INTENT TO SUBMIT

The Intent to Submit process is designed to support you in submitting your funding application, and in planning your project. When you click "submit", this form will route to your department and to the myRESEARCHnavigators team.

Principal Investigator

1. Are you the PI for the project? Yes/no
2. PI Name:
3. PI Email:
4. Is the PI a first-time PI at Duke? yes/no
5. Is the PI regular rank faculty, or if not, do they have PI status at Duke (see PI Eligibility policy)? Yes/no
6. What department should this proposal be routed through?

Funding Application Information

7. Project Title _____
8. Sponsor/Funder _____
9. Is this an industry-sponsored clinical trial? Y/N
10. Funding Opportunity Number or URL _____
11. Which activity best describes this project?
    (Options: Research, Clinical Trial, Conference, Inst. Training Program or CME, Fellowship, Public Service, Institutional Support, Equipment, Construction/Renovation)
12. Sponsor Due Date _____
13. Planned submission date _____

Project Activity Information

14. Planned project start date _____
15. How long is the project period?

- 5 years
- 4 years
- 3 years
- 2 years

- 1 year
- Other

15. Draft study aims, goals, abstract or brief description of project

16. Does this application have potential similarities/overlap with other submitted or awarded research projects? (more info available here) Y/N

17. To make sure we are prepared to assist with deadlines, required documents, and complex situations, please mark which of the following conditions apply (all yes/no/unsure)
    - The study has multiple PIs
    - Duke subaward(s) to another organization
        - If yes, approximately how many (1-3; 4-6; more than 7)
    - Duke as a Sub-Contract (i.e., Sub-Awardee)
    - Historical Site (i.e., Chesterfield Building)
    - Institutionally Limited submission requiring nomination
    - In Kind/Cost Sharing (Not Including NIH Salary Cap)
    - VA involvement. (if yes...)
        - will any portion of the scope of work be completed by VA personnel, be done using VA facilities, or involve use of VA data?
    - Involves Human Subjects
    - If yes, Will there be patient care costs?
    - Involves vertebrate animals
    - Requires Institutional Biosafety Committee review
    - Involves technologies, including using or developing mobile and web applications, websites, etc.
        - [If yes] Briefly describe the technologies involved
    - Will use existing internal/administrative Duke University or Duke Health data
        - [if yes] Briefly describe the type of data that will be used
    - Needs specialized storage and/or computing environments (e.g., sensitive/restricted data, patient data, proprietary data, large files, etc.)
        - [If yes] Briefly describe the computing needs [
    - Use of a Duke core facility, or other space/service/procedure provided by another department? (e.g., Regional Biocontainment Laboratory, shared resource, etc.)
        - [If yes] Briefly describe the facility, space, or resource
    - Involves investigational drugs, biologics, devices, and/or tobacco products, which would include, for example, a completely novel product or an FDA-approved product off label.

    Please mark if any of the following apply to this project:

o Manufacturing of a medical product that will be administered to human subjects. This includes, but is not limited to, compounding of novel products, cellular therapies, and changes to an FDA-approved product.

o Involves FDA Regulatory Affairs for "Commercial" Activities – to support an investigational application where the product under investigation is intended to be commercialized at a later date (ex. requires the submission of a commercial IND), an FDA marketing application (ex. 510(k) or BLA), or modification of an FDA-cleared/approved product (ex. label change).

o Involves FDA Regulatory Affairs for Coordinating Center Role – to support large, multi-center studies or projects that require use of a coordinating center.

o Involves FDA Regulatory Affairs for Multi-Project Programs – to support large, multi-project research activities, such as Program Project/Center Grants (P series), Cooperative Agreements (U01), or projects of similar magnitude.

· This study involves International Activities

I. · [if yes]

· Please mark which of the following apply to your work outside of the US

o will use Duke funds to hire and directly pay local staff as contractors, employees, or casual day laborers
o will open a local bank account
o will buy or lease vehicles
o will lease office or residential space
o will engage in human subjects or animal activities
o will engage in clinical trial(s)
o will have Duke faculty, staff, or students spend significant time (i.e. > 4 mos per year) supporting the project outside the US
o None of the above

· If any of the above are selected (except 'None'):

o In what country or countries are you planning to conduct your research/activities? (text entry)
o In 2-3 sentences, briefly describe the activities that will take place outside of the US.
o Have you identified a trusted in-country partner that can support the in-country activity you need? If so, specify who.

18. Would you like a free 10-15 minute project planning consultation to ensure awareness of resources that can benefit your project? The consultation will be completed by an expert from the myRESEARCHnavigators team. This is supplemental to your departmental grants management team who will be automatically notified about this intent to submit. [yes/no]