SAMHSA Decision Tree for Determining Compliance with 45 CFR 46, Protection of Human Subjects

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101

The *SAMHSA Decision Tree for Determining Compliance with 45 CFR 46, Protection of Human Subjects* is designed to help applicants of SAMHSA-funded grants as they address the "Protection of Human Subjects Regulations" section of the funding announcement. Because of the confidential nature of the work in which many SAMHSA grantees are involved, it is important to have safeguards protecting individuals from risks associated with their participation. All applicants have to address the eight bullets under the "Confidentiality and Participant Protection" section, which appears before the "Protection of Human Subjects Regulations" section.

In most cases, applicants will not have to comply with 45 CFR 46 as described in the "Protection of Human Subjects Regulations" section because the evaluation/performance assessment component that SAMHSA requires of their application will not meet the criteria. However, applicants are able to propose a more extensive evaluation/performance assessment. Applicants need to look at the decision tree to determine if their evaluation/performance assessment meets the criteria for compliance with 45 CFR 46, Protection of Human Subjects, which entails Institutional Review Board (IRB) approval and compliance with various subparts of the regulation. The decision tree hyperlinks to the actual regulation, which can be viewed at:

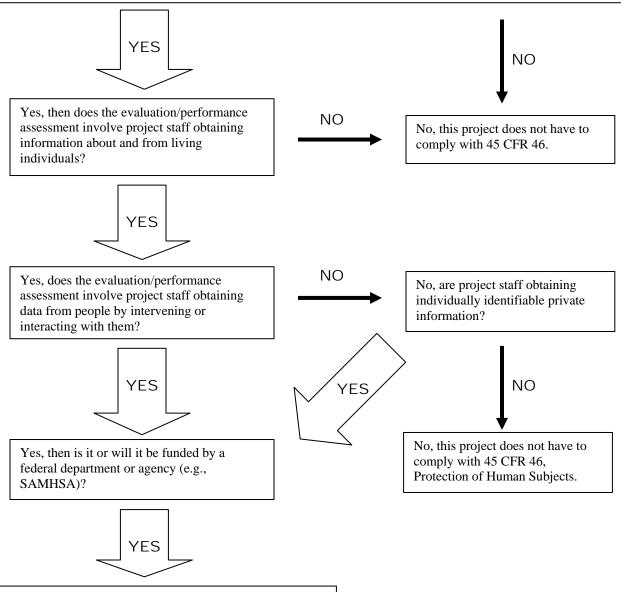http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

If applicants find that they need to comply with Human Subjects, they need to describe the process for obtaining IRB approval in the application. They do not need to obtain IRB approval before submitting an application. This decision chart is available on SAMHSA's Intranet and Internet websites. If applicants have questions, they should contact the project officer listed as a contact person in the announcement.

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http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101

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#46.102

Generalizable knowledge is new information generated from the project that has relevance beyond the population from which the knowledge was collected. The information learned can be generalized and applied to other populations and primarily benefits society as a whole instead of the pool of participants bearing the risks of participation. It should be noted that most SAMHSA programs collect Government Performance and Results Act performance measures (GPRA data). GPRA data are used to monitor the effectiveness of the programs and progress toward achieving national goals. The law emphasizes collecting, reporting, and reviewing data to hold agencies accountable for achieving results with public funds. Most SAMHSA grantees are required to collect and report GPRA data for monitoring purposes, not to create generalizable knowledge. Therefore, collecting GPRA data in order to comply with the SAMHSA requirements is not for generalizable knowledge.

YES ↓ | **NO** ↓

YES → Yes, then does the evaluation/performance assessment involve project staff obtaining information about and from living individuals?

NO → No, this project does not have to comply with 45 CFR 46.

YES ↓

Yes, does the evaluation/performance assessment involve project staff obtaining data from people by intervening or interacting with them?

NO → No, are project staff obtaining individually identifiable private information?

YES ↓ (from intervening/interacting box)

Yes, then is it or will it be funded by a federal department or agency (e.g., SAMHSA)?

YES ↙ (from identifiable private information box) → (to comply box)

NO ↓ No, this project does not have to comply with 45 CFR 46, Protection of Human Subjects.

YES ↓

Yes, then the project has to comply with 45 CFR 46, obtain IRB approval, and comply with the subparts if they are applicable. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm