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

The purpose of this document is to describe the FASD subcontractors' purpose and the processes they use to protect their clients and keep their information confidential. This information is provided to obtain SAMHSA's review and concurrence that these FASD subcontractors are not conducting research and are not subject to the requirements of 45 CFR 46. Of course, the protection of subcontractor clients and confidentiality are important and will be achieved by the subcontractors.

Purpose of the SAMHSA FASD Center for Excellence and the FASD Subcontractors

The purpose of the SAMHSA FASD Center for Excellence, as described in the Statement of Work, is to reduce the number of infants born prenatally exposed to alcohol, increase the functioning of persons with an FASD, and improve the quality of life for individuals and families affected by FASD. The statement of work also states that there is a need for more effective FASD services to be integrated into existing systems of care throughout the nation.

Northrop Grumman is the contractor for the SAMHSA FASD Center for Excellence and it has 23 subcontractors that are to integrate FASD prevention or FASD diagnosis and intervention services within their organizations. The 15 FASD prevention subcontractors are to integrate specific evidence-based interventions into existing service delivery organizations. There are three evidence-based interventions being integrated into these organizations. Eight subcontractors are providing screening, diagnosis, and intervention to children are integrating FASD-related procedures into there existing services.

The subcontractors are integrating FASD related-activities into existing services. The subcontracts are not intended to be separate programs. In fact, the goal is for the added FASD- related services to continue as part of these organizations after the subcontracts end. The focus is upon improving existing services to address FASD prevention or FASD diagnosis and intervention.

The subcontractors' data collection is mainly related to what is needed to conduct the FASD-related activities. The data collection at intake is related to identifying those that need intervention (e.g., asking pregnant women if they drink; screening children to see if they should be referred for an FASD diagnostic evaluation.). Followup data collection is to document that the programs were implemented and performance of the programs was achieved. Much of this data collection will continue after funding ends because it is data collection required to operate the program.

Below is a brief synopsis of the programs:

- Seven projects provide screening and brief intervention with pregnant women. This screening and brief intervention is being integrated into their existing WIC and Health Start programs.
- Six programs provide alcohol interventions and contraceptive counseling to women participating in residential and outpatient alcohol treatment.
- Two programs provide intensive case management and assistance to pregnant or post-partum women in alcohol treatment programs.
- Two projects provide FASD screening, diagnosis, and intervention with youth under the jurisdiction of the juvenile courts.
- Two projects provide FASD screening, diagnosis, and intervention with children under the supervision of dependency courts (in foster care).
- Four programs provide FASD screening, diagnosis, and intervention to young children served by mental health or developmental disabilities programs.

Subcontractors Are Not Conducting Research

The regulations described in 45 CFR 46 are applicable to research projects. The criteria for determining if a program is research is, "Is the evaluation/performance assessment part of your project designed to develop or contribute to generalizable knowledge?" http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

The subcontracts are not designed to generalizable knowledge. There are no experimental designs or control groups to allow results to be generalizable. The data collected determines who should receive services, counts people served, and assesses if these people received benefits and if the programs achieve intended results. The data collection is for program operation and monitoring purposes only.

Safeguards to Protect Clients and their Confidentiality

The subcontractors use the consent or parental consent obtained for participation in their services. Because the FASD component being added is intended to be part of their usual care, their usual consent process is used.

The data collected is to be part of their client record and be useful for clinical purposes. Hence the subcontractors protect the data collected in their client records. Some of the followup data collection will be part of the client record and some will be for monitoring purposes.

The data to be transmitted to Northrop Grumman and SAMHSA will not contain any personal identifiers as defined in HIPAA. Subcontractors will send data with unique, non-personal identifiers that meet HIPAA regulations.

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