



To: NCTSN Members/Centers
From: Data Core Manager: Patrick Loebbs
RE: Web-based Collection of NCTSN Core Data - Spring 2004
Date: March 4, 2004

Network Members:

I am very pleased to inform you that we are about to enter an important phase of data collection by launching a web-based software tool (called "InForm") for collection of Core Data across the NCTSN by early spring 2004. We are working diligently to be ready to start using the Core Data Set and its web-based entry forms by then. In preparation for this launch and before the NCCTS can receive data from your center, we need what are commonly referred to as "assurances" (or regulatory documentation) in place at your center and at the Duke Clinical Research Institute (DCRI). The assurances, detailed in the enclosed assurances document, meet the NCCTS requirements as determined by the Duke University Health System IRB, who reviewed this data collection activity as a Quality Improvement initiative. There may be additional assurances your IRB requests from your center; you will know this after you submit your regulatory documents for review. For example, the Duke IRB requires that we receive written notification from your IRB regarding whether your Center views this data collection activity as a QI initiative or as research. The rest of the "assurances" you have to provide are listed in the document.

In an effort to help you with your submission process we have provided you with copies of all of the documents that were submitted to the Duke IRB. Hopefully, these documents will assist you in your submission process and save you time. As you know, you should allow ample time and effort for the submission process as many IRB's only meet at scheduled times for review of documents.

If you have any questions or concerns please contact **Patrick Loebbs, Data Core Manager, at (919) 668-7818** or loebbs001@dcri.duke.edu.

Here is the list of the documents/resources on the NCTSN website:

- **Program Summary** – This document could be used as a guide or template for use while you prepare your submission documents and was used to briefly describe the network, the data collection effort and the associated data management procedures and processes.
- **Request for Exemption** - This document is also available to you as a potential guide for use during the preparation of your submission documents and was used to position this data collection effort as a Quality Improvement initiative.
- **List of Assurances** – This document lists all of the "assurances" that are required by the Duke IRB to comply with regulatory guidance's pertaining to the Common Rule and as well as the Health Insurance Portability and Accountability Act (HIPAA). DCRI needs the following before we can receive data from your center:

1. A letter from your IRB acknowledging this data collection effort as either a Quality Improvement initiative or research
2. A letter from your Center stating that, when sending the limited data set to DCRI, you will not send any information containing direct client identifiers
3. A signed Data Use Agreement

Items 1 and 2 should be sent to this address:

Duke Clinical Research Institute
2400 Pratt St., Rm. 0311 Terrace Level
Durham, NC 27705
ATTN: Liz Everett; Child Trauma
Ph: (919) 668-8182; Cubicle 4564
evere017@dcri.duke.edu

The Data Use Agreement (Item 3) process will be coordinated by **Tiffany Yancey** at DCRI (email link and phone number included). Tiffany is in the Contracts Department at DCRI and will serve as your main contact for all DUA requests and questions. Submit your request for a DUA through Tiffany's email address listed on the web and the process will commence. Tiffany will answer any and all questions you have and is tracking DUA's for the Data Core.

ATTN: Tiffany Yancey, Child Trauma
Ph: (919) 668-8287
yance001@dcri.duke.edu

- **Crosswalk and Instructions** – The Crosswalk is an example/template for you to use/revise in any way that allows for a means of recording client identifiable information (not allowed to be seen by DCRI) along with a link code (i.e., a number that InForm will generate automatically for you when you enter a client) that will connect crosswalk information to the Core Data Set. The Crosswalk should remain in a secure location and should not be made available to any NCCTS staff.
- **Frequently Asked Questions (HIPAA and QI VS R)** – These FAQ's were added to help address major issues regarding HIPAA and the major differences between Quality Improvement and Research.
- **Federal Wide Assurance (FWA)** – the DHHS requires that each institution "engaged" in human subject's research apply for, and receive a FWA number. This assures that your center will protect human subjects and private health information. If your center does not already have an FWA, you can go on-line (<http://ohrp.osophs.dhhs.gov/irbasur.htm>) and fill out the necessary paperwork (3 page form) electronically. If you have an SPA (Single Project Assurance) under the current grant, then you are covered until the grant expires. The OHRP website is very helpful if you have questions or concerns about this process.