Cancer Epidemiology Cohorts: Research Opportunities for Established Studies

PAR Concept Proposal, BSA

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December 8, 2021

PURPOSE

- Provide continued support for established cohort studies that address novel, innovative research questions across the cancer control continuum
  - *Established* cohort studies- defined as studies that have achieved their initial planned recruitment goal

- This PAR will replace the expiring PAR 20-294 (Cohort Infrastructure for Cancer Epidemiology Cohorts)
  - *Those currently funded by PAR 20-294 are not eligible to receive funding until after the expiration of their current grant*

NCAB WORKING GROUP ON POPULATION SCIENCE RECOMMENDATIONS

- NCI should continue to providing sufficient infrastructure support for cohorts to conduct or facilitate research that addresses critical scientific gaps

- Peer-review process should include review of justification for continued follow-up of the cohort including scientific yield

- Cohorts should consider current and emerging gaps in research and comprise appropriate populations
  - Survivor cohorts should address current and emerging research gaps by cancer type and/or treatment

NATIONAL CANCER INSTITUTE

COHORT STUDIES ADVANCE KNOWLEDGE

- Prospective cohort studies have identified environmental, behavioral, and genomic factors associated with cancer incidence, morbidity, and mortality

- Informed interventions and guidelines to prevent or mitigate the effects of cancer and its treatment

- Rich resource of data and biospecimen collections from diverse populations
  - Great potential for innovative research into cancer risks and outcomes following cancer diagnosis

RESEARCH-DRIVEN COHORT SUPPORT

- Leverages the significant investment made in established cohort studies to address innovative questions

- Ensures use of appropriate methods and data collection

- Continues to advance scientific knowledge

GUIDELINES FOR APPLICANTS

- Must address key scientific gaps

- Aims must include hypothesis-based research questions
  - Core infrastructure support is expected

- Must justify study methods (e.g., data collection, proposed assays) based on the research in aims

- Priority given to novel research that
  - Includes understudied populations
  - Directly informs future interventions, guidelines, and/or clinical management strategies

RESPONSIVENESS CRITERIA:

Non-responsive and will not be reviewed, including those that:

- Initiate new cohorts
- Do not include hypothesis-based research based on data from an established longitudinal cohort study in the specific aims
- Have data and/or resource sharing plans that do not comply with NIH policy and follow the FAIR (Findability, Accessibility, Interoperability, Reusability) principles

MECHANISM AND BUDGET

- PAR: U01

- Two receipt dates per year for three years

- Applicants should propose up to 5 years of funding

- Budget: No specific cap
  - Required pre-submission meeting for budgets above ≥$700k direct costs/year
  - Awaiting Receipt of Application for above ≥$500k direct costs per year

- A program announcement with review (PAR) by a special emphasis panel is requested
  - Recommended review with *Cancer Epidemiology Cohorts: Building the next generation of research cohorts*.
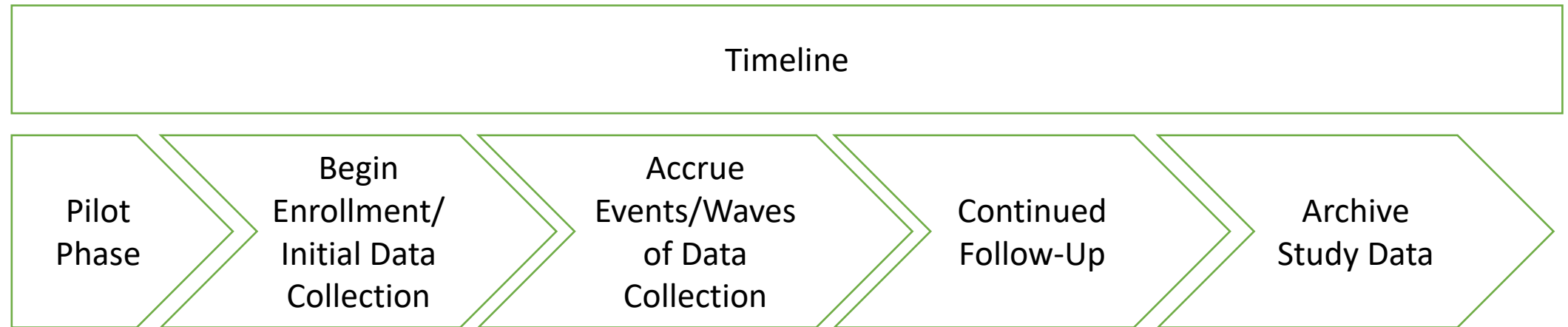
PORTFOLIO ANALYSIS

- 31 cancer epidemiology cohorts in the current DCCPS portfolio
  - 1.1 million participants
  - More women (76%) than men
  - Racial/ethnic distribution: 66% White, 17% Black, 7% Asian, and 6% Hispanic
  - Many of the longstanding cohorts have older populations (>65 years old)

- Distribution roughly reflects the proportion of White, Black, and Asian Americans, the number of Hispanics included in these cohorts is considerably less than current US population (18% in the 2020 Census)

"TYPICAL" TIMELINE OF CANCER EPI COHORTS

Timeline

Pilot Phase → Begin Enrollment/ Initial Data Collection → Accrue Events/Waves of Data Collection → Continued Follow-Up → Archive Study Data

Comments from our Reviewers-
Drs. Robison (chair), Bondy, and Rathmell

- Additional clarification requested for:
  - How/when transition would take place for cohorts currently funded through *PAR 20-294*
  - Non-responsive criteria
  - Desired breadth of portfolio
    - Diversity and innovation are important. Will consider participant age, cancer site, race/ethnicity, and urban/rural among other factors.

Thank you for your time and effort in review

Thank you