

Clinical Trial Participation Costs Survey

ASPE Generic Clearance for the Collection of Qualitative Research and Assessment
OMB Control Number 0990-0421, Expires 2/28/2027

Supporting Statement – Section B

Submitted: May 30, 2024

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B. STATISTICAL METHODS

1. Universe and Respondent Selection

This project seeks to explore the ways in which the COVID-19 pandemic impacted clinical trial participant costs for individuals with cancer, particularly in the context of participant diversity. On behalf of ASPE, our contractor Mathematica, in collaboration with the American Cancer Society Cancer Action Network (ACS CAN), will conduct a survey, sending a questionnaire to members of the ASC CAN Survivor Views panel. Survey data will allow us to a) better understand the monetary and non-monetary costs incurred by cancer clinical trial participants and b) determine if the COVID-19 pandemic resulted in modifications to the clinical trial structure that facilitated participation and/or reduced participation costs. This is a one-time survey. All participation is strictly voluntary.

The ACS Survivor Views panel is a web survey that is conducted every two to three months. Recent survey topics include drug shortages and delays in cancer care, LGBTQ+ cancer patients and discrimination in the health care setting, and compliance with cancer screening.

We anticipate that the screened Survivor Views panel members will be clinical trial participants at some point between 2018 and 2024 and will complete the full questionnaire (n=250), which can be found as Attachment A.

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2. Procedures for Collecting Information

ACS CAN will deploy the Clinical Trial Participation Costs Survey to Survivor Views panel members over a 6- to 8-week period between June and July of 2024. The survey is structured so that it will take approximately 15 minutes to complete. ACS CAN will provide each respondent with a \$25 gift card following completion of the survey, which they are free to decline.

ACS CAN will use their InMoment web survey platform to manage survey administration. Collecting data in this manner reduces burden on respondents and improves data quality. For example, InMoment employs (1) secure log-ins so respondents can save and complete the survey in multiple sessions, (2) drop-down response options so respondents can quickly select their responses from a list, (3) dynamic questions and automated skip patterns so respondents only see questions that apply to them (including those based on answers that they provided previously in the survey), and (4) logical rules for responses so respondents' answers are restricted to the range intended by the question. Data are transferred, in real time, from the respondent interface to a secure server hosted by ACS CAN and dedicated to Survivor Views work with access limited to Survivor Views project staff. A deidentified data file will be created by ACS and shared electronically with Mathematica and ASPE via secure transmission.

Respondents can decline to respond to questions that they do not want to answer. To encourage candid responses, however, the invitation and reminder emails will remind respondents that the study team will keep their responses private. Survey data will be stored separate and apart from personally identifiable information so that the analytic file is deidentified and devoid of information that can directly or indirectly identify the respondent.

3. Methods to Maximize Response

After receiving OMB approval, our contractor will send an invitation email to selected Survivor Views members. The invitation letter will include a unique link so that respondents can easily access the web survey. The invitation email will summarize the background and purpose of the study, the voluntary nature of the survey, and the emphasis we place on safeguarding the data collected. It will also contain contact information if potential respondents have questions about the study. We will follow the invitation email with a series of reminder emails, as depicted in Exhibit 1, to help reduce non-response. As reference above, we also plan to encourage response by offering survey respondents a \$25 gift card, which they may decline.

Exhibit 1. Draft survey deployment schedule

Action	Day ¹
Invitation email	1
Reminder email #1	7 to 10
Reminder email #2 / Tailored email ²	17 to 24
Reminder email #3 / Tailored email ²	31 to 33
Last chance email	40 to 42

¹ Field period may be reduced or extended depending on the response rate.

² The tailored email will be used if warranted based on the number of web survey break-offs.

4. Testing of Procedures

The survey instrument was developed by survey methodologists and was iteratively reviewed by experts in cancer care and clinical trials. Once the survey instrument was in draft format, our contractor pilot tested it in April 2024 with five individuals that had participated in cancer clinical trials between 2018 and 2024. Individuals were asked to complete the survey and record the time required to do so. They were then asked to review the survey items a second time, taking notes about content that was difficult to understand, questions that were not clear, response options that were missing, and anything else that made answering questions and completing the survey difficult. After completing the survey, our contractor engaged each participant in a 20–30-minute phone call to discuss the survey content and to learn about their experience completing the survey. Based on feedback received, the contractor modified the questionnaire prior to submitting this clearance package to OMB. In addition, the pretest provided an accurate estimate of respondent burden (15 minutes) as required by OMB.

5. Contacts for Statistical Aspects and Data Collection

Subject matter experts were consulted on the development of the questionnaire. Statisticians provided input on technical and statistical issues.

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