

## The National Child Traumatic Stress Network (NCTSN) - Data Core

Amendment to IRB #3254-02-10R1BP: Consideration of the NCTSN Core Data Set as a  
Quality Improvement Initiative; Request for Exemption

Submitted January 20, 2004

### List of Assurances Needed:

1. Data Use Agreement (DUA) initiated by DCRI and signed by each participating Center and Duke University (limited data set recipient) with copies retained at DCRI.
2. “Crosswalk” or client log (a template form) sent by DCRI to each participating Center. Center staff will fill this out and it will be retained at the Center in a safe and secure area. DCRI is not allowed to view this log nor will it have possession of it.
3. Documentation from participating Centers stating that, when sending the limited data set to DCRI, no client information (i.e., no information containing direct client identifiers), has been transferred, nor will it be. Copies of this documentation will be retained at DCRI.
4. Documentation from DCRI that, when receiving the limited data set from participating Centers, no client information (i.e., no information containing direct client identifiers) has been received, nor will it be requested. DCRI will also document that all data received will be de-identified and anonymized upon receipt.
5. Documentation from each participating Center’s IRB stating whether or not this initiative was viewed as a Quality Improvement Initiative or Research. Copies of this documentation will be retained at DCRI and sent to the IRB coordinator for this study (Jo Llewellyn).

**Note:** All documentation will be collected, tracked and maintained by the Project Leadership staff at DCRI and will be retained in the Regulatory Files for the Project.