

Agreement

Between ERNICA and IIRTA

Background

IIRTA is the International Intestinal Rehabilitation and Transplant Association. The International Intestinal Failure Registry (IIFR) is a registry for paediatric intestinal failure patients, hosted at the Transplantation society (TTS), Montreal, QC, Canada.

ERNICA is the European Reference Network for Rare Inherited and Congenital (digestive and gastrointestinal) Anomalies, which is coordinated by Erasmus MC, Rotterdam, The Netherlands and is currently funded by a grant of the European Commission until October 2027.

The IIFR Registry serves as a dedicated registry for patients with intestinal failure and is owned and managed by the IIRTA. The IIFR ongoing management is provided by a dedicated IIRTA sub-committee, and its daily activities are coordinated by a director and a research coordinator appointed by the IIRTA, currently housed at SickKids Hospital, Toronto, ON, Canada. The registry aims to improve quality of life for children with intestinal failure by acting as a reliable resource, promoting research, developing best practices, and guiding evidence-based management in paediatric intestinal failure.

A few years ago, the ERNICA Intestinal Failure Working group initiated its quest for a sustainable registry for intestinal failure patients treated in ERNICA centers. Upon selection of the IIFR as the registry, only a few ERNICA centers have inputted their data into the registry, primarily due to two challenges: (1) Lack of clarity on data ownership and (2) Lack of certainty about the authorship of publications.

Steps taken

A meeting held on March 20th 2024 discussed these above mentioned challenges and potential solutions. Following the meeting, the project manager of ERNICA, in partnership with the Erasmus MC legal department, explored the possibility of formalizing an agreement between ERNICA and the IIFR Registry. Since ERNICA lacks a legal entity status, a significant obstacle to establish a legal binding contract between the two parties became apparent.

Considering alternatives, the option of creating a contract between Erasmus MC, representing ERNICA, and IIRTA, was explored. However, Erasmus MC lacks the authority to enter contracts on behalf of ERNICA, as Erasmus MC does not represent the other ERNICA centers legally, making such contractual agreements not feasible.

As a result, it has been concluded that each ERNICA Health Care Provider (HCP) (whether an ERNICA full member center, affiliated partner center or supporting partner) must independently establish its own hospital-based agreement regarding data transfer and ownership with the IIRTA. ERNICA will stimulate that all ERNICA HCP's which are recognized expert centers for intestinal failure in ERNICA, will connect with the IIFR Registry. An ERNICA Health Care Provider is also called an ERNICA center.

Gentlemen's agreement

This document constitutes a gentlemen's agreement aimed at fostering mutual understanding, cooperation, and progress to address the challenges encountered by ERNICA HCP's in their contributions to the IIFR registry. It outlines the terms and conditions governing the inclusion of ERNICA HCP's in the IIFR registry, with a specific focus on publications and participation in the scientific committee of the IIFR.

A) Scientific committee

- The IIFR sub-committee includes a minimum of two representatives from ERNICA HCP's.
- The two ERNICA representatives in the IIFR sub-committee will be determined by ERNICA and announced to the IIRTA.
- Research inquiries originating from any ERNICA HCP must be formally submitted to the IIFR sub-committee for review and approval of the research proposal.
- Research proposals focusing solely on the data of ERNICA centers are also permitted.
- Annually, ERNICA centers will submit research proposals to the IIFR Registry scientific committee, according to the process that governs research proposal submission to the IIFR.

B) Authorships


- (Co-)authorships on scientific publications arising from IIFR Registry data are determined based on collaborative status, ensuring that site Principal Investigators (PIs) are not merely acknowledged but are listed as collaborator in the paper.
- Utilizing this collaborative status, the manuscript of the paper will be shared with all participating centers (referred to as collaborating authors), allowing them a period of two weeks to provide feedback.
- In the event that the collaborating author does not agree with a specific section within a manuscript they are encouraged to discuss this with the senior author. Modifications to the manuscript can be done based on this discussion but ultimately be under the discretion of the senior author. In extreme cases, a collaborating author can withdraw from the publication. However, their center data will still be used for the research in an anonymous, pooled manner.

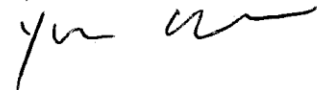
C) Acknowledgments

- The paper will explicitly acknowledge and cite all centers whose data has been utilized for the research.
- When data from ERNICA HCPs is used for research, ERNICA will be explicitly acknowledged in the paper, provided that at least two different ERNICA centers from two different EU countries are participating.
- When ERNICA centers conduct research using data from the IIFR Registry, the paper will explicitly acknowledge the IIFR Registry as the data source.

D) Data

- Each center owns their own data, making it available upon request from the IIFR manager.
- ERNICA HCP's may also conduct research exclusively based on ERNICA data.
- IIRTA will provide an annual ERNICA report including data on number of patients, general demographics, key outcomes and quality assurance data (missing field etc.) of all ERNICA HCP's combined that have submitted the data in the IIFR registry. This report will be sent to the leads of the ERNICA IF working group.
- Costs are associated with conducting a deeper analysis of the data. The needs for deeper analyses by the IIFR will be determined upon request.
- Methodological support for data analysis by IIFR is possible, although costs are associated.

The Centre: ERASMUS MC / ERNICA
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Date: 21/6/2024
Signature: 

The Centre: IIRTA
By: Yaron Avitzur
Title: Secretary - Treasurer
Date: June, 21, 2024
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The Centre: IIRTA
By: Jonathan Hind
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