

IRB Resources

While the NOMs data collection is an administrative requirement of SAMHSA, CMHS recognizes that some grantees may want to obtain IRB approval for the collection of this required data. The following document provides information that is typically required for IRB approval applications. Each grantee will need to prepare their IRB application according to the grant's guidelines. This information is meant to assist you with that process.

Note: In the sections that follow, the term “consumer” refers to a person who is actively in treatment with a CMHS funded program. You may replace “consumer” with the term “client” if you or your grant staff find it more appropriate or customary to your program; this will not change the meaning of the material.

1. Objectives, purpose, and rationale of the study

CMHS Services grantees are required to report client-level outcome measures identified for the mental health field. The authorization for the client-level outcome measures is Section 501(d)(4) of the Public Health Service Act (42 USC 290aa), which mandates the collection of statistical data on mental health programs and on the persons who receive services from them.

This data is required of all CMHS grantees in order to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its programs, which are consistent with OMB guidance.

This data collection allows CMHS to be consistent with the specific performance domains that SAMHSA is implementing, known as the National Outcomes Measures (NOMs), to assess the accountability and performance of its grant programs. In addition, the client-level outcome measures will be used as the GPRA measures for mental health treatment services funded through CMHS. This will result in a consistent set of measures across the various grant programs.

This data collection is needed to provide objective data to demonstrate SAMHSA's monitoring and achievement of its mission and goals to improve the quality and availability of treatment and prevention services for substance abuse and mental illness. It provides a level of consistency in SAMHSA-wide data collection and reporting of performance measures across all of its Centers and programs.

This particular activity promotes the use of consistent measures among CMHS programs, grantees and contractors funded through the Programs of Regional and National Significance (PRNS) and the Children's Mental Health Initiative (CMHI) budget lines.

2. Description of the study population

All grantees funded through the PRNS and CMHI within its discretionary program portfolio that provide direct clinical services to mental health consumers are required to submit client-level outcome data. Data must be collected from all consumers that receive grant-funded services.

3. Data collection – methods, frequency, and details

A consistent approach to data collection is used for all respondents; client-level data is collected at baseline with a periodic reassessment being conducted as long as the consumer remains in treatment. In addition to questions asked of consumers related to the NOMs domains, programs are required to report information on consumer demographics at baseline and abstract information from consumer records on the services received.

Information technology is used to reduce program respondent burden. The CMHS electronic system, referred to as the **TRAC (Transformation Accountability) System**, provides a data repository service that accommodates the specific client-level outcome measures. This web-based repository service includes methods for receiving the data, data quality checks, storage, and data presentation in reports by individual performance measure or grouped with other performance measures. This web-based system is intended to allow for easy data entry and access to reports for grantees that are required to submit the client-level outcome data for consumers.

The TRAC web system is a secure environment that requires a unique password to access the data entry and reports function. Grantees are only allowed to see data and reports from their grant. The architecture for the TRAC system has passed Certification and Accreditation (C&A) by SAMHSA. The C&A involves an independent review of the system security by a SAMHSA information technology (IT) contractor and validates the security of the IT infrastructure as well as the operational procedures used, including backup and recovery.

Mental health programs typically collect data at admission and then conduct periodic reassessments of consumers while the individual remains in treatment. When feasible, mental health providers also often conduct an assessment when the consumer is discharged. The data collected for the CMHS NOMs parallels this model.

Information and data collection procedures are the responsibility of individual grantees and may vary by type of program. Typically, baseline information is obtained by intake workers and/or counselors. For consumers still in treatment 6 months later, the information is most likely collected by the counselor as part of the case review. This does not interfere with ongoing program operations.

Some programs collect their consumer information using paper and pencil methods. Programs submit their data electronically via a web-based data entry process either

directly or by first collecting information on paper and then entering into the web-based system.

Required data collection points are:

BASELINE: For consumers new to the grant, baseline data is collected at the time of enrollment and each time a new episode of care is initiated. For consumers already enrolled in the program at the start of the TRAC project, administrative baseline data should be collected within 30 days. The timing of any subsequent data collection point(s) is anchored to the baseline point.

PERIODIC REASSESSMENT: CMHS requires collection of client-level outcome measure data every six months while the consumer is receiving CMHS-funded services. Ongoing periodic status review is viewed as consistent with good clinical practice.

DISCHARGE: Grantees must provide information on the type of discharge on all consumers who are discharged. When the discharge is a planned event, the consumer is asked the questions on the client-level outcome measures data collection tool. The one exception to this requirement is when a consumer had responded to these same questions within the past 30 days as part of a Reassessment interview. If a discharge interview cannot be conducted, administrative data is submitted.

Data for the annual GPRA plan/report are needed by SAMHSA on an ongoing basis.

4. Data collection tools

To facilitate SAMHSA-wide reporting, the agency has identified ten domains of particular interest for accountability and performance monitoring. These domains are:

1. Access/Capacity
 2. Functioning
 3. Stability in Housing
 4. Education and Employment
 5. Crime and Criminal Justice
 6. Perception of Care
 7. Social Connectedness
 8. Retention
 9. Cost-Effectiveness
 10. Evidence-Based Practices
- CMHS has identified client-level measures for eight of ten domain elements. The measurement strategy for cost-effectiveness and evidence-based practices domains is under development. Specific measures in each of the remaining eight domains have been identified. An instrument has been developed to collect these measures for both adult and child programs.

A paper version of the Consumer NOMs Tools can be downloaded from the TRAC website by visiting <https://www.cmhs-gpra.samhsa.gov>.

5. Management of information and confidentiality

Levels of access to the web based system is defined for users based on their authority and responsibilities regarding the data and reports. Access to the data and reports is limited to those individuals with a username and password.

Electronic submission of the data promotes enhanced data quality. With built in data quality checks, and easy access to data outputs and reports, users of the data can feel confident about the quality of the output. The electronic submission also promotes immediate access to the dataset. Once the data are put into the web-based system, it will be available for access, review, and reporting by all those with access to the system from Center staff to the grantee staff.

This CMHS data collection process involves gathering confidential information. Program respondents are expected to meet the requirements of the HIPAA and its associated Privacy Rule that sets the standards for the use and disclosure of an individual's health/mental health information. Since the data reported for each consumer is provided to the CMHS contractor only by number and not by name, the data cannot be directly linked to a specific person. The grantee providing the data maintains the link between the identifier and the name of the consumer. The CMHS contractor does not have access to existing consumer clinical records, which are under the control of the respondent programs. Neither the CMHS contractor nor CMHS can link individual consumers to the data reported by the respondent programs.

Data is available to CMHS staff and grantees through a series of reports available through the web-based TRAC system. Roles determine user access. Individual grantees are only allowed detailed access to data from their grant. They have access to summary information across all grants in their program. CMHS staff access is determined by their span of responsibility.

The data for those consumers with both baseline and periodic reassessment data are matched using a unique encrypted consumer identifier developed by the grantee. Grantees are clearly instructed not to use identifying information (i.e., social security number) as the consumer identifier.

6. HIV testing

No HIV testing is conducted for the purpose of this data collection activity.

7. Potential risks to study population

Most of the data that is submitted by each grantee is data that most of the grants are already routinely collecting. This primarily includes data on consumer demographics, mental health condition/illness and treatment history, services received, and consumer outcomes. These issues are essential to the service/treatment context. Risks to the consumers providing information for this data collection activity are minimal.

8. Potential benefits to be gained by the individual subjects as well as, the benefits which may accrue to society in general as a result of the planned work

This data collection activity provides an opportunity to the consumers of mental health services to provide feedback on the quality of services received by them and the impact it made on their lives. At a larger scale, it provides information to the grantees, to CMHS, and to SAMHSA regarding access and quality of care received by consumers of mental health services.

SAMHSA's legislative mandate is to increase access to high quality substance abuse and mental health prevention and treatment services and to improve outcomes. Its mission is to improve the quality and availability of treatment and prevention services for substance abuse and mental illness. To support this mission, the Agency's overarching goals are:

- 1) Accountability—Establish systems to ensure program performance measurement and accountability
- 2) Capacity—Build, maintain, and enhance mental health and substance abuse infrastructure and capacity
- 3) Effectiveness—Enable all communities and providers to deliver effective services

Each of these goals complements SAMHSA's legislative mandate. All of SAMHSA's programs and activities are geared toward the achievement of these goals and GPRA performance monitoring is a collaborative and cooperative aspect of this process. This NOMs data is collected for the GPRA reporting purposes to support CMHS' goals of fundamentally transforming mental health services in support of SAMHSA's mission for improving access and quality of all services.

9. Informed consent

TRAC does not require informed consent. The informed consent procedures are left to the discretion of each grantee. Grant projects use informed consent forms as required and as viewed appropriate by their individual organizations.