

Answers to questions received from 2021-22 Community Subcontract Program prospective bidders to the *Request for Proposals*, focused on educational initiatives and programs aimed at increasing awareness about chronic obstructive pulmonary disease (COPD) as a serious lung disease and a leading cause of death and disability in the United States and that furthers implementation of the COPD National Action Plan.

March 31, 2021

- 1. We are a non-profit community-based organization that provides COPD educational workshops. Participants will be referred to our program from clinical referral sources. If each clinical partner is able to track utilization at baseline (before educational workshops) and after educational workshops and provide us with summary information (no specific patient identifying information) of expected overall decrease in COPD-related ED visits and hospitalizations following COPD education, would we still require IRB approval?**

Yes, review by an Institutional Review Board (IRB) must take place for all projects involving research with human subjects. Per the RFP, this includes living individuals about whom “(1) data is obtained through intervention or interaction with the individual; *or* (2) information is obtained that is both private and identifiable.” Because the project as described involves collection of data through interaction with the individuals, IRB oversight would be required, even if personally identifiable data are not collected.

- 2. Are potential applicants required to submit a Letter of Intent to be eligible to submit an application?**

No, submission of a Letter of Intent is not a requirement for application. It is helpful in providing a sense of how many applicants to expect.

- 3. Are we still eligible to submit an application if we do not submit questions by the question deadline?**

Yes, you are still eligible to bid even if you do not submit questions. However, no additional questions will be answered prior to the proposal submission date of April 14, 2021, at 3 pm EDT.