NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE)

Request for Applications (RFA)

Release Date: April 3, 2023

SUBMISSION:	DUE ON:	SUBMIT TO:
LETTER OF INTENT (as PDF file)	**5 pm ET on April 24, 2023**	NAVIGATE RFA at CSP@va.gov Attn: Colleen Shannon
APPLICATIONS (as PDF file)	**5 pm ET on May 12, 2023**	NAVIGATE RFA at CSP@va.gov Attn: Colleen Shannon
INQUIRIES MAY BE DIRECTED TO		VA Cooperative Studies Program at CSP@va.gov Attn: Colleen Shannon

Program Overview

The Department of Veterans Affairs (VA) Veterans Health Administration (VHA) and the National Cancer Institute (NCI) established an interagency agreement through the VA Office of Research and Development (ORD) to enhance VA participation in NCI clinical trials and offer greater opportunities for Veterans with cancer to participate in trials with novel therapeutic options. This effort, the NCI And VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE), has an overall goal to establish and grow a VA consortium of sites that will successfully participate in NCI National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) activities. NCI NCTN activities include cancer treatment trials and are considered part of the standard of care, while NCORP activities focus primarily on cancer prevention and symptom management trials. Emphases will be placed on a coordinated set of systematic activities between the agencies aimed at enhancing recruitment of Veteran participants, improving efficiency in fulfilling operational and regulatory requirements for NCTN and NCORP clinical trials within the VHA health care system, and optimizing VA's ability to contribute to these critical studies. To achieve these objectives, NCI has provided funds to support the infrastructure needed for VA site participation. NAVIGATE is jointly managed by the agencies. Funding is available for up to 4 sites for up to three years. It is expected that during this time, these VA sites will establish long-term capabilities to continue participation in NCI trials beyond this award via other mechanisms and to contribute to a larger VA effort for building a cooperative clinical and research network for its cancer initiatives.

NAVIGATE was initiated in 2018 with 12 selected VA sites. In an effort to expand the reach of NAVIGATE across VA, up to 4 more sites will be selected to participate in the NAVIGATE program. Support for personnel will be provided to: develop or enhance existing processes related to NCTN membership; identify successful pathways for rapid initiation of NCTN and NCORP trials; successfully execute an agreement with the NCI Central Institutional Review Board; and work collaboratively with other VA sites to identify appropriate trials for the VA population. Additional information about NAVIGATE is available here: NAVIGATE - NCI and VA Interagency Group to Accelerate Trials Enrollment - NCI (cancer.gov). This VA consortium will follow a model established by the Cooperative Studies Program (CSP) Network of Dedicated Enrollment Sites (see: https://www.research.va.gov/programs/csp/nodes.cfm). At a minimum, a participating site is expected to have a lead Oncologist (physician with specialized training in any area of oncology: medical, radiation, surgical, other) and a Research Coordinator with research experience in program areas. Individual sites will be part of a larger consortium of VA sites and receive the support, experience and opportunities offered by NAVIGATE. NAVIGATE and its consortium are overseen by an Executive Committee comprised of VA and NCI leadership charged with ensuring effective coordination on key activities between the agencies and that program milestones are achieved. CSP will provide support for coordination and executive activities.

RFA Objectives

Awards under this RFA will provide funding support to individual VA medical centers/facilities to participate in NAVIGATE. The NAVIGATE site awards have three main aims:

1) Increase Veteran participation in NCTN and NCORP studies;
2) Enable a sustained, long-term capability for participating in NCI clinical trials after the initial NAVIGATE support; and
3) Establish the operation and organization of a national consortium of VA sites focused on improving VA participation in NCTN and NCORP studies and potentially other cancer trials by different sponsors.

The NAVIGATE program will be of mutual benefit to both the VA and NCI in a number of major ways including:

- Enhancing the ability for eligible Veterans with cancer to gain access to a larger range of promising new treatment options, including "precision medicine" and "immunotherapies"; similarly enabling more VA clinical investigators to offer novel/alternative treatments to their patients.
- Providing new opportunities for minority populations within the VA to participate in NCTN and NCORP clinical trials.
- Accelerating accrual of Veterans (including ones from minority populations) to NCTN and NCORP trials resulting in more timely completion of these clinical trials.
- Providing opportunities for VA clinical investigators to participate in and provide leadership in clinical cancer research; opportunities may include NCI's Disease-Specific and Scientific Steering Committees meetings, serving on scientific committees in the NCTN and NCORP Groups, contributing expertise to identifying studies of importance to the VA cancer population and possibly serving as co-investigators or study champion for VA sites.
- Establish a model of interagency collaboration between the NCI and VA aimed at overcoming common barriers to clinical trials.

Key Dates

Deadline for Letter of Intent submission **April 24, 2023**
Deadline for full application submission: **May 12, 2023**
Expected date of award: **Fall 2023**

Eligible Applicants

Any VA facility with a Federal Wide Assurance (FWA) to perform human subjects research and a VA non-profit corporation (NPC) is eligible to apply. Only one application may be submitted per VA medical center, which must be submitted by the VA research office or the VA NPC. Applicant sites must be an existing or former NCTN member that left in good standing. Prior to selection, applicant sites should anticipate enrolling into NCTN studies, and be able to communicate their proposal to obtain NCTN membership, if an active membership does not exist.

Applicant sites must have an authorizing agreement with the NCI CIRB or have a plan in place for securing this agreement in order to utilize the NCI CIRB as an IRB of Record (see below for further information). If the applicant site does not have an authorizing agreement, the reasoning must be explained. If selected, sites must also be able to accept award funds through their VA NPC.

Rules for eligible Principal Investigators (PIs) generally follow those for VA awards, particularly with regard to a clear career commitment to the VA health care and research missions. An application must come from an eligible VA investigator (medical/surgical/radiation oncologist) with a minimum of a 5/8ths VA appointment. PIs with less than a 5/8ths appointment may request a waiver from the Cooperative Studies Program through their Associate Chief of Staff for Research (ACOS-R). However, approved waivers for NAVIGATE are expected to be rare given the VA prerequisites involved. PIs must demonstrate the following:

- Experience in conducting oncology clinical trials and oncology research (preferably within VA).
- Knowledge of the cancer patient population for their respective facility/region.
- Strong leadership and supervisory capabilities in the clinical, scientific and operational management of a local trial program (e.g., methodology, recruitment, regulatory affairs and personnel management, committee chair).
- Previous success in building and establishing programs that require senior leadership/administration support and leveraging of resources (experience working with local VA leadership is strongly encouraged).
- A record of working collaboratively and engaging a broad range of stakeholders.

Application Requirements

Applicants must first submit a **Letter of Intent (LOI)** to indicate interest in being considered.

- This LOI should be no more than one page that includes:
    - the PI's name
    - the name and location of the VA facility
    - the name of the VA non-profit corporation, and

- a statement signed by the PI, ACOS-R&D, and NPC Executive Director indicating an understanding of the goals and conditions of participating in the NAVIGATE consortium as outlined in this RFA.

- While not required, applicants may include information to highlight anticipated elements that will be included in the full application.
- Applicants may proceed to completing a full application immediately after submitting the LOI; however, official notice of LOI approval by the NAVIGATE program office must be included in the final application.
    - LOIs approvals should be provided within two weeks of receipt.

Full applications must include the following:

- Completed face page *(see Appendix A)*
- Cover letter highlighting:
    - Key reasons for the VA facility's interest and its capabilities for contributing to program goals
    - PI qualifications
    - Level and nature of leadership support (from the ACOS-R, VA facility director, and NPC Executive Director)
    - Plans for immediate and long-term program goals for cancer clinical trials at the site including:
        - increasing Veteran participation in NCTN and NCORP studies
        - long term sustainability of the established research program
        - contribution to the national consortium of sites for cancer trials
- Copy of LOI approval from the NAVIGATE program office

- Main Application**:**
  Applications should be no more than 5 single-spaced pages using 12-point font organized by the section headings below. Other than the indicated required items, **it is up to the applicant to determine what and how details are presented and/or if items are relevant to their respective application**. Within each section, suggested areas for further description are provided. Applicants with existing relationships to their academic affiliates for NCTN and/or NCORP activities are strongly encouraged to maintain these ties as part of the application.

    - Section I. Program Goals – Suggested 2-page limit
        - Describe overall, short- and long-term visions for the site if selected for the NAVIGATE consortium.
        - Describe how the site's participation in NAVIGATE would particularly contribute to achieving overall program goals for NCI and VA and how the site would benefit from participating in NAVIGATE (e.g., scientific, operational, or regulatory).
            - Indicate how the site's participation in NAVIGATE will incorporate other programs (e.g., VA Precision Oncology or other Research Networks) and clinical infrastructures to enhance and improve organizational collaboration and synergy.

- Describe proposed plans and activities for achieving/exceeding recruitment goals in NCTN and NCORP trials.
    - Indicate disease areas and potential trials of interest for your site. Current trials can be found at: https://www.ctsu.org/Master/SimplePage.aspx?ascx=ProtocolsReport
    - Innovative approaches demonstrating an understanding of barriers and keys to success are encouraged.
- Describe how participants from minority populations would be recruited, including how veteran patient advocates might be engaged to collaborate.
- Describe plans for how local NAVIGATE activities would be coordinated with other groups (e.g., academic affiliate, cancer center, or NCORP site) involved with NCI or other oncology group trials.
- Describe specific plans for how this award would be leveraged to establish a long-term sustainable activity for future NCI clinical trials.
- Any other unique details or factors that NAVIGATE leadership should consider in the site's ability to achieve to program goals.

- Section II. PI qualifications – Suggested 1-2 page limit
    - Indicate PI leadership qualities and experience, particularly in clinical trials research.
        - Please specify any experience with NCI funded research/clinical trials
        - An NIH format bio-sketch **must be included** as an appendix but will not count toward page limits. Format found at: https://grants.nih.gov/grants/forms/biosketch.htm
    - Describe successes in designing and/or conducting cancer clinical trials.
    - Describe any particular achievements in conducting clinical research: fulfilling regulatory affairs/operational requirements, recruitment goals, and/or promoting patient engagement.
    - Describe any experience with collaborative activities in clinical research (e.g., consortia, work groups, multi-site trials, data monitoring committees, etc.).
    - Describe experiences in working with leadership/administration (e.g., hospital or academic).
        - Include any specific activities/achievements that demonstrate how their support/engagement was obtained or other involvement maintained.
    - Describe experiences in working with institutional hiring processes or related administrative practices.

- Section III. Institution / Local environment – Suggested 1-2 page limit
    - Provide information on the institution's background and experience with oncology research **is required** (e.g., VA Cooperative Studies, federally or industry funded clinical trials).
        - Please use *Appendix B* Template to summarize this experience – This table is not counted as part of page limits.
        - Specific reference to experience with NCI clinical trials should be included.

        - Sites with no currently active NCI trials may demonstrate some effort, within the past three years, of initiating NCI trials at their sites.
        - For sites that were former NCTN members and left in good standing - provide the rationale for departure and describe plans to overcome issues that led to the inactive status.
    - Describe the regional/facility's cancer patient population.
        - Provide local cancer registry data from the past three years (five years preferred).
        - Inclusion of information on minority populations is strongly encouraged
    - Describe the institution's clinical and research infrastructure and how the infrastructure will be able to support this activity.
    - Describe institutional or programmatic approaches to training and education of local research staff, including research coordinators and research nurses.
    - Indicate how adherence to research quality standards has been demonstrated (e.g., previous audit findings from NCTN trial participation, etc.).
    - Describe local leadership support, including how any key individuals are engaged as partners in this initiative, and their roles.
        - Individuals may include clinical, research, administrative and/or other key personnel.
    - Provide details of any active authorizing agreement with the NCI Central IRB.
        - If no authorizing agreement currently exists, a written plan (including timelines and any key personnel) for how an authorizing agreement would be obtained may be provided instead. While the NAVIGATE program office will assist sites with obtaining authorizing agreements, applicants should demonstrate a working knowledge for local requirements and procedures involved.
    - Indicate any partnerships with local community-based or academic affiliates including any NCI cancer centers, NCORPS, etc. and the nature of these relationship (e.g., support provided, joint activities, etc.).
    - Describe the VA non-profit corporation and its support of clinical trials.

- <u>Section IV. Details of Support</u> – These items are not counted toward the 5-page limit.
    - A PI statement of acknowledgement **is required** that indicates his/her understanding and commitment that receipt of award involves an active commitment to participate in and contribute to a consortium of VA sites coalesced under the NAVIGATE initiative (e.g., conference calls, face-to-face meetings, progress reviews, participation in strategic planning, and/or coordinating activities for fulfilling initiative goals).
    - Indication of support by hospital leadership (e.g., Medical Center Director, Chief of Staff, PI supervisor and/or ACOS-R)
        - **A letter of support from the VA facility director and ACOS-R is required.**
    - A statement/letter of support from the VA non-profit corporation **is required**.
    - A confirmation from the VA Research Office that the applicant has at least $5/8^{th}$ FTE VA appointment and % effort of protected time **is required.**

- Letters of support and understanding of commitment from partnering services are strongly encouraged. Any inclusion of letters should indicate the level of capacity and willingness to provide clinical services, the importance of integration and partnership between research and clinical care, and awareness of financial impact of federally funded studies. Examples of impacted services may include nursing/medical service, pharmacy/research pharmacy, pathology, imaging services, radiation oncology, etc. Examples of research activities above standard of care include the potential collection and transfer of additional biopsies, blood collection, imaging, as well as the management of investigational agents, etc.
- Letter of support from applicable NCTN Group(s) and/or NCORP Research Base(s) indicating intent to support applicant.
- Letter(s) of support from local community-based or academic affiliates (if applicable) including any NCI cancer centers or NCORPs indicating intent to support applicant.
- A proposed allocation of award funds at the site **is required** (for more information see Funding section below)

Submission

The Letter of intent should be submitted as a PDF file via email to CSP@va.gov by April 24, 2023. Please indicate in the email's subject heading: NAVIGATE RFA – [Location name].

Complete applications should be submitted as a PDF file via email CSP@va.gov by May 12, 2023. Please indicate in the email's subject heading: NAVIGATE RFA – [Location name].

Evaluation Criteria

Applications will be evaluated through a peer-review process involving a diverse set of perspectives/expertise in oncology and clinical trials. The NAVIGATE Executive Committee will make the final decision based on scores and recommendations of the review committee. NCI and VA seek to have a diversity of sites with various experiences and perspectives to help contribute to NAVIGATE goals. Prior experience in NCI clinical trials will not be a predetermining factor for site selection, though sites must strongly demonstrate how they will effectively build their program to activate NCI trials and recruit to them within the expected timeframes of this initiative. Reviews will consider overall strengths of applicants towards meeting short and long-term goals to help with ensuring NAVIGATE's success. Applications will be evaluated based on the following criteria:

- Overall understanding of and plans for achieving NAVIGATE goals.

- Investigator qualifications in clinical, research and leadership/management for successfully conducting (especially for recruitment) clinical trials.
    - clinical capabilities and support to conduct cancer clinical trials experience and history with oncology clinical trials and research
- Local environment and support to allow a cancer clinical trial site to grow and succeed.
    - Clinical, research and leadership support
    - Patient population
    - Partners (e.g., academic affiliate, VA non-profit corporation, etc.)
    - Demonstrated history of success in patient retention and data quality
    - Engagement of clinical services and operational partners
- Long-term vision and ability to execute plans for establishing a successful and self-sustaining cancer clinical trials site

Particular priority may be given to applications that can demonstrate:

- Clear understanding of barriers in conducting clinical trials within VA
- Innovative and/or strategic abilities to establish solutions in conducting clinical trials within VA
- Ability to successfully recruit across multiple studies of different cancer types
- Potential for enhanced minority recruitment
- Factors suggesting an active and fruitful partnership between the site and the NAVIGATE Executive Committee and consortium sites to achieve NAVIGATE goals.

Funding

NAVIGATE funding is intended to facilitate the site's ability to establish a sustainable program of cancer clinical trials activities. Funding under this award will be provided to those applicants that demonstrate outstanding ability to achieve the goals of the initiative and who have high levels of merit and innovation. For selected sites, funding will be provided in block amounts up to $175,000 per year (inclusive of overhead costs) to the applicant's VA NPC. Details will be provided upon announcement of the award. It will be up to the Principal Investigator to negotiate all local costs and budget including any overhead with their VA NPC. Awards will be provided to the Principal Investigator's affiliated VA Non-Profit Foundation from the Boston VA Research Institute (BVARI). Final awards are subject to availability of funds.

Funding of the NAVIGATE initiative is expected to be for at least 24 months with an additional 12 months pending progress/performance. Funding will support the following:

a. Personnel. Funding is expected to support at a minimum 0.5 FTE of a Research Coordinator. Together with the NAVIGATE PI, the Research Coordinator should have a primary responsibility for overseeing NCTN/NCORP study requirements including meeting administrative, recruitment and compliance requirements for all NCTN trials conducted at the site.

b. Travel. Funds should be budgeted to allow for staff to attend NCTN cooperative group meetings.

The Principal Investigator should utilize the funds in a manner that maximizes program success based on local needs. The application should provide plans and justification for how funds will be utilized.

NOTE: Funding for accrual to NCTN/NCORP studies conducted at the VA facility will be provided through existing NCTN and NCORP mechanisms and not through this award.

Performance Assessments and Criteria

The NAVIGATE Executive Committee will periodically evaluate patient enrollment by the participating VA sites and determine the advisability of continuing funding or not at a given site. Individual site performance will be evaluated by the committee using a variety of performance metrics including:

- Time and ability to establish NCTN/NCORP membership
- Time to establish an MOU with the NCI Central IRB
- Time and ability to initiate a new study, including:
    - bringing on new study personnel (if applicable)
    - completing IRB submissions
    - completing study-specific credentialing (if applicable)
    - enrolling the first patient into a study
- Recruitment and enrollment rates, including minority populations
- Number of active NCTN/NCORP trials
- Regulatory compliance and protocol adherence
- Obtaining valid informed consent for study participants
- Data timeliness, completeness and quality
- Response time to queries
- Appropriate pharmacy investigational agent accountability and security measures
- Budget management
- External research funding in oncology research beyond this initiative
- Contribution to national Consortium efforts
- Evidence of sustainability

The VA Office of Research and Development may further examine other areas of performance and progress to meet its obligations to NCI under the Interagency Agreement.

APPENDIX A: APPLICATION FACE PAGE

NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE)

APPLICATION FACE PAGE

APPLICANT INFORMATION

VA Medical Center:	
Principal Investigator:	
Degree and Title:	
Address:	
City, State, Zip Code:	
Email:	
Phone:	

ADMINISTRATION

Administrative Contact:	
Email:	
Phone:	

VA NON-PROFIT CORPORATION

Name:	
Contact:	
Address:	
City, State, Zip Code:	
Email:	
Phone:	

APPLICATION CHECKLIST	☐ Completed Application Face Page ☐ Cover Letter ☐ LOI approval from NAVIGATE program office ☐ Main application ☐ PI Biosketch ☐ Table of Trial Experience ☐ Details of Support (note application requirements)

APPENDIX B. Site Accrual Record

Instructions: Complete this table for representative Oncology-specific clinical trials active at your site for up to the past 7 years (i.e., January 1, 2016 to present). Assume the review committee will recognize challenges in conducting trial during the COVID-19 pandemic. Use additional sheets if necessary.

Trial Sponsor/Support (VA, Industry, NCTN, NCORP)	Trial Type (Treatment, Prevention, Control, Screening)	Phase of Trial	Brief Title of Trial and NCT Identification Number (Include Substudies)	PI Name	Date Open for Patient Accrual	Site Accrual to Date/Site Accrual Target*	Notes/Comments

*Please include the total accrual target for the entire trial in parentheses, if known.