

[NAME] Network
[Data Use Agreement (DUA)/Business Associate Agreement (BAA) AGREEMENT]
FAQ Sheet

Why is sharing of data so important in the Learning Health System Network Model?

Networks depend on a commitment to the shared purpose of helping patients and their families live healthier lives. Networks have a culture of transparency, generosity, inclusivity, honesty, empowerment, continuous learning, and community. Sharing is a very big part of the network. Networks produce results by pooling knowledge, know-how, data and work.

Why do we have a participation and data use agreement?

The use of data generated from patients and patient-clinician interactions are the foundation of a Learning Health System Network. The Learning Health System Network will involve formal membership in the [NAME] Network that will be facilitated by the [NAME] Foundation, as well as sharing data with Cincinnati Children's Hospital where the [NETWORK] enhanced registry will reside during the 18-month project.

Legal agreements are necessary to enable sharing of data across the network. Your site will need to indicate your acceptance of what participation in this initiative means. This will be accomplished by signing the [NETWORK] Data Use Agreement and Business Associate Agreement (if your institution hasn't already signed one with CCHMC).

[Our records show that your institution has already signed a Business Associate Agreement (BAA) with Cincinnati Children's and therefore you do not need to seek signature for a new one.]

What are the benefits of the participation and data use agreement?

This agreement sets forth the legal terms that will govern your participation in the [NETWORK]. Having such an agreement is important, because it clarifies the relationship between participating centers and the project team that supports the LHS, as well as the responsibilities of each party. It is also a regulatory prerequisite to sharing data for research and for quality improvement purposes.

Why are these documents being sent to me?

You have a key role to play in facilitating the execution of these important foundational documents so it is very important that you take the time to understand them and how you can help. We have prepared an annotated version of the Data Use Agreement to help you understand the key provisions of the agreement. We have also shared a description of what a Learning Network is. You may find it helpful to use this document to explain the project to individuals in your organization.

Who should sign these documents?

Please forward the [NETWORK] Network Data Use Agreement and Business Associate Agreement (if applicable) packet to the individual in your institution who is authorized to sign institutional or legal documents (often called the Designated Institutional Official). If you are part of a hospital or health system, this may be a member of the Legal Department, the Departmental Administrator, the President, or the Chief Medical Officer. We will

attempt to identify the appropriate individual in your organization. If you are part of an independent practice, this is likely to be someone in leadership or high-level administration.

Do these documents need to be reviewed by your Institutional Review Board (IRB)?

The Epilepsy LHS activities will have a research component. Therefore, your legal team may want to know that your institution's IRB is reviewing the IRB protocol and consent form.

Why do I see CCHMC listed in the agreement?

Over the next 18 months, data from the [NETWORK] Network will be sent to Cincinnati Children's because CCHMC will be providing the registry software for the initiative. Therefore, your site must agree to share data with CCHMC.

How much time do I have to send these signed documents back?

The sooner we have these signed documents back, the sooner your site can start receiving and sharing data and reports. Without a signed agreement in place, your ability to participate will be severely limited. We are aiming to have all participating agreements signed by Month DD, YYYY. We appreciate your support in meeting this deadline.

How can I send these documents back to you?

After the Data Use Agreement and Business Associate Agreement (if applicable) have been signed please scan and return with signature to [PROJECT NAME] at [EMAIL ADDRESS].

Who can I contact in [PROJECT NAME] if I have any questions on the documents?

Please contact [PERSON RESPONSIBLE FOR COORDINATING] by email [INSERT EMAIL] or by phone [INSERT PHONE NUMBER] if you have any questions or need clarification.