

APPLICANT QUESTIONS
Epidemiologic Cohort Study of Interstitial Cystitis
RFA-DP-21-002

1. I noticed that there is no language about biomarkers. Was that intentional? Is there interest in continuing biomarker/metabolomics work that was done in the prior NOFO or is the goal of the new NOFO to focus solely on clinical information?

RESPONSE: Under Part 1. Overview Information, Executive Summary, the “Purpose” includes the following text:

“The purpose of the research NOFO is: (1) to obtain estimates of the incidence of IC comorbidities, (2) define the demographic, treatment, and clinical patterns of IC, (3) examine health disparities, and (4) document IC's impact on the health of affected people over time. This must be achieved using data from an existing and established baseline cohort of IC participants. In addition, the purpose includes translating the scientific knowledge on IC to support public health action, including; patient strategies for improving quality of life: provider awareness and education; and medical and self-management of IC.”

In section IV Application and Submission Information, subsection #5 PHS 398 Research Plan Component, Research Plan the text reads:

“The applicant's research plan should address activities that will be performed over the entire performance period and should include the following items:

1. State the study design (e.g., a prospective cohort study) and the outcomes to be achieved.
2. Describe in detail how participants are sampled so that obtained estimates can be generalized to the US population.
3. Does the study sample size comprise at least 200 participants with IC?
4. Include details about data collection. Does data collection occur over the phone, mail, in-person, or a hybrid process? What variables will you ascertain and how many? Describe each variable in detail. Which variables are measured via self-report and which are objectively measured? Which variables examine sociodemographic patterns, healthcare access, quality of life, other chronic conditions, and mortality? Include variables that align with the purpose of the NOFO.
5. Describe the proposed data collection methods (e.g., over the phone, mail, in-person).
6. Describe in detail the variable, in alignment with the NOFO purpose, and how they are measured using self-reports or other methods such as those used to examine sociodemographic patterns, healthcare access, quality of life, chronic conditions, or mortality”

No text within this NOFO restricts the collection of biomarker/metabolomic data, as long as the required elements that appear in the sections listed above are adhered to and budget ceilings are honored.

2. We were going to apply to gain insights on IC/BPS through surveying a cohort who have interstitial cystitis and are willing to answer surveys and share information on their experiences with the condition. Does that sound appropriate?

RESPONSE: CDC cannot comment on the appropriateness of a potential application. Potential applicants should ensure that they are meeting the purpose and criteria in the NOFO. As stated in the NOFO, **Part 2. Full Text, subsection, Purpose:** “This study will work towards establishing rigorous and standardized diagnostic criteria for IC in order to better estimate the incidence of IC in the US population. It will examine how an IC diagnosis may impact a multitude of other health outcomes over time. The results from this study will provide a better

understanding of the epidemiology, healthcare utilization, health disparities, clinical patterns and treatment of the disease.”

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