

NCTSN

The National Child
Traumatic Stress Network

Regulatory Documentation Guidelines

When **Duke University Health System (DUHS) IRB** serves as the IRB of Record for Centers or Affiliates, provide the following completed/executed documents to Duke Clinical Research Institute contact for submission to the DUHS IRB:

Document Group 1: Handled by Duke Clinical Research Institute (DCRI) Contracts Group (Amelia Smith, amelia.smith@duke.edu)

1. Data Use Agreement (Amelia will supply the DCRI Project Leader (PL) with a copy to send to the site)

Document Group 2: Handled by NCTSN Centers or Affiliates and the DCRI PL at the National Center for Child Traumatic Stress (NCCTS)

2. Site Consent form in Duke consent template (using standard Duke language and standard Duke HIPAA language)

3. Personal Health Information Letter (DCRI PL has template to provide to sites). This letter states that centers will not send any of the HIPAA health identifiers to NCTSN, or to any of its member sites including DCRI. The de-identification process helps protect personal data identifiers from being shared.

4. Certificate of Insurance (from the centers Administrative or Legal Department showing insurance/liability coverage at the institute level and usually includes coverage for individual claims (Limits of Liability) and the aggregate.

5. Federal Wide Assurance (FWA) Application[†] used for filing for an FWA number from the Office of Human Research Protections (OHRP), a division of the Department of Health and Human Services (DHHS). The application can be pre-filled by Bart Evans and then sent to each center for signature. The OHRP website is: http://www.hhs.gov/ohrp/assurances/assurances_index.html

6. In addition to the completed FWA application approved by OHRP, the DUHS IRB requires that the investigator execute an IRB Authorization Agreement[‡] (IIA). This document will be provided by the DUHS IRB via the DCRI PL.

7. List of all center personnel working on the NCTSI program (everyone at the center who is in direct contact with client-level data has to be trained on Good Clinical Practice (GCP) basics, including the protection of human subjects in research)

8. Documentation or Certificates of Human Subjects Protection Training from the Clinical Trial Network Best Practices (CTN BP) website, CITI modules for each person included on the list above (www.citiprogram.org).

Document Group 3: Generated by DUHS IRB

9. IRB Approval Letter (DCRI PL will send to the center for filing)

* Copies of all of the above will be collected by:

Bart Evans, B.S.
Project Leader, Data and Evaluation Program
bart.evans@duke.edu
PHO: 919.668.8981
Cell: 919.724.0703
FAX: 919.668.7005
2400 Pratt Street
Room 0311 Terrace Level
Durham, NC 27705

And

Julie Gardner, B.S.
Clinical Trial Assistant, Data and Evaluation Program
julie.gardner@duke.edu
PHO: 919.668.8808
FAX: 919.668.7106
2400 Pratt Street
Room 0311 Terrace Level
Durham, NC 27705

† NOTE: Please keep in mind that the FWA Signatory Official must be a high level institutional official who has the legal authority to represent the institution named within the FWA. This person is usually the President, Chancellor, Chief Executive Officer, Chief Operating Officer, etc. The intent in requiring that the Signatory Official be a high level individual is two-fold. First, OHRP encourages institutions to promote a culture of conscience for the ethical conduct of human subject's research at the highest level within the institution. Second, the Signatory Official should be at a level of responsibility that would allow necessary administrative or legal action should that be required, as well as to minimize the potential for conflict of interest. Therefore, the Signatory Official cannot be the chair or a member of the IRB reviewing research to be conducted. Ideally, the Signatory Official should not be integrally involved in the research being conducted and should not be involved in the solicitation of research funds for the institution.

‡NOTE: The IRB Authorization agreement can not be completed until an FWA number has been granted by OHRP, as the document requires it for processing.

**When Duke University Health System IRB *Does Not* Serve as the IRB of
Record for NCTSN Centers or Affiliates
(i.e. center/affiliate utilizes their local IRB or a central IRB)
Submit the following documents to the DUHS IRB**

When a **local NCTSN IRB** serves as the IRB of Record for Centers or Affiliates, provide the following completed/executed documents to Duke Clinical Research Institute contact for submission to the DUHS IRB:

Document Group 1: Handled by Duke Clinical Research Institute (DCRI) Contracts Group (Amelia Smith, amelia.smith@duke.edu)

1. Data Use Agreement (Amelia will supply the DCRI Project Leader (PL) with a copy to send to the site)

Document Group 2: Handled by NCTSN Centers or Affiliates and Bart Evans (DCRI PL) at the National Center for Child Traumatic Stress (NCCTS)

2. Local IRB Approval Letter

3. Personal Health Information Letter (DCRI PL has template to provide to sites). This letter states that centers will not send any of the HIPAA health identifiers to NCTSN, or to any of its member sites including DCRI. The de-identification process helps protect personal data identifiers from being shared.

4. FWA Number for the NCTSN Center

Document Group 3: Generated by DUHS IRB

5. IRB Approval Letter (DCRI PL will send to the center for filing)

* Copies of all of the above will be collected by:

Bart Evans, B.S.
Project Leader, Data and Evaluation Program
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