

Email Template #1: Use as Cover Letter to the LHS PI Organization

Dear [NAME]:

As you know, the Anderson Center for Health Systems Excellence at Cincinnati Children's Hospital is serving as the program office for the PCORI LHS Communities project. In this capacity, we are providing coaching and support for the program including the development and configuration of an Enhanced Registry technology to serve the needs of the four awarded PPRNs. There is a very significant opportunity to streamline the regulatory and ethical infrastructure needed to accelerate the implementation of the LHS model of all four networks within the timeline of the grant.

We appreciate just how challenging it can be to develop and implement a legal and ethical infrastructure that can address the evolving needs of a network as it matures. Our goals are to develop an approach that can support the [NAME] Network in developing a Learning Health System network, while taking advantage of work that has already been done by other networks. We want to avoid having networks reinvent the wheel. Many of the institutions that are participating in your network already have agreements in place with other similar networks. We believe this is an opportunity to create a more standardized approach that will reduce the administrative burden for participating institutions. Guiding us in this effort are [NAME] Cincinnati Children's Senior Counsel. [NAME] will be the person working with your legal team. [NAME], Senior Director of the Office of Research Compliance and Regulatory Affairs will also help with the IRB aspects of the project.

The Program Office reviewed the existing DUA being used as part of Dr. [NAME]'s project to determine the extent to which it can support an LHS network which uses data for clinical care, improvement and research. The DUA created by Cornell is set up to support a time-bound research project, not an enduring initiative that will require access to personal health information and sharing of performance data for improvement and research. We have attached an annotated version of that DUA where we have identified contract terms that would typically be included in a learning networks agreement.

We also identified the institutions that are participating in Dr. [NAME]'s project. Many of the institutions in which the pediatric epilepsy centers are located are participating in other learning networks and already have network agreements with Cincinnati Children's in place. As a result, these institutions are already familiar with the contract forms used. We believe we can leverage these relationships and existing signed agreements to reduce time required for the [NAME] Network. We also have agreement from the Chairs of the Departments of at least 8 pediatric institutions that they will assist us by working with legal teams in their own institutions and also reaching out to colleagues in other institutions to accelerate this process.

We are proposing to establish contracts for the Epilepsy Network ("the network") similar to the other learning networks, in which each participating institution enters into network agreements with a coordinating entity like the Epilepsy Foundation and with CCHMC to provide the technology support infrastructure and to make use of the enhanced registry. We have also written the DUA in a way that also imagines a scenario in which the registry might move to another organization.

Enclosed with this letter, you will find documents that support the scenario we are proposing, including:

- A cover letter explaining the legal agreements and rationale for their signature
- An FAQ Sheet that contains information that should answer most questions centers may have
- The original Pediatric Epilepsy Data Use agreement with annotations comparing it to the Cincinnati Children's learning network agreement
- The Participation and Data Use Agreement using the Cincinnati Children's template
- An annotated version of the Cincinnati Children's Participation and Data Use that explains key clauses
- A list of epilepsy centers with which Cincinnati Children's already has a Business Associate Agreement in place

- The standard Cincinnati Children's Business Associate Agreement
- Learning Networks Brochure which may be useful to educate institutional lawyers about what a network is

We know that achieving the goal of a standardized approach will require significant collaboration and co-design. We will also need to work together with your team to support participating centers. We will also help connect directly with senior leaders, legal counsel, and IRB teams at participating institutions. We hope this top down, bottom up approach to establishing contracts will raise the visibility of the LHS documents within the participating institutions and ensure that signatures are secured by December 2018, in time for the launch of the registry.

We look forward in going to work on this with you.

Thank you,

[NAME] credentials
Program Director
PCORnet LHS Communities Initiative

[NAME] credentials *{List name of the Project PI}*