**Contracted Analytics Policy**

1. **Background**
   The ChiLDReN Network (Network) studies include well-characterized populations of individuals with various pediatric liver diseases for whom data are collected and stored by the Data Coordinating Center (DCC) and the biological samples are processed and stored in the NIDDK repository. Because the Network possesses such valuable and rare data, private companies might wish to have access to this data to develop clinical trials or for regulatory information. The policies governing the use of data in such contracted analytics are detailed in this document.

2. **Definition of Contracted Analytics**
   Contracted analytics is a contractual arrangement between an external private company and the DCC to provide Network data and analysis outside of the scientific objectives of the Network. Contracted analytics will be funded in full through a direct contract between the private company and the DCC, with oversight by the Network and NIDDK. The data will remain the property of the Network and the Network will have sole rights for publishing. Unlike an ancillary study, a Network investigator will not need to support a private company that requests contracted analytics. The Network will approve any contracted analytics proposals and will assist in prioritizing DCC resources in any case where a contract analytics agreement would be likely to adversely affect Network analyses or other DCC work.

3. **Proposal Submission**
   A requesting company will contact the NIDDK to express their interest in obtaining analyses of ChiLDReN data. The NIDDK will communicate this request to the DCC and will determine whether this request should be submitted as an ancillary study or a contracted analytics arrangement. If it is determined to be contracted analytics work, the DCC will ask the requesting company to fill out a CONTRACTED ANALYTICS form. This form will outline the terms and conditions of the agreement, including:
   a. A signed non-disclosure agreement
   b. A signed data use agreement including, among other details:
      i. No rights to publish or present in scientific forums
      ii. No exclusive rights to data or analytic results
      iii. No access to raw data or any data containing protected health information
      iv. Access primarily to descriptive statistics and limited inferential statistics
      v. Access only to existing data
vi. No de-novo data collection
vii. No rights to publish analyses
viii. No permission to transfer analyses or other work product to third parties, other than U.S. Food and Drug Administration and foreign regulatory equivalents for the purposes of scientific evaluation only, with prior Network notification.

The CONTRACTED ANALYTICS form will be reviewed by the DCC for feasibility and scientific aims and by the NIDDK. Once approved, the DCC will present the proposal to the Executive Committee (EC). Upon approval by the Executive Committee, the proposal will be reviewed by the Steering Committee (SC), and considered for a vote for approval. Proposals must receive a majority of votes of approval to be considered approved.

4. DCC Review for Feasibility and Scientific Aims
   The DCC with the assistance of the EC will conduct a review of the feasibility and scientific aims of the proposal. To do this, several important factors will be considered in each proposal:
   a. Scientific merit.
   b. Justification of the burden placed on the Network. In the event of competition for limited DCC resources, the DCC will seek Network input and guidance on prioritization of tasks.
   c. Whether the Network can meet the needs of the proposed study.
   d. Plans for funding. All costs must be covered by the requesting company.
   e. Conflict or major scientific overlap with another study.

5. NIDDK Technology Advancement Office (TAO)
   The TAO agrees to review the CONTRACTED ANALYTICS form but will not need to perform a separate review of each new proposal. Representatives from TAO will be available for consultation if necessary.
6. **Review Process**

- Company approaches NIDDK with proposal for data.
- NIDDK communicates request to DCC.
- DCC conducts an internal feasibility review to determine if the request fits better with an ancillary studies model or a contracted analytics model within 7 business days.
- If approved by the Executive Committee, the DCC presents the proposal to the Steering Committee. The DCC informs the company of the Executive Committee decision.
- The DCC reviews the Contracted Analytics form; acceptable proposals are presented to the Executive Committee (EC).
- DCC sends a Contracted Analytics form to be completed by the requesting company.
- The DCC presents the proposal to the Steering Committee, followed by a vote to approve or disapprove. The DCC informs the company of the Steering Committee decision.
- If approved, the DCC initiates contract negotiations with the company.
- After contract execution, the DCC performs contracted analytics and provides regular updates to the Steering Committee.

7. **Network review and oversight**
   As described above, the Network will be involved in the process of reviewing any requests for a contracted analytics arrangement, and will ultimately provide the approval or disapproval to move forward. Existing meeting forums, such as the EC and SC meetings, will be utilized as opportunities to provide updates on these activities. The Network will be notified immediately if there are any issues or problems that are encountered while the work is being conducted. Additionally, if any changes in scope are requested by the contracting company, the Network will be notified and such changes will be reviewed and acceptance of them will be determined by the Network. The Network is indemnified from the conditions of the contact and will not be held liable for data and analyses.
8. **Use of and destruction of data provided from the ChiLDReN Network DCC**

   It is understood that data provided by the Network for contracted analytics are to be used only for the purpose expressly detailed in the proposal. If a requesting company discovers a new use for them, no matter how potentially valuable and timely to an emerging field of study, they must submit a new contracted analytics proposal detailing the proposed use, which will undergo full review.

9. **Conflict of interest**

   The Network has in place a thorough duality of interest policy that will affect potential conflicts of interest with requesting companies. According to the ChiLDReN Duality of Interest Policy, duality of interest statements shall be updated annually at the beginning of each calendar year and at any time during the year that changes occur. Verbal updates to duality of interest disclosure will be requested at the beginning of each SC and EC call/meeting and other calls as needed. Prior to any SC or EC discussion (and possible vote) related to a specific company and that company’s competitors, attendees will be asked to report any known potential conflicts to determine whether those attendees can participate in the discussion and/or possible vote. A duality of interest disclosure statement shall be submitted and reported by every member who participates in Network discussions and whose contributions to those discussions could influence Network decisions related to commercial entities/partners.