**MEMORANDUM OF UNDERSTANDING**

**BETWEEN**

*Recipient & Hosting Entity*

**Mayo Clinic**

200 First St. SW

Rochester, MN 55905

**AND**

*Submitting Entity*

**Entity Name**

Street Address

City, State Zip code

1. **PURPOSE**

The purpose of this Memorandum of Understanding is to define the working relationship between the submitting, receiving, and hosting entities. This agreement clarifies the collaborative roles and responsibilities of all entities with respect to data transfer, ownership, security, use, and storage.

1. **DEFINITIONS**

**Access approver** – the person identified & responsible for approving requests to access the data of one or more submitting entities.

**Anonymized data** – irreversibly identifiable data, edited by the submitting entity, which has had all personally identifiable information removed for privacy protection and is not identifiable by the hosting entity or users from different locations.

**CLIR (Collaborative Laboratory Integrated Reports)** – the copyrighted software supported by the receiving entity and hosted by the hosting entity.

**Data submitter** – the person responsible for supplying source data from the submitting entity systems of record.

**Hosting entity** – the organization hosting the CLIR application & database, currently Mayo Clinic.

**Receiving entity** – the organization receiving data and supporting the CLIR application & database; Mayo Clinic.

**Submitted entity data – the data submitted by the submitting entity to the receiving entity.**

**Submitting entity** – the organization that owns the data supplied to CLIR.

1. **DATA SUBMITTER ROLES & RESPONSIBILITIES**

The data submitter will abide by the following requirements:

* 1. Data Preparation & Submission. Submitted data have been collected, processed, anonymized via a unique alphanumeric value not to exceed 12 characters, & transferred to CLIR in accordance with all local, state, regional, national or federal laws applicable to the data submitter.
     1. Minimum Initial Submission. The initial data submission for new-born screening applications should be at least 10,000 reference cases, inclusive of covariates (age in hours, birth weight in grams, gestational age in weeks, and sex). This requirement is a function of being recognized by the adjustment builder as a meaningful contribution to the regression model used to create covariate-adjusted reference and disease ranges.
     2. Source Data. The submitting entity is responsible for retaining the source data in its system of record.
  2. Local Laws. If requested by the recipient, the data submitter will provide copies of relevant data protection laws of the country in which the data submitter is established. The recipient only commits to complying with applicable local and federal data protection and privacy laws as stated in section 4a.
  3. Data Control and Ownership. The submitting entity retains ownership and control of the submitted entity data, including the following:
     1. No Restrictions to Use. The submitting entity retains the right to use the submitted entity data for any purpose, including research or academic uses, without restriction. The submitting entity retains the right to the intellectual property associated with the submitted entity data.
     2. Withdrawal of Submitted Entity Data. The submitting entity retains the right and ability to remove, without notification, any previously submitted entity data. If the data submitter removes all submitting entity data from a particular application; the entity will forfeit access to all CLIR applications that utilize such data, but retain access to other applications, when applicable. If the submitting entity no longer has access to CLIR and wants to remove the submitted data, the submitting entity should send an email to the CLIR support team, who will remove the submitted data within 5 business days.

*\* Note: Deleted data will exist in database backups, which are purged according to the hosting institution’s enterprise standards. If a disaster recovery is needed, all submitters will be notified following standard enterprise procedures AND are responsible for removing unwanted data, if it should exist, after the restoration is complete.*

* + 1. Continuity of Contributed Data. If the submitting entity fails to provide new reference and case data within a 12 consecutive month period, a warning will be issued followed by removal of the submitting entity’s access to CLIR. Access will be reinstated promptly following a new data submission
    2. Rules ii & iii apply to all users sharing the same entity as their primary affiliation within CLIR.
  1. Academic Use of CLIR. An entity is encouraged to use CLIR for academic purposes with the following limitations:
     1. Right to Review. A submitter using CLIR to generate data or figures intended for publication in a peer reviewed journal agrees to allow CLIR administrators to review and possibly enhance CLIR-related material prior to submission for publication. A review is not required for slide presentations or posters.
     2. Right to Approve. A submitter agrees not to publish data or figures generated by CLIR without approval from CLIR administrators. If the CLIR core team finds the data or figures are being presented inaccurately and the entity does not take steps to resolve the inaccuracies prior to publication, the entity will lose access to CLIR.
     3. Crediting CLIR. A submitter using CLIR to generate data or figures intended for publication in a peer reviewed journal agrees to credit the CLIR application as appropriate in the submitter’s manuscript and will not use the CLIR trademark in any news release, publicity, advertising, endorsement, or commercial communication without the prior written approval from a CLIR administrator. Requests for approval should be submitted at least 5 business days prior to the date on which a response is needed to the CLIR support team, at the following E-mail address: [RSTCLIRSUPPORT@mayo.edu](mailto:RSTCLIRSUPPORT@mayo.edu).
     4. Crediting Receiving Entity. The submitter will not use the name or trademarks of the receiving entity in any news release, publicity, advertising, endorsement, or commercial communication without the prior written approval of the receiving entity. All requests for approval for the use of the receiving entity’s name pursuant to this section must be submitted to the receiving entity’s Public Affairs Business Relations Group, at the following E-mail address: [BusinessRelations@mayo.edu](mailto:BusinessRelations@mayo.edu) at least 5 business days prior to the date on which a response is needed.
  2. Grant of Copyright. The submitting entity hereby grants the receiving entity and all other submitting entities the right to use any submitting entity data in the CLIR software as described in this agreement.

1. **DATA RECIPIENT / HOST ROLES & RESPONSIBILITIES**

The data recipient retains all right, title and interest in the CLIR software and all related intellectual property relating to operating CLIR both prior to the effective date of this agreement or conceived and/or reduced to practice, fixed in any tangible medium of expression, or created during the term, including all improvements, modifications, and derivative work. Nothing in this agreement shall be construed as granting any rights to the CLIR software to submitting entities.

The data recipient and hosting entity will abide by the following requirements:

1. Data Commitments. Data submitted to CLIR will be handled in accordance with the following precepts:
2. Data Processing. Anonymized data submitted to CLIR will be processed in accordance with local, state, and federal laws applicable to the receiving entity.
3. Data Storage. The anonymized data submitted to CLIR will be stored in accordance with local, state, and federal laws applicable to the hosting entity.
4. Data Protection. The hosting entity will execute appropriate institutionally-approved security policies to protect the submitted data against loss, destruction, alteration, & unauthorized access with a level consistent with other applications of the same class/tier.
5. Data Access. To maintain the confidentiality and security of the data, the receiving entity will provide access to CLIR applications only after receiving written approval by the submitting entity’s designated access approver.
6. Data Transfer. Mayo Clinic will not disclose or transfer submitted data to third parties without the explicit approval from the submitting entity’s designated access approver.
7. Software Use Commitments. The receiving entity agrees to process data only for the following purposes:
   * 1. Clinical Use. Submitted data will be used to develop clinical decision support tools. The CLIR software is made available with the explicit stipulation that the post-analytical tools are intended to assist in the interpretation of laboratory results and are not a substitute for professional judgment. All guidelines, interpretations, figures and calculations must be confirmed by qualified healthcare professionals before clinical use.CLIR data is furnished as is, with all faults and without warranty of any kind, express or implied, including any warranty of merchantability or fitness for any particular purpose.
     2. Academic Use. Submitted data may be used for academic purposes, including quality improvement, test development, and research, with the following limitations:
        1. All research activities will be covered by active protocols approved by the Institutional Review Board (IRB) of the receiving entity.
        2. Members of the receiving entity will not unilaterally publish data or figures generated with submitted data without providing authorship and/or proper credit or acknowledgement in the submitted paper.
8. Support Commitments. The receiving entity agrees to the following support commitments:
   * 1. Organizational Contact. In the event of security or data loss concern, the receiving entity will provide an individual for direct contact to collaborate with the members of the submitting entity.
     2. Infrastructure Support. CLIR is provided using the institutionally supported software of the receiving entity and hardware infrastructure of the host institution, without cost to data submitters or end users.
     3. No Cost Service. CLIR will remain available without cost in perpetuity to all for uses related to newborn screening, clinical biochemical genetics, and pediatric medicine.
9. Succession Commitment. The receiving entity agrees to the following succession commitments:
   * 1. Discontinuation of Service. If CLIR is discontinued, the receiving entity will ensure secure deletion of all submitted data from the hosting entity.

**IN WITNESS WHEREOF**, the parties hereto have executed this agreement in duplicate by proper person there unto duly authorized.

1. **SIGNATURES**

|  |  |  |
| --- | --- | --- |
| **Submitting Entity** |  | **Receiving Entity** |
|  |  |  |
| Name |  | Name |
| Title |  | Title |
|  |  |  |
| Date |  | Date |
|  |  |  |
| Signature |  | Signature |