

## ASPE Comments on NIH/NIDA Generic Sub-study

Information collection under Generic 0925-0675:

Request to Conduct Focus Groups to Support Development of E-cigarette and Hookah Questionnaire Items under Generic Clearance for Methodological Studies in the Population Assessment of Tobacco Health (PATH)

ASPE has reviewed the sub-study request and we have the following comments:

1. Supporting Statement: Under the Efforts to Identify Duplication, it states that this sub-study will “explore regional variation in terms and practices associated with e-cigarette and hookah use.” ASPE strongly cautions NIDA against using this statement to support the case that this sub-study does not duplicate other studies. No information is provided in the sample selection to indicate that focus group participants will be selected based on region. While the online recruitment and participation for six of the eight focus groups expands the geography for participants, there is nothing in the description of the sample selection specifically stating that region is a selection factor. In addition, the sample size of 40 participants for the online focus groups (6 online focus groups x 8 participants per group) is not large enough for meaningful analysis of regional variation. OMB has recently required the withdrawal of several sub-studies submitted under generic approvals because of concerns regarding methodology. Significantly greater justification is required to substantiate such a claim. ASPE recommends removing references to using the sub-study to explore regional variation because the methodology for this sub-study is not sufficient for this purpose.
2. NIDA may want to provide a sentence or two to simply state that the agency recognizes the potential bias from the six focus groups that will be conducted online. It is often beneficial to provide OMB with a brief statement acknowledging that the use of the Internet may result in some bias while noting that this information is qualitative in nature and will not be used to generalize to a broader group.

**Please Note:** All of ASPE comments were incorporated into the Justification memo of this request. (Per Seleda Perryman NIH/PCB on behalf of the PATH study NIH/NIDA)

If you have any questions, please contact Susan Queen ([Susan.queen@hhs.gov](mailto:Susan.queen@hhs.gov)) or Rachel Hornstein ([Rachel.hornstein@hhs.gov](mailto:Rachel.hornstein@hhs.gov))