

**American Psychiatric Institute for Research and Education
Practice Research Network
Data Use Agreement Policy**

I. Definition and Goals

A data use agreement (DUA) is a formal agreement between the American Psychiatric Institute for Research and Education (APIRE) and qualified researchers outside of APIRE under which APIRE makes available to those researchers data from the APIRE Psychiatric Practice Research Network (PRN) for specified scientific purposes. APIRE believes that data use agreements provide a flexible and efficient mechanism (i) for making PRN data available to the research community, and (ii) for helping to support both collaborative relationships and professional development of PRN staff and those involved in collecting and analyzing PRN data.

This Policy statement sets out the types of DUAs that are available, the process for entering into a DUA, and the terms and conditions that pertain to the use of PRN data. This policy replaces previous APIRE policies on DUAs. It should be noted that if there is any conflict between any statement set out in this Policy and any provision in an executed DUA, the provision in the executed DUA shall govern.

II. Categories of Research Activities

Generally, PRN data are available for the following research activities: (1) analyses conducted under the leadership of internal PRN or APIRE staff; (2) analyses conducted under the leadership of an external researcher working in collaboration with PRN or APIRE staff; (3) analyses conducted by external researchers independent of PRN or APIRE staff; and (4) analyses conducted by graduate-level students for educational purposes under the supervision of a course instructor, independent of PRN or APIRE staff.

- A. *Internal data analysis* is research on PRN data conducted with a PRN or APIRE staff member serving as the lead, with the assistance of other staff. Internal data analysis typically reflects research areas in which the PRN intends to focus its research activities or pursue external funding, and does not require a formal DUA.
- B. *Collaborative data analysis* is research on PRN data conducted under the leadership of either an APIRE researcher in collaboration with external investigators, or an external investigator in collaboration with PRN or APIRE staff. Collaborative research addresses issues that are of significant interest to the PRN so that PRN staff time is devoted to these efforts. Collaborative data analysis also typically

reflects research areas in which the PRN intends to focus its research activities or pursue external funding. The lead investigator is responsible for preparing and submitting an application to use PRN data. Once the application is approved, all researchers, whether internal or external, are required to sign a [Collaborative Data Use Agreement](#).

- C. *External data analysis* is research on PRN data conducted under the leadership of an external investigator, independent of PRN or APIRE staff. Commitment of PRN staff and resources to these efforts is minimal; PRN staff do not serve as co-investigators. Proposals for external data analysis are generally approved on topics that are not of high priority to the PRN. The PRN is cited as the source of the data. APIRE may provide a users' manual similar to those for other public use data sets to help facilitate use of the data. Applications for this type of research activity are submitted by the external researcher. Once the application is approved, all key members of the external researcher's team are required to sign an [External Data Use Agreement](#).
- D. *Data analysis for educational purposes* is research conducted by graduate-level students as part of a course curriculum for instructional purposes in a university setting, under the supervision of the course instructor, and independent of PRN or APIRE staff. Proposals for educational analyses typically do not address research issues of significant interest to the PRN. Applications for this type of activity are submitted by the primary course instructor. Once the application is approved, the primary course instructor and all key members of the course team are required to sign an Educational Data Use Agreement.

III. Application for Data Use Agreement

Subject to certain exceptions, investigators who wish to use PRN data must first submit a written proposal that includes the title, purpose, specific aims, potential impact, and description of the proposed analyses. The application should also include proposed co-investigators and a timeline for completion of the work. The information to be provided is described in detail in [Components of a PRN DUA Application](#).

IV. Roles of Individuals Involved in the Development and Oversight of DUAs

The PRN Director provides advice and feedback on plans for initial data use agreement proposals. PRN senior staff may advise or play an active role in aspects of certain studies as appropriate. PRN staff are minimally involved in studies covered by External DUAs. In the case of data analyses covered by a Collaborative DUA, development and subsequent implementation of the DUA must involve a lead or principal investigator and a senior PRN researcher. Under Collaborative DUAs, PRN senior staff may play a lead or active role in the study design, planning,

implementation, analyses, and reporting of findings. The APIRE Associate Director for Management is responsible for administrative oversight of DUAs.

V. Authorship

The lead investigator is typically the lead author on publications. All authors are expected to review relevant literature, contribute to the manuscript, and meet standard authorship requirements. The roles of the lead and co-authors are described in more detail in the [PRN Policies and Procedures for Scientific Communications](#), incorporated here by reference.

VI. Funding

Investigators may request funds from private foundations or public agencies to conduct analyses of PRN data under an approved PRN DUA. Any request for funding must be based on a DUA that is currently approved (see section VIII. Review and Approval Process). The proposal to request funding, clearly stating the source of funding, must be approved by the PRN Director or one or more APIRE senior research staff.

VII. Other Terms and Conditions

All data analyses must be performed using a software package that can adequately adjust for the PRN sampling design and the study weights (e.g., SUDAAN or STATA). Please refer to [Components of a PRN DUA Application](#) for additional details.

APIRE reserves the right to terminate the data use agreement and may re-assign the project to other PRN staff or collaborators as appropriate.

VIII. Review and Approval Process

All applications for DUAs must be reviewed and approved by at least two APIRE senior research staff. A decision regarding an application for a DUA will be made as expeditiously as possible.

Review of applications for Collaborative DUAs will include the following criteria: 1) scientific merit; 2) clinical and public health significance; 3) feasibility, including the appropriateness of the data for the proposed analyses and the capability of the proposed DUA study team to carry out the proposed analyses; and 4) the extent to which the topic is consistent with the PRN's mission and research agenda.

DUAs which address research areas that are not consistent with the PRN mission and research agenda will generally be designated as applications for External Data Use

Agreements. Review of applications for an External DUA will include the following criteria: 1) scientific merit; and 2) feasibility, including the appropriateness of the data for the proposed analyses and the capability of the proposed DUA study team to carry out the analyses.

Review of applications for an Educational DUA will include the following criteria: 1) educational merit for research training purposes; 2) feasibility, including the appropriateness of the data for the proposed instructional purpose and the capability of the instructional team to supervise the appropriate use of the data.

All scientific communications such as articles, reports or meeting abstracts involving data made available under Collaborative DUAs must be reviewed and approved in writing or by e-mail by the PRN Director or one or more APIRE senior research staff prior to submission. Scientific communications emanating from External or Educational DUAs do not require review and approval prior to submission. However, PRN strongly encourages External and Educational DUA users to acknowledge the PRN as the data source in all publications and presentations. All lead authors for External and Educational DUAs are expected to keep the PRN Director apprised of plans and progress and provide the PRN Director with electronic copies of all published manuscripts and other scientific communications in a timely fashion.

APIRE reserves the right to modify any policy set forth herein at any time.