

### ***Purpose of the Study***

The Early Psychosis Intervention Network (EPINET) National Data Coordinating Center (ENDCC), operated by Westat, Inc. on behalf of the National Institute of Mental Health (NIMH), will lead efforts to (a) harmonize early psychosis common data elements, standard measures, and uniform data collection procedures across multiple early psychosis Coordinated Specialty Care (CSC) clinics within regional networks; (b) build informatics infrastructure and pipelines necessary to gather and store de-identified, patient-level data collected across all regional clinics; (c) develop data analysis, presentation, and reporting tools to facilitate timely quality improvement and program evaluation efforts across regional networks; (d) identify innovative CSC assessment, intervention, and quality improvement practices for broad dissemination; and (e) make national CSC data available for practice-based research to improve early identification, diagnosis, clinical assessment, intervention effectiveness, service delivery and health outcomes in early psychosis. The ENDCC will combine regional datasets into a national repository of early psychosis common data elements, clinical measures, assessment and intervention strategies, and de-identified person-level data from patients receiving CSC services. Data assembled by the ENDCC will facilitate large-scale, practice-based research to improve early identification, diagnosis, clinical assessment, intervention effectiveness, and health outcomes in clinics offering evidence-based care to persons in the early stages of psychotic illness (“EPINET research”).

In addition to coordinating regional EPINET activities; curating standard measures, common data elements, and clinical assessment strategies; optimizing health informatics within and across regional hubs; offering data analysis, presentation, and reporting tools; supporting practice-based research; and disseminating CSC resources to clinical practices and scientific communities, the ENDCC is also responsible for depositing the data collected from EPINET Hubs and Sites (“EPINET Partners”), including patient-level data, in the NIMH Data Archive (<https://data-archive.nimh.nih.gov/>) every 6 months.

### ***Scope and Use of the Data***

NIMH requires that Westat and EPINET Partners (EPINET Hubs and EPINET CSC sites) comply with NIMH Data Archive Standards (<https://nda.nih.gov/contribute/harmonization-standards.html>) and standard operating procedures (<https://nda.nih.gov/about/standard-operating-procedures.html>).

EPINET CSC sites are the locations of patient care and primary data collection. Each EPINET CSC site will conduct their EPINET data collection in accordance with their respective EPINET Hub protocol, EPINET policies, and NIMH requirements.

EPINET Hubs will collect primary research data from their associated CSC sites into a single data set (“Hub Data”). EPINET Hubs will de-identify and submit their respective Hub Data to Westat for harmonization and submission to the NIMH Data Archive on a routine basis as agreed upon between Westat and the EPINET Hub. EPINET Hubs may also engage in EPINET research.

As envisioned by NIMH, Westat, for purposes of operating the ENDCC, will:

- Perform data harmonization, imputation, aggregation, and transformation on the submitted data
- Combine submitted data with other data sets
- Create summary-level reports for consumption by EPINET members and other stakeholders for operational and EPINET management needs
- Host patient-level data for the EPINET analytic platform
- Share the collected data or a subset thereof with selected EPINET partners
- Produce analytics and reports based on the submitted data
- Promote EPINET-wide result dissemination

The ENDCC will not conduct single-site/single-origin analysis for non-operational purposes (e.g., original research) unless requested by and in collaboration with the original data owners at the EPINET Hub or CSC site level, and will honor data-ownership and incorporate original data owners in any publications or research efforts.