

## <u>Appendix 3</u>: Request form for collaboration of external researchers with the PREDIMED PLUS study to gain access to data generated during 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 outside researcher is requesting collaboration with researchers from the PREDIMED PLUS study:

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

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

- List the variables being requested, and the number of participants for which data are required. For a meta-analysis of aggregate data in which the raw data for the variables are not required, the variables being requested must also be listed. In this case, please indicate that the request involves aggregate data, and specify the detailed statistical models as well as the control variables to be used:

- Specify how this external collaboration will contribute to the PREDIMED PLUS study (funding, articles, projects, etc.):

The requesting researcher commits to adhering to the *Guide for External Researchers Requesting Data Sharing Collaboration with the PREDIMED PLUS Study* (Appendix 4).

## 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 of individual patients.
- To ensure the security and integrity of the data received, keeping the file in a location that is secure and protecting it against alteration or copying of the data or distribution of the data to other persons.
- To submit the syntaxes used for the data analysis.
- To follow the publication policy and data management and sharing plan for the PREDIMED PLUS study.

Data Management Plan and Data Sharing Policy (Appendix 3) 1 May 2018

• To establish the pertinent collaboration agreements with the researchers responsible for the specific variables requested.

Date:

Full name of requesting PI:

Signature of requesting PI: