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# Shaping of Human Immune Systems by Environmental Influences Early in Life

*A Data Management Plan created using DMPonline-test*

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## **Project abstract:**

Studies of environmental influence in humans are complicated to perform because of the many simultaneous factors of influence. Still, understanding these environmental influences is essential since they explain most of the variation in immune system composition and function among individuals (Brodin et al., 2015). By studying newborn children facing many environmental factors for the very first time, adaptive changes induced by environmental exposures never seen before, are more interpretable. By simultaneously analyzing frequencies, phenotypes and functional responses of all immune cell populations and across many plasma proteins, we reason that coordinated changes can be uncovered and regulatory relationships inferred. By comparing such immune system changes in children born at term or preterm, by vaginal or cesarean delivery and fed breast milk or formula, we aim to investigate the influences of such broadly different initial conditions on immune development. Since newborn children, particularly those born preterm are at increased risk of both infectious diseases and inflammatory conditions, this study holds potential for clinical impact by enabling earlier detection and treatment of such devastating conditions. In a longer perspective, by understanding the timing and mechanisms of environmental imprinting on human immune systems, we hope to understand immune variation, predict risk of immune mediated disease and improve vaccine effects by optimizing vaccine schedules to the state of newborn immune systems.

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## **Copyright information:**

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## General Information

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## Description of data – reuse of existing data and/or production of new data

Data will be in the form of biomedical data from immune cells and proteins obtained by various high-throughput methods from blood samples. We will assess cell phenotypes, plasma protein concentrations, mRNA-expression. Also, fecal samples will be obtained and composition and function of gut microbes are analyzed by Shotgun next generation sequencing. Finally, clinical information is gathered into a database to use for correlation analyses between clinical metadata and biomedical data.

Single-cell data obtained by Mass cytometry and single-cell mRNA-sequencing. Plasma protein relative abundances by Olink assays. Fecal microbiome composition and function by Shotgun next generation sequencing. Clinical data obtained from electronic health records.

## Documentation and data quality

All data is coded by individual patient without unnecessary identifiable information like names, personal numbers or addresses and all data is gathered into a relational database. This ensures good quality control, version control and tracability of all data. The Database is located at SciLifeLab (cytof.scilifelab.se) and is owned by department of women's and children's health, Karolinska Institutet.

All data are longitudinal in nature. Sample preparation is optimized to be done as soon as possible after collection with minimal technical variation (Ref Brodin et al, Immunity, 2019). Using a relational database instead of excel tables or similar ensures quality. The database does include experimental data, protocol files and analyses scripts are available in GitHub to reproduce the analyses.

## Storage and backup

Relational database custom written for the project by the Brodin lab an hosted in our lab server within the firewall of KI

the database is fully password protected and only known IPs can gain access. The database is hosted in our lab server within the firewall of KI

## **Legal and ethical aspects**

In accordance with GDPR we have minimized the amount of data collected to the bare minimum needed for analyses. We code all patients and remove personal numbers, names and other unnecessary, sensitive information before adding data to the databases. The info is fully traceable because there is a locked key to decode study IDs to personal numbers. Only the clinical study coordinator have access to this. All subjects have consented to participation of the study after receiving both written and oral study information.

Safe data storage system, with full traceability and all informed consent. All data is removed upon request from study participants.

## **Accessibility and long-term storage**

The data is accessed for analyses purposes only by Brodin lab members and clinical study coordinators. A minimal number of individuals have access as imposed by GDPR. Longterm storage is ensured by backup of the relative database within the KI firewall.

Yes by Brodin lab data manager responsible for data infrastructure as well as the KI IT department in charge of the university infrastructure.

All analyses and data handling, storage and management is done by custom code written by the Brodin lab. We have a GitHub repository for our group where all analysis code is stored and version controlled. We share all code to reproduce all analyses in the form of a Docker system with every publication to allow readers and researchers to reproduce all our analyses as is state of the art in our field of research.

These are only available to study coordinators within our closed database.

## **Responsibility and resources**

KI Data protection officer is Mats Gustavsson. All management of data is managed by Petter Brodin and his lab members involved in the study, as well as clinical collaborators headed by Kajsa Bohlin.

Full time data infrastructure manager employed by the Brodin lab. A dedicated server is in place within the firewall of KI. All necessary infrastructure is available and suitable to ensure FAIR principles.