



Region 4 Genetics Collaborative
 Advisory Group Telemeeting Agenda
 January 29, 2008 *** 1:30 p.m. EST/12:30 p.m. CST

- | | | |
|------|--|------------------------|
| I. | Welcome and Introductions | Cameron/Advisory Group |
| II. | Outlook and Ruminations from around the Nation (Program Director's Report) | Cameron |
| III. | Vision and Mission (Handout 1) | |
| III. | Quarterly Reports and Project Progress | |
| | A. Administrative | Cameron |
| | 1. Advisory Group Member changes | |
| | 2. Follow up on HRSA site visit to provide input into program guidance | |
| | 3. Project Summary and Re-application for grant year 2 due February 2008 | |
| | 4. Carry Over | |
| | 5. HRSA Performance Review | |
| | 6. National expectations | |
| | a. Baseline Data Collection | Cameron |
| | b. National workgroups | |
| | 1. Data Collection | Berry |
| | 2. Transition | |
| | 3. Evaluation | Cameron |
| | 4. Emergency Preparedness | |
| | 5. NCC Planning | Bach |
| | 6. National Website | Cameron |
| | 7. Sharing state blood spot data | Cameron |
| | 8. Telemedicine | |
| | c. Conference calls and onsite meetings | |
| | d. On-demand reporting/articles | |
| | e. Collaboration with other Regions | |
| | 1. Medical Foods and Formulas Survey | |
| | 7. Data Sharing & Authorship (Handout 2) | |
| | B. Base Funding | Cameron/Hiner |
| | 1. Recruitment for Workgroups | |
| | 2. www.region4genetics.org | |
| | C. Priority 1 – NBS by MS/MS | Rinaldo |
| | D. Priority 2 – IBEM-IS | Berry/Anderson |
| III. | Regional Meeting | Cameron/Bach |
| | A. September 16 & 17 | |
| | B. Format | |
| | C. Participants | |
| IV. | Adjourn | |



Draft
Region 4 Genetics Collaborative

Vision

All newborns will receive state-of-the-art newborn screening and follow-up; children and youth with heritable disorders will have access to genetic expertise and coordinated care in the context of a medical home.

Mission

The mission of the Region 4 Genetics Collaborative is to:

- 1) Provide a forum for families, public health, and clinical providers to share best practices and models for improving newborn screening, follow-up and genetic care coordination
- 2) Support state public health agencies in improving infrastructure for genetic service delivery to children with heritable disorders
- 3) Facilitate data collection and analysis to guide decision-making regarding screening cut-offs, diagnosis and long term treatment of heritable disorders
- 4) Increase access to information about newborn screening and genetic resources, services and family support systems
- 5) Link Region 4 states with regional and national initiatives for improving the quality of newborn screening and genetic service delivery

Region 4 Genetics Collaborative
Data Sharing and Publication Policy
Draft 01/29/2008

This document specifies the conditions for the release of Region 4 Genetics Collaborative data for the purpose of legitimate public health or related research. The intent of these policies is to facilitate the sharing of data with interested investigators and to provide a mechanism for tracking and archiving data requests, intended analyses and publications related to and resulting from Region 4 Genetics Collaborative data.

Data Requests:

- I. Requests for data must be made in writing to the Region 4 Project Director
- II. The requestor shall provide a study protocol that includes: the research question(s), objectives for the use of the data, rationale for data use, methods for processing the data, the specific data requested, a list of variables needed to carry out the study, each proposed analysis that will be conducted (including software that will be used and named lead investigator), storage and security measures for the data, study timeframe, and how the data source will be acknowledged/cited.

The purpose of listing each proposed analysis is to allow and facilitate investigators considering similar projects to collaborate and to identify an individual taking responsibility for the use and reporting of requested data.
- III. Requestors will need to obtain IRB approval and will need to provide IRB numbers and expiration dates.
- IV. Accessible data will include data that fall under the definition of a "limited Data Set" as defined in 45 CFR Part 164.514.
- V. Approval to analyze the data applies only to the topic described in the protocol. If a requestor desires to conduct additional analyses, a separate proposal is required.
- VI. The dataset, or any part thereof, may not be released to any persons other than those listed as collaborators in the provided protocol.
- VII. Upon completion of the analysis described in the protocol, requestor must confirm in writing that their copy of the data has been destroyed and/or return the data to Region 4.

Publication, Authorship, and Data Ownership

Regardless of what subset of data is used in analyses or publications, as part of the User Agreement, investigators will be asked to agree to the Publication Policy, as follows:

- A. A copy of any report or other distribution of information resulting from the use of the data will be submitted to the Region 4 Genetics Collaborative Project Director for review and approval prior to release.
 - a. Slides, posters, abstracts, etc. will be submitted prior to presentation
 - b. Manuscripts will be submitted prior to submitting to a peer reviewed journal
- B. Presentations will include appropriate acknowledgements using language recommended by the Region 4 Genetics Collaborative.
- C. All manuscripts will acknowledge the methods of Region 4 Genetics Collaborative data gathering using language recommended by Region 4.
- D. All manuscripts will acknowledge the support of HRSA using the HRSA grant number for the specific Region 4 Genetics Collaborative Project.
- E. In addition to the named authors, all manuscripts will be submitted with an acknowledgement of the Region 4 Genetics Collaborative project on the author line using an authorship phrase followed by an asterisk. The asterisk will point to a printed listing (if allowed by the journal) or a web site listing that will list the names of the Region 4 Genetics Collaborative project leadership, key senior contributors to the Region 4 Project design and/or organization.
- F. Full citation of the manuscript will be provided to the Region 4 Genetics Collaborative upon acceptance of the manuscript.
- G. A copy of the manuscript will be provided to the Region 4 Genetics Collaborative. If permitted by the Journal, a version of the article or link to the article will be available on-line at www.region4genetics.org.
- H. All data provided under the data agreement are the sole property of the Region 4 Genetics Collaborative and may not be copied or reproduced for distribution to others.