INSPIRE-T data access application

(To be sent to: ihuos_inspiredataaccess@chu-toulouse.fr)

Date of application:

Project Leader	
Name :	
Current Position/Role in a few words:	
Institution / Organisation:	
Address :	
City :	Country :
Phone number :	e-Mail :

Project Title

Funding
Is your project funded? ☐ yes ☐ no If yes, please specify the source of funding:

Recent literature on the subject and justification of proposal

Study outline (Research question)

In this section, the following elements must be described:

- *hypothesis,*
- *primary, secondary, and exploratory objectives*
- *primary, secondary, and exploratory outcomes*

Proposed methodology

In this section, please detail the methodology to be used, including the statistical analysis and power calculations

Do you require access to the INSPIRE-T biobank?

☐ yes ☐ no

If YES,
- Appendix 1 must be completed to describe the biological material requested.
- *Please note that the results of any bioassays must be provided to the INSPIRE-T principal statistician (in .csv, excel or SAS form). This data will be integrated into the INSPIRE-T database, and will be made available to other researchers, following an embargo period (after publication of the primary results relating to this data, and/or patent application, as outlined in the "INSPIRE-T cohort data access and sharing: policy and procedures" document). Access to clinical data is dependent on the provision of the results of bioassays.*

Subjects of interest

Whole study population ☐	Sub-population(s) ☐ (please define):

Do you require access to the INSPIRE-T database?

☐ yes ☐ no

If yes, please describe the variables of interest (including time points)

Additional requests
Methodological support ☐ yes ☐ no If yes, please give details of the required support:
Statistical support ☐ yes ☐ no If yes, please give details of the required support:

Project timeline	
Expected start date)	
Expected end date)	
Publication submission (expected date)	
Anticipated target Journal (if applicable)	

Details about the project team					
Name	Current position	Institution/ organization	Email	Data access	Role in the project (please specify who will perform the statistical analysis)
				Yes ☐ No ☐	
				Yes ☐ No ☐	
				Yes ☐ No ☐	
				Yes ☐ No ☐	
				Yes ☐ No ☐	
				Yes ☐ No ☐	
				Yes ☐ No ☐	

Appendix 1: Description of Biological Material Requested (to be joined to the Material Transfer Agreement)
Name of user: Name and status of the institution: Head Office location: Legal representative: Scientific Responsible Name: Phone number: Email:

Project Title

The Identity of the hosting site (country, address, email, phone) : Address: Email: Phone:

Role of Toulouse University Hospital:

Role of Recipient/user:

Samples and data provided by the Toulouse University Hospital	
Scientist responsible for the INSPIRE-T samples within the Toulouse University Hospital	Name : Vellas Bruno Department : Gérontopôle, CHU de Toulouse Phone : 05.61.77.70.47 Email : vellas.b@chu-toulouse.fr
Nature of samples requested by the user (for information, all samples are stored at -80° in the INSPIRE-T	Nature: ☐ blood samples -please, specify (plasma, serum, whole blood, RBC, PBMC…):

Biobank)	☐ DNA ☐ RNA ☐ Proteins ☐ urine ☐ CSF ☐ saliva ☐ dental biofilm ☐ feces ☐ hair bulb ☐ skin biopsy (OMICS) ☐ fibroblasts ☐ Tumour ☐ Healthy tissue ☐ Cells from cell cultures ☐ Secretions (specify which ones): ☐ other (specify): Requirement for storage: Requirement for shipping (packaging, period…): Other, to be determined:
Number, quantity, volume of biological samples requested by the user	Number of subjects: Number of samples (/subject): Volume per sample:
Genetic analysis	☐YES ☐ N0
Associated data requested (coded data)	☐YES ☐ NO If yes, exhaustive list:
Will the biological samples be sent to external platform/biotech for their analysis? If yes, please specify its name, location country and role.	☐YES ☐ NO If yes, provide the external platform/biotech name, location country and their role in the use of the material:

Outcomes of the samples made available by the CHU			
Samples processing:	Creation of a biobank by the User:	Destruction of biosamples by the User at the end of the project:	Return of samples by the User to the CHU at the end of the project:

☐YES ☐ NO	☐YES ☐ NO	☐YES ☐ NO	☐YES ☐ NO
If yes, please specify the derived product:		If yes, please provide a justification to the CHU	If yes, please give a return deadline for the CHU:

Delivery of samples
- <u>Delivery address</u>: **- <u>Name and contact details of the person who will receive the shipment</u>:**
- Frequency of delivery: **- Responsible of delivery (user himself, approved carrier by the Toulouse University Hospital or by user, other provider):** **- Financial support: ☐Toulouse University Hospital ☐ FINAL USER**

Personal Data Transfer Conditions
- Name of the responsible Data Controller in charge of the processing according to the article 24 of the GDPR: …….. (If any) Name of the responsible Joint-Data Controller in charge of the processing according to the article 26 of the GDPR: …….. - Name of the Data Processor in charge of the processing under the instructions of the Data Controller according to the article 28 of the GDPR: ……. - (If any) Name of any Subcontractor acting as a Data Processor under the direct authority of the Controller or Processor and is authorised to process personal data according to the article 28 and 29 of the GDPR: ……. - Data flow (including conditions for data safety) : …… …… - Data format: …… - Identity and contact information of the DPO for each party: For the CHU; Mme Charlène SEGURA, DPO@chu-toulouse.fr Pour the USER:

Ethics Documentation

The Recipient of the research material understands that he is legally responsible for having achieved any ethical and regulatory procedures required in his home country law to obtain, store and process the samples/data requested for the declared research purposes. The information requested below must be provided in good faith in the respect of transparency and honesty principles. In no case the Provider can be held responsible for false declarations or failure in compliance duties from the Recipient individual/institution.

- <u>The project for the purposes of which samples will be provided received ethical approval according to applicable national laws</u>:

☐ **YES** ☐ **NO**

If yes, all the documents must be kept and made available to the Data Access Committee upon request.
If no is ticked, please, provide detailed explanations (note that in certain circumstances the access can be delayed until the achievement of applicable procedures or denied)**:**
……..

- <u>The parties involved in the processing of personal health data provided are duly authorised to perform such activities according to applicable national laws</u>:

☐ **YES** ☐ **NO**

If yes, all the documents must be kept and made available to the Data Access Committee upon request.
If no is ticked, please, provide detailed explanations (note that in certain circumstances the access can be delayed until the achievement of applicable procedures or denied)
……..