



**Appendix 5: Request form for collaboration of external researchers with the PREDIMED PLUS study to gain access to samples generated during the PREDIMED PLUS study. This form must be used only in cases where samples are being requested, but not any of the data associated with them.** If data are also being requested, the form corresponding to a collaboration request for access to data and samples simultaneously must be filled in (Appendix 7).

*This type of request is required when the external collaboration only involves a request to perform determinations on biological samples, but not to receive the data associated with those samples because the requesting researcher is delegating the subsequent data analysis corresponding to those samples to 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 a summary of his or her CV, research projects in progress, and institutional affiliation during the course of the collaboration.*

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:

Type of study that would be undertaken, hypothesis and objectives, and which researcher(s) from the PREDIMED PLUS study would be responsible for associating the sample analyses with the corresponding data.

In the case of collaboration involving meta-analysis or analysis of data jointly with other groups, the names of the other groups must be specified as well as the approximate total sample size for the study that would be carried out:

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 will be transferred, the terms and conditions for the collaboration, and the estimated time required for the determinations and duration of the study.

The requesting researcher commits to adhering to the ***Guide for External researchers Requesting Sample Sharing Collaboration with the PREDIMED PLUS Study (Appendix 6)*** and:

***The undersigned PI hereby commits to the following principles:***

- To maintain the confidentiality and privacy of the data and refrain from making any attempt to identify the records (IDs) of individual patients
- To maintain the security and integrity of the samples, ensuring that transport takes place under appropriate conditions of freezing/refrigeration and storage
- To use the samples exclusively for the determinations approved by the PREDIMED PLUS study, with no permission to perform additional determinations or to transfer samples to other researchers
- To return any remaining samples after the determinations have been completed, under optimal conditions of preservation

- To submit the results from the sample analyses no more than 2 years after the samples are received; in exceptional cases it will be possible to request an extension
- To provide the data corresponding any papers produced using the determinations from the requested samples to the PREDIMED PLUS nodes that provided the samples used for the determinations, at the time when the paper is being sent out for review
- 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 incorporate those data
- To establish the pertinent collaboration agreements with the researchers who will subsequently perform data analyses using resulting determinations
- To follow the publication policy and data management and sharing plan for the PREDIMED PLUS study

Date:

Full name of requesting PI:

Signature of requesting PI: