

HOW TO PREPARE AND SUBMIT A DATASET FOR THE PACT/R ARCHIVE

The PACT/R Archive team will work with investigators to help ensure that datasets are submitted in a manner that is ready for inclusion in the Archive and harmonization across studies.

Contact the PACT/R Archive team at childtraumadata@email.chop.edu with any questions.

Basic steps to prepare a dataset for submission

1. Complete the Agreement to Submit a Dataset with information on data ownership, ethics approval, and data de-identification / anonymization.
 - Form available via REDCap (get link from PACT/R team)
 - This form requires (e-)signature from the investigator who has the authority to submit the dataset.

2. Complete the PACT/R Dataset Submission Form with information regarding study design, sampling / study participants, and the nature and timing of study measures. It is especially important to provide information on any modifications to standard research measures.
 - Form available via REDCap (get link from PACT/R team)
 - Complete Measure Modification Form if applicable. Upload to ShareFile (see below).

3. Remove any identifiable information from dataset(s) to be submitted.
 - See information below on de-identifying / anonymizing datasets.

4. Prepare an SPSS dataset with item-level data in a format compatible with Archive standards.
 - See information below on required core data elements.
 - Refer to “PACT/R Variable Naming Conventions” document for variable names, labels, and formats
 - Non-SPSS datasets may be submitted with special permission. Contact the PACT/R team.

5. Create a data dictionary for your prepared dataset linking all variable names to specific measures. Upload to ShareFile (see below).

6. Go to secure ShareFile folder (get link from PACT/R team).
 - Upload prepared dataset
 - Upload other documents related to your dataset:
 - data dictionary for this dataset
 - ethics approval document for the original study
 - study abstract
 - consent/assent form(s) from study
 - copies of measures - especially any that were modified for this study from a standard measure
 - Measure Modification Form

Core data elements that must be included for submission to the PACT/R Archive

At a minimum, each dataset should include, about each participant (case):

- Unique CaseID – which must be unrelated to any identifying information
- Calendar year in which first assessment data point was collected
- Demographic data: Age (in years) at time of trauma, Sex, Race and/or ethnicity
- Type of potentially traumatic event experienced
- Item-level data regarding at least one potential predictor / risk or protective factor assessed within 6 months of the event (note: could be pre-existing factor)
 - Time (in days) from event to predictor assessment (for each participant)
- Item-level (i.e. symptom-level) data regarding the presence and severity of posttraumatic stress (or other related) outcomes assessed 1 month or more later (or at least 1 month post-event)
 - Time (in days) from event to outcomes assessment (for each participant)

Additional data points are highly desirable, and may include:

- Data about the potentially traumatic event: More about the nature of event, severity of exposure
- Item-level data regarding additional risk or protective factors assessed at multiple time points
- Item-level data regarding the presence and severity of relevant outcomes other than posttraumatic stress
- Data regarding other relevant factors that may serve as covariates in predicting PTSD risk following acute trauma exposure

De-identifying / anonymizing datasets before submission

All datasets must be de-identified / anonymized by the investigator before submission to the PACT/R Data Archive. Cases in the dataset should be identified via a unique Case ID variable that does not contain any information as to the individual participant's identity.

To ensure that datasets are anonymous / de-identified, the following elements should NOT be included in datasets submitted to the PACT/R Data Archive:

- Names
- Geographic subdivisions, smaller than a state or province
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers or other national insurance / national identity numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers
- Device identifiers and serial numbers
- Web URLs
- Internet protocol (IP) address numbers
- Biometric indicators, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code