



Appendix 7: Request form for collaboration of external researchers with the PREDIMED PLUS study to gain access to data and samples generated during the PREDIMED PLUS study

This type of request tends to be submitted in contexts in which an international research project is being developed that includes external researchers and internal researchers from the PREDIMED PLUS study.

Note: When submitted, this form must be accompanied by a formal introduction letter from the external researcher requesting the collaboration, including his or her CV, a list of research projects in progress, and institutional affiliation during the course of the collaboration. It must also be indicated whether the request for samples and data corresponds to a request for joint funding for a project funded by various international agencies.

Full name of PI	
Position	
Institution/Country	
Postal address	
E-mail	

Brief explanation of the reasons the external researcher is requesting collaboration with researchers from the PREDIMED PLUS study in relation to access to samples:

If the request for samples and data is part of an additional collaboration for development of a research project funded by multiple agencies, indicate the specific call for proposals that will be responded to, the name of the researcher or researchers from the PREDIMED PLUS study who will be participating in submitting the proposal for the research project, the deadline for submitting proposals, the title of the study, and the funding to be applied for. In addition, a project request sheet must be filled in using the official PREDIMED PLUS form:

Type of study that would be undertaken, hypothesis and objectives, and sample size:

Description of the data requested from among the data already obtained in relation to the PREDIMED PLUS study, and description of the additional data that would be generated:

List the types of samples requested, the quantity of sample required, the concentration, the transport conditions, the technique that will be used for taking measurements, the data that will be generated, the metadata, how the file with the results will be transferred, the terms and conditions for collaboration, the estimated time required for the determinations, and the duration of the study:

The requesting researcher commits to adhering to the ***Guide for External Researchers Requesting Data and Sample Sharing Collaboration with the PREDIMED PLUS Study*** (Appendix 8) and:

The undersigned PI hereby commits to respecting the following principles:

- To maintain the confidentiality and privacy of the data and refrain from making any attempt to identify the records (IDs) of the participants
- To maintain the integrity of the data
- To maintain secure data storage environments
- To refrain from distributing any data to unauthorised third parties
- To use the data provided only in relation to the specific objectives for the collaboration
- To destroy the data provided at the end of the active establishment period for the Collaboration Agreement
- To maintain the security and integrity of the samples, ensuring that their transport takes place under appropriate conditions of freezing/refrigeration and storage
- To use the samples exclusively for the determinations approved in the PREDIMED PLUS study, with no permission to perform additional determinations or transfer the samples to other researchers
- To return any remaining samples after the determinations have been completed, under optimal conditions of preservation
- To submit a copy of the results from the determinations performed to the central database for the PREDIMED PLUS study, or to the federated database that will be designated for this purpose if there are technical restrictions on the formats, in order to allow that data to be incorporated after a maximum period of 2 years has passed after reception of the samples. *In exceptional cases it will be possible to request an extension.*
- To provide each node with a copy of the data corresponding to the samples it provided whenever a paper is produced using determinations performed on samples from multiple nodes
- To establish the pertinent collaboration agreements with internal PREDIMED PLUS researchers, who will carry out data analyses using the determinations produced
- To adhere to the publication policy and data management plan and sharing policy for the PREDIMED PLUS study

Date:

Full name of requesting PI:

Signature of requesting PI: