**Processing of sensitive data in NBFC**

Fulfillments related to the E.U. Regulation 2016/679 (GDPR) with regard to NBFC's scientific activities have been particularly concerned with protocols that have involved or will involve processing of special data of healthy and/or affected individuals as detailed below.

Beyond the fulfillments that each individual participating entity implements, within its own functional organization and organizational model, to ensure compliance with the regulation, an effort was made to evaluate a common procedure to address privacy issues related to the protocols of interest.

 Although the case histories and cohorts considered are different, as different are the partners involved, the actions taken are essentially similar and are aimed at addressing all the requirements of the regulation itself with respect to the type of treatment under consideration.

Although reported consequentially, the planned activities were often carried out in parallel so that the process of initiating treatments could be optimized, consistent with the scheduling of scientific activities.

For each data processing it was important to define “ab initio” who were the partners to be involved in the processing and what was the role of the partners involved, with respect to the data processing. Based on the definition of these roles, co-ownership agreements were prepared and signed, in accordance with Article 26 of the GDPR, if the partners jointly decided on the means and purposes of processing. If between partners or with external parties involved in the data processing process, it was necessary to define data controllers, pursuant to Article 28 of the GDPR, responsibility agreements were prepared and signed.

As part of the preparation of documents to be sent to relevant ethics committees called upon to give ethical opinions on study protocols, disclosures regarding data processing in the case of co-ownership relationships were prepared in agreement.

Where necessary, Impact Assessments (DPIAs) have been prepared, in the case of projects involving co-ownership between the partners involved.

Summary table of the documents collected for each of the patient cohorts, studied in Spoke 6-NBFC.

| **Cohort** | **Ethical Committee documents (data, n. of protocol)** | **Informed consent** | **DPIA** | **Co-responsability of Co-ownershipContract** | **Partners**  |
| --- | --- | --- | --- | --- | --- |
| **EXPOSITION -** EXPosome, Oxidative Stress and InflammatioN in persons with multiple sclerosis | Protocol approved on 25 July 2023 by the Lombardy region ethics committee (LREC) 6. (Prot. N. 0040083/23) | Yes, in the document for the LREC | Yes | Yes, joint ownership contract Mondino-University of Pavia -IBSBC (ex IBFM) | Multicenter study involving: IRCCS Foundation Istituto Neurologico C. Mondino (PV), University of Pavia, National Research Council (CNR) |
| **Coorte DISBIOSI\_AMBIENTE –** Study of the role of environmental factors in the etiopathogenesis of dysbiosis associated with Chronic Gastrointestinal Disorders | Starting protocol presented to ethics committee on 21.12.2022 (protocol n.PAR 109.22 OSS), amendment presented and approved on 17.05.2023. | Yes, in the document for the LREC (Document revision 2 on 05.05.2023) | To do | To do | Multicenter study involving:: Campus Biomedico (Roma), University of Pavia, National Research Council (CNR) |
| **LIMIT -** LIfestyle and Microbiome InTeraction Early AdiposityRebound in Children[Published protocol : De Giuseppe *et al.*Metabolites 2022, 12, 809. [https://doi.org/10.3390/metabo12090809]](https://doi.org/10.3390/metabo12090809%5D)  | The study was conducted following the Declaration ofHelsinki. Ethical approval was granted by the Ethical Committee of the IRCCS Policlinico San Matteo(Pavia) (protocol 0020200/22, 11/04/2022). + Positive opinion as a non-substantial amendment by the Ethical Committee of IRCCS Policlinico San Matteo(Pavia) (protocol number: 0024604/24; accepted: 02/05/2024)+**Protocol deposition on the platform** [www.clinicaltrials.gov](https://www.clinicaltrials.gov/) (ID: NCT04960670   | Yes, in the document for the EC and for the amendment  | To do | To do | University of Pavia,  (single-center study ) |
| **EMERGE –** inquinamEnto atMosferico E marcatoRi epiGenetici di infiammazionE (air pollution and epigenetic markers of inflammation) | Starting protocol presented on Ethical Committee on 10 Sept.2024, negative opinion on 03 Dec. 2024; correction to the document presented to the CE will follow (in January) | Yes, in the document for the EC | To do | To Do  | Multicenter study involving: Università Campus Bio-medico di Roma, Consiglio Nazionale delle Ricerche (CNR), Università “La Sapienza” di Roma  |
| **IDEA** (partner di BAC) - Impatto dell’ambiente urbano sull’età biologica: effetto della qualità dell’aria e dello stress lavorativo a Pavia su citochine infiammatorie e profilo di metilazione del DNA (Impact of the urban environment on biological age: effect of air quality and work stress in Pavia on inflammatory cytokines and DNA methylation profile) | Starting protocol presented on Ethical Committee on 16 July 2024, approved | Yes, in the document for the EC (To be amended);  | To do  | To do  | ICS Maugeri IRCCS ofPavia (single-center study ) |