section 1.2** <u>Defined Terms</u>. Capitalized terms used in this Addendum without definition shall have the respective meanings assigned to such terms by HIPAA.

#### II. OBLIGATIONS OF Data Recipient

**Section 2.1** <u>Permitted Use and Disclosure of Registry Data</u>. Data Recipient may use and disclose the Registry Data only for the purpose of conducting the Study in accordance with the applicable protocol for the Study and performing such other services in support of the Study and as otherwise Required by Law. Data Recipient may provide the Registry Data to members of its Workforce and its contractors supporting Data Recipient's provision of services to ASCO under this Addendum including any contractor supporting Data Recipient's provision of services under this Addendum that constitutes an agent of Data Recipient, consistent with Section 2.5.</u>

#### Section 2.2 Conditions of Use and Disclosure of Registry Data.

- a) Data Recipient may not use or disclose the Registry Data in any manner that would violate HIPAA if done by a Registry Participant.
- b) Data Recipient may not use the Registry Data to identify or contact any Individual who is the subject of the fully-identifiable Protected Health Information from which the Registry Data was created. For the avoidance of doubt, this restriction will not be construed to prohibit Data Recipient from engaging in the permitted use of any other information to identify or contact an Individual as to which Data Recipient has the authority or permission to identify or contact in accordance with applicable law.

**Section 2.3** <u>Safeguards Against Misuse of Information.</u> Data Recipient will use reasonable and appropriate administrative, technical, and physical safeguards to prevent use or disclosure of the Registry Data other than as provided for by this Addendum.

Section 2.4 <u>Reporting of Unauthorized Uses or Disclosures</u>. Data Recipient will report to ASCO any use or disclosure of the Registry Data not provided for by this Addendum ("**Unauthorized Use or Disclosure**") no later than three (3) business days after Data Recipient becomes aware of such Unauthorized Use or Disclosure.

**Section 2.5** <u>Disclosures of Registry Data to Third Parties</u>. Data Recipient will enter into a data use agreement, which meets the requirements set forth at 45 C.F.R. § 164.514(e)(4) and includes the same restrictions and conditions that apply to Data Recipient under this Addendum, with any agent to which Data Recipient provides Registry Data. Any such disclosure will be subject to prior approval by Data Provider.

#### III. TERMINATION AND GENERAL PROVISIONS

**Section 3.1** <u>Termination Upon Breach of Addendum</u>. Notwithstanding Section 9 of the Agreement, ASCO may immediately terminate this Addendum in the event that Data Recipient breaches any provision contained in this Addendum and fails to cure such breach within thirty (30) days after receipt of notice of such breach.

**Section 3.2** <u>Return or Destruction of Registry Data Upon Termination</u>. No later than 60 days following the termination or expiration of this Addendum, Data Recipient shall, at ASCO's direction, either return or destroy all Registry Data that Data Recipient has received, created, or maintained in connection with this Addendum, including, without limitation, any Registry Data maintained by Data Recipient's agents or contractors at the time of such termination or expiration.

**Section 3.3** <u>Effect</u>. The provisions of this Addendum shall control with respect to Registry Data that Data Recipient receives from or on behalf of ASCO and the terms and provisions of this Addendum shall supersede any conflicting or inconsistent terms and provisions of the Agreement, including all exhibits or other attachments thereto and all documents incorporated therein by reference, to the extent of such conflict or inconsistency. This Addendum shall not modify or supersede any other provision of the Agreement.

**Section 3.4** <u>HIPAA Amendments</u>. Any future amendments to HIPAA affecting data use agreements are hereby incorporated by reference into this Addendum as if set forth in this Addendum in their entirety, effective on the later of the effective date of this Addendum or such subsequent date as may be specified by HIPAA

#### Appendix C. Grant Terms & Conditions

Each applicant selected to receive an ASCO Registry Melanoma Research Grant, and his or her Sponsoring Institution, must execute a separate Terms and Conditions document with Conquer Cancer in order to receive an ASCO Registry Melanoma Research Grant. This section of the RFP sets forth selected provisions of the Terms and Conditions that the PI and their Sponsoring Institution should review carefully before submitting an application for an ASCO Registry Melanoma Research Grant. 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 PI 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) The Principal Investigator 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 to the Research Project.

#### Funds: Payment and Use

- (3) The Award total is \$30,000, paid on or about September 15, 2022 subject to compliance by Recipient and Sponsoring Institution with these Terms and Conditions. The Award funds will be paid to the Sponsoring Institution by wire transfer.
- (4) The Award will be used solely as detailed in the Research Project (including the grant proposal and budget).
- (5) Award funds must be maintained in a separate fund dedicated to the charitable purpose of the Award. Such a separate fund may be either 1) a physically separate bank account restricted to the described charitable purpose, or 2) a separate bookkeeping account (limited to the described charitable purpose) maintained as part of Recipient's financial records.
- (6) No more than 5% of total costs (\$1,500) will be applied to overhead or indirect costs of the Sponsoring Institution in administering the Research Project. At least \$28,500 of the Award funds will be applied to research support. Salary limits will be equivalent to the NIH applicable limit.
- (7) Award funds may not be used to pay for: ASCO Membership Fees; fees for courses or classes; costs for proposal development for additional funding; travel to the ASCO Annual Meeting or other international congresses or conferences; political campaigns; direct donations, grants, or scholarships to individuals; lobbying; bribery; illegal activity; or any costs that are not directly

related to the Research Project. No funds should be allocated to travel unless it is directly related to the Research Project itself.

(8) Award funds will not be used for expenditures incurred prior to the first day of the Award Period, or after the last day of the Award Period. No additional expenses may be paid from Award funds after Conquer Cancer has received the Principal Investigator'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.

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 Principal Investigator may move funds between budget categories or into new budget categories without prior written approval of Conquer Cancer. Notwithstanding the foregoing, budget limits on indirect costs will be strictly followed and cannot be adjusted.
- (10) Any request for a no-cost extension or budget change must be made through the application portal at least 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.
- (11) 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.
- (12) If a no-cost extension is granted by Conquer Cancer, the Principal Investigator will submit additional progress reports and financial expenditure reports every six months during the extension term.

#### Change of Personnel

(13) The Principal Investigator is permitted to transfer the Award to a co-investigator or the primary oncology clinician or primary data scientist/biostatistician on the research team that is named in the original application. Any request to transfer the Award to an individual at the Sponsoring Institution who meets the criteria of Principal Investigator (must hold a doctoral degree and is an oncology clinician or data scientist/biostatistician) but was not named in the original application must be submitted by the Principal Investigator through the application portal. Conquer Cancer will approve or disapprove the request at its discretion.

#### Changes in Research Focus and Project Scope

- (14) 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.
- (15) Major changes in research design require prior written approval from Conquer Cancer. A request must be submitted by the Principal Investigator 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.
- (16) Minor changes in research methodology are not subject to prior approval by Conquer Cancer, but must be explained and justified by the Principal Investigator in the mid-year or annual progress report.

#### Institution Transfer

- (17) If the Principal Investigator accepts an appointment at another institution during the Award Period, and desires to have the Research Project transferred to the new institution, the Principal Investigator 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.
- (18) If the Principal Investigator is unable or not permitted to transfer the grant to a new institution, the Principal Investigator 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

(19) Throughout the Award Period, the Principal Investigator will submit expenditure reports and progress reports regarding the Research Project through the application portal. It is the responsibility of the Principal Investigator 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. Principal Investigator and Sponsoring Institution

will comply with the then-current procedures of Conquer Cancer regarding submission of progress and expenditure reports.

- (20) 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.
- (21) 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

- (22) The Principal Investigator will respond to Conquer Cancer's requests for information following the Award Period. The information may be used for program evaluation and alumni communications. The Principal Investigator understands that this obligation survives the Award Period and that there is an ongoing obligation to provide this information.
- (23) 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.

#### Provision of Information to Funder (the Melanoma Research Foundation)

- (24) The Principal Investigator acknowledges, agrees, and consents to Conquer Cancer providing his or her current and future contact information to Funder.
- (25) The Principal Investigator 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

(26) Conquer Cancer strongly encourages Principal Investigator to submit the results of Research Project for publication or other public release. In the event the Principal Investigator's results are published or otherwise publicly released either during or after the Award Period, the Principal Investigator 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). (27) Conquer Cancer supports the widest possible dissemination of funded research results. Principal Investigator 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

- (28) Conquer Cancer will announce the Award and recipient of the Conquer Cancer Melanoma Research Foundation ASCO Registry Melanoma Research Grant. 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.
- (29) The Principal Investigator 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 Principal Investigator 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 Melanoma Research Foundation ASCO Registry Research Grant. 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 Melanoma Research Foundation."

#### Intellectual Property Rights

(30) Conquer Cancer and the 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 D. Helpful Tips for Using the Application Portal

#### Getting Started

To access the application portal, go to awards.asco.org

- <u>If you have an existing ASCO account</u>, 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.
- <u>If you do not have an ASCO account</u>, go to <u>awards.asco.org</u> 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**".

#### 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 <u>grants@conquer.org</u>.

#### 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!

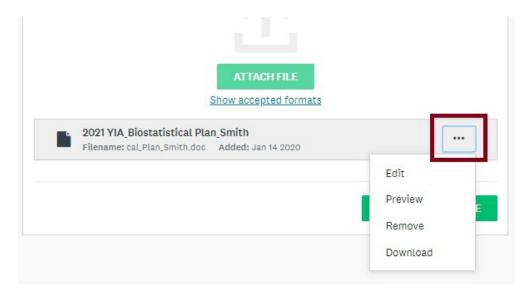


#### **Receiving Notifications**

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

#### Uploading a Document

- Click "Show accepted formats" to determine the file formats accepted. Documents <u>should not be</u> <u>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".



#### 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.

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