OneFlorida
Clinical Research Consortium

RESEARCH APPLICATION

Basic Study Information.

Application Date: May 8, 2017

Project Title: An Evidence-Based Eligibility Criteria Design Tool for Cancer Clinical Studies

Grant deadline: June 14, 2017

Link to the RFA: https://grants.nih.gov/grants/guide/pa-files/PAR-15-332.html

Principal Investigator Information:

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Additional Team Member Information (optional):

Name	Jiang Bian
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Role on Project	Co-PI (MPI)
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Study Design:

☐	Interventional Study (Continue)
☒	Observational Study (Skip to General Project Information on Page 2)

If you are planning an interventional trial, what type:

- ☐ Drug
- ☐ Medical Device
- ☐ Behavioral
- ☐ Other _____ (specify)

Did you include any of the supporting documentation listed below (OPTIONAL)? Please select all that apply:

☒	Abstract
☐	Proposal/Protocol/Grant application
☐	Letter of intent
☐	Technical specifications
☐	Other (please specify _____)

Describe the study purpose and specific aims.

We propose a web-based tool for supporting the evidence-based eligibility criteria deign in cancer studies and help assess study feasibility and *a priori* generalizability. This tool will allow trial designers to iteratively refine the study's eligibility criteria (consequently, the study population), addressing three key gaps: 1) reducing the subjectivity and the vagueness of criteria through making the criteria computable, 2) helping selection of study sites to maximize enrollment rates (i.e., through visualizing (in-)eligible patients based on sites' clinical data warehouse), and 3) quantifying the population representativeness of the study during the design phrase (i.e., *a priori* generalizability). The initial design of the tool will focus on breast and colorectal cancer trials.

Note that this is a resubmission application, and the previous application has been approved by the OneFlorida Executive Committee (the previous letter is attached).

Describe the potential impact and innovation of the proposed study.

This project aims to fill an important gap in evidence-based medicine with a novel data-driven tool that helps cancer trial designers fine tune eligibility criteria while discerning the feasibility and generalizability of a study during its design phase.

Describe the intervention(s). If the study is observational, describe the comparisons that will be made.

The study is the development of informatics tools to help investigators design clinical trial eligibility criteria. The comparison will be between the investigators who use the tool vs. the investigators who do not use the tool, in terms of the quality (e.g., whether the criteria are subjective, vague, or not evidence-based) of the eligibility criteria, and the generalizability of the study.

Study Outcomes of Interest:

Primary Outcome	The quality of the clinical trial eligibility criteria
Secondary Outcome(s)	The generalizability of the study

Estimated Project Timeline:

Anticipated start date	4/1/2018
Anticipated end date	3/31/2021
Months of intervention (if interventional)	

Targeted Population (Inclusion/Exclusion Criteria):

We will need data from OneFlorida Data Trust on patients with breast and colorectal cancer.

Sample Size and Rationale (PATIENTS):

All patients with breast and colorectal cancer, as one of the goals of the tool is to help investigator visualize patients who meet the clinical trial eligibility criteria.

Recruitment Strategy (if interventional):

OneFlorida Overall Resource Request. Please review the OneFlorida mission and resources, described on the website (http://onefloridaconsotrium.org). A brief consultation will be scheduled at your convenience after this application has been submitted. If you would prefer to discuss these questions during your consultation, please indicate this in the form below.

Which OneFlorida resources are you interested in?:

	Resource Requested
☒	Data Trust
☐	ResearchACTS
☐	Practice Facilitators
☐	Data Management
☐	Site Visits
☐	Study Coordination
☐	Research Coordination
☐	IRB Coordination
☐	Training/Education
☐	Other
☐	I would prefer to discuss my needs during the consultation

How does your proposal fit with the mission of OneFlorida? Please select all that apply:

☐	Patient-centered
☒	Focuses on the mission of OneFlorida
☐	Uses one or more health systems that comprise OneFlorida
☒	Uses the OneFlorida data trust and/or the practice-based research network and/or OneFlorida infrastructure/resources
☐	Demonstrates how patients, clinicians, and other relevant stakeholders are engaged in the design, conduct, analysis, or dissemination of the research

Describe any existing or proposed affiliation or engagement with PCORnet Clinical Data Research Networks CDRNs or Patient-Powered Research Networks PPRNs (if applicable):

N/A

OneFlorida Data Trust. ***If your study will utilize the OneFlorida Data Trust, please complete this page. If not, please skip to the OneFlorida Practice Network on page 5.***

Has your team developed a "computable phenotype" or other analysis code that you would like to use for this query?

- ☐ Yes (Include the code with this request and skip to the OneFlorida Practice Network section)
- ☒ No (Complete the table and questions below)

The Data Trust Program can help you develop analysis code. Please complete all applicable boxes in the table below to the best of your ability. If needed place the codes on an accompanying excel spreadsheet or word document.

	Applicable?	Description	Details/List
Inclusion criteria	☒ Yes ☐ No	Please include a text description of the patients to be included in the query	Patients with breast and colorectal cancer.
Exclusion criteria	☐ Yes ☒ No	Please include a text description of the patients to be excluded in the query	
Diagnosis (ICD) codes	☐ Yes ☐ No	Include a list of ICD 9 and/or 10 codes and how they are related to the inclusion/ exclusion criteria	Breast cancer: ICD-9: 174.*; ICD-10: C50.* Colorectal cancer: ICD-9: 153.*, 154.*; ICD-10: C18.*; C20.*; C21.*
Procedure (PCT) codes	☐ Yes ☒ No	Include a list of CPT codes and how they are related to the inclusion/ exclusion criteria	
Common Data Model (CDM) variables	☒ Yes ☐ No	Include a list of CDM variables you would like included in the query	ALL
Date range	☐ Yes ☒ No	If yes, include data range. If no, all available data will be included in the query	

Please include any other information you feel will be needed to write an appropriate query for this request. If you have an example of the needed table or formatting requirements for how the results are returned to you, please enter below.

Do you need the patients counts stratified by any variables of interest?

- ☒ Yes (If yes, please enter a stratification plan in the text box below)
- ☐ No (If no, please skip to the OneFlorida Practice Network section)

Age, gender, race, and ethnicity.

OneFlorida Practice Network. If your project will utilize the OneFlorida Practice Network, please complete this page. If not, please skip to Study Funding.

Practice Type Requested and Rationale:

Number of Patients Needed to Enroll at Each Site:

Sample Size and Rationale (PRACTICES):

Practice Involvement/Study Procedures with Potential Impact to Sites:

Practice Supports Needed:

Potential Benefits to Practices to Participate:

Study Funding:

Have you already obtained funding?

- ☐ Yes
- ☐ No, but I have already applied for funding
- ☒ No, but I plan to apply for funding
- ☐ Not applicable
- ☐ Other_____ (specify)

To which funding agency (agencies) have you or will you apply to in order to fund this research?

- ☐ PCORI
- ☒ NIH
- ☐ Industry
- ☐ Foundation
- ☐ Other_____ (specify)
- ☐ N/A (internally funded)

Which funding mechanism(s) did you or will you target (please list the RFA number(s) is available)?

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Terms of Data Use.

Investigator herby agrees to not to use, disclose or distribute the results of exploratory queries or any data provided for the described purposes to any entity or individual for any purpose other than (1) to serve as preliminary data in research funding proposals, (2) in Institutional Review Board applications to conduct research based on results from OneFlorida, (3) other uses individually approved by the OneFlorida Executive Committee, or as required by law, and (4) to abide by the OneFlorida Authorship and Intellectual Property Guidelines. The User acknowledges responsibility for ensuring appropriate use of the query results, publications, and presentations.

☒ Yes
☐ No, I have questions (please describe below):

Investigator herby agrees to not use the results of exploratory queries or any data that may be supplied specific for any other study or research purposes other than those outlined in this document. Any other uses of the data require that a new prep to research application or research application document is submitted to the OneFlorida Executive and Steering Committee.

☒ Yes
☐ No, I have questions (please describe below):