Draft: Terms of Clearance for PATH

This approval only covers the baseline wave of data collection. A full revision is necessary for the second wave. Before submitting the second wave of data collection to OMB for approval under the PRA, NIDA/FDA should report to OMB regarding the response rates associated with the baseline (screening, interview completion, and bio-specimen response, the results of their nonresponse analysis and statistical approach for addressing non-response, as well as implications for the study going forward.

NIDA and FDA will create a public use dataset from each wave's data, making it available to the public on-line within 18 months of completion of each wave. Data underlying government-funded scientific publications will be made available to the public, consistent with NIH guidelines for implementing OSTP's Public Access to the Results of Federally Funded Research.

This study is not specifically designed to provide nationally representative estimates of prevalence. As such, FDA and NIDA will always present such cross-sectional prevalence estimates in conjunction with estimates from HHS' signature nationally representative studies such as CPS-TUPS, NHIS, NATS, and NSDUH .

Results based on the bio-specimen data cannot publicly disseminated until OMB approves a change request under the PRA that explains the statistical approach to be applied to the bio-specimen data to address potential non-response bias from lower consent and cooperation rates with this aspect of the study.