

## PROPOSAL FOR ANALYSIS OF UDC DATA

*Before beginning, please note:*

- *The UDC data set contains persons of both genders and all ages; persons with hemophilia and von Willebrand disease, as well as some with other clotting factor deficiencies. Please be specific when stating your population of interest.*
- *Please review the data collection forms to make sure your proposed data elements exist, and that the data collected are appropriate to your analysis. Copies of the data forms can be requested from Meredith Oakley at [moakley@cdc.gov](mailto:moakley@cdc.gov) or (404) 498-6729.*
- *Complete all items on this proposal.*

- **Date**

- **Title**

- **Initiating Investigator**

Name:

Institution:

Address:

Phone #:

Fax #:

E-Mail Address:

- **Co-Investigators and Collaborations**

- **Identified member.**

Is the initiating investigator an identified member of an HTC UDC project and listed with the IRB monitoring the UDC project? Yes/No

If Not, this initiating investigator must sign and return Prevention of Bleeding Disorder Complications through Regional Hemophilia Treatment Centers/UDC Confidentiality and Data Use Agreement, Appendix E , prior to receipt of data. The initiating investigator will be bound by the agreement.

- **I understand** that a working group will be assigned to assist me in the development of this concept. I agree to work with this group including participating on conference calls about my project and providing regular updates about the progress.

Signature: \_\_\_\_\_

- **Proposed Audience/Journal**

- **Background and Rationale** (Include any preliminary data)

- **Specific Aims of the Study**

- **Study Plan**

1. Hypothesis
2. Overall design (i.e., cohort study, case-control, if known)
3. Study population (inclusion/exclusion criteria)
4. Study outcomes or end points
5. Study variables
6. Statistical considerations (sample size, power calculations, special analyses) and analysis plan (table shells, model equations, test statistics)
7. Staged timeline for completion of project

- **Specimen Requirements**

If this project calls for the testing of stored UDC serum specimens, complete Appendix A of this template.

- **Data Requirements**

1. UDC data elements that will be used, including the form on which they are collected, the item number, and the text of the question. **Example:**

<b>Form Name</b>	<b>Item #</b>	<b>Text of Question</b>
Annual Visit	10	Highest inhibitor titer since and including the last annual visit
Annual Visit	14	Home infusion

2. For variables which must be calculated or transformed (ex. - BMI, age, decrease in range of motion), explain how they will be calculated or transformed.
3. Additional data not in UDC that will be required.
4. If additional data are needed, how do you propose to obtain it?

- **Data presentation**

Include a format such as a table or figure that demonstrates how you anticipate the final data will be presented. For example if you wish to compare the annual number of joint bleeds and soft tissue hematomas in babies with hemophilia A broken down by severity your table might look like the following:

	Median # joint bleeds/yr	Median # soft tissue hematomas/yr
Severe hemophilia A		
Moderate hemophilia A		
Mild hemophilia A		

(This is only an example. Depending upon your analysis, your data presentation may be quite different.)

- **Resources**

1. What components can the investigator accomplish (i.e., data collection, analysis)?
2. What components would require assistance from CDC?
3. Will funding be available to the investigator for work on this study (e.g., K12 Career Development Award, grant)?

*Please address any questions and submit proposals via email to Meredith Oakley at moakley@cdc.gov. You will receive acknowledgment of your submission within one week.*

## Proposal for Analysis of UDC Data Appendix A. Specimen Requirements

1. Explain the significance of these results and this analysis for the bleeding disorders community.
2. List and define the characteristics of the specimens to be tested.
3. Are there special specimen quality requirements (serum vs. plasma; storage conditions; processing interval; etc.)? If yes, please contact Meredith Oakley to discuss.
4. What test will be performed?
5. What is the testing algorithm?
6. What volume of specimen is required?
7. Is the test FDA approved?
8. What lab will perform the test?
9. Is the lab that performs the test CLIA approved to perform this test? If so, what is its CLIA number?
10. Who will pay for the test?
11. Describe the context in which results of this test are clinically relevant.
12. Are HTC practitioners likely to be familiar with this test and its interpretation and use? If not, what information needs to be provided to them about the test, its interpretation and use?
13. If HTC practitioners have questions about this test and/or its results, who can they contact for more information?
14. What information will be reported on the results report? Please attach a copy of the results report that will be provided to the HTCs.
15. Who will report results back to the HTC?
16. By what means will results be reported?
17. Is the reporting agency capable of using the CDC ID to report these results back to the HTC?