

**Protection of Human Subjects and Confidentiality Issues
Related to the Fetal Alcohol Spectrum Disorders (FASD) Subcontractors
For Review with SAMHSA**

Summary

The subcontracts are not research projects, but programs that add essential FASD prevention or FASD diagnosis and intervention services to existing service delivery organizations. The data collection is required to operate the programs and to monitor the performance of the programs. Usual procedures for informed consent and confidentiality will continue to be maintained.

Action

- SAMHSA concurs that the subcontracts are not research projects and that regulation 45 CFR 46 does not apply (i.e., subcontractors do not need to obtain Institutional Review Board approvals)
- SAMHSA does not concur that the subcontracts are not research projects and IRB review is required

SAMHSA OFFICER:

Name: Patricia C. Redels
Signed: Patricia C. Redels

Dated: 9/03/08