Author’s response to reviews

Title: Barriers to Timely Diagnosis of Interstitial Lung Disease in the Real World: The INTENSITY Survey

Authors:

Gregory Cosgrove (gcosgrove@pulmonaryfibrosis.org)
Pauline Bianchi (pauline@veracyte.com)
Sherry Danese (sherry@outins.com)
David Lederer (dl427@columbia.edu)

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Dear Editor,

Thank you very much for your kind review. In response to your questions regarding IRB and Informed Consent. Please see below:

Market research is guided by CASRO, which is the Code of Standards and Ethics for Market, Opinion, and Social Research. Under Section Ia, the following language appears with regard to active research participants.

a. Active Research Participation: Research participation is considered active if an individual is asked to participate in research (e.g., a survey, a focus group, or other research project, either in-person or via some other means of communication, such as telephone, mail, or online). When research participation is active, the individual is most often referred to as the "respondent" as research surveys are typically used. In this situation, research participation is voluntary, and is always based on informed consent. With active research participation, individuals must be: (a) willing participants in the research process; (b) appropriately informed (about the intentions of the research and how their personal information and responses will be used and protected); and (c) treated respectfully, in such a way as to maximize the likelihood that they will be satisfied with the experience and willing to participate in research in the future.

Our respondents were active participants in that they opted-in to participate in the research based on their choice to continue from the screener to the survey. Moreover, our respondents were informed that their participation “gives you an opportunity to share your experiences when being diagnosed with PF”. Publication is the expression of this sharing of experiences.
This study is neither conducted nor supported by a federal department or agency, and compliance with 45CFR §46 is not compulsory. However, the research would be considered exempt based on the American Association for Public Opinion Research policy category 2.

Exempted projects must meet one or more of the following criteria listed in 45 CFR 46.101(b):

Category 2 - Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

Thank you again for your consideration and please let me know if there are other concerns I can address.

Sincerely,

Greg Cosgrove, MD