APPLICATION FOR EXTERNAL COLLABORATION "GUIDELINES"

I. PROPOSE OF THE GUIDELINES

- to contribute to research with high scientific quality
- to contribute to rapid publication of important results from the study
- to make data for research purposes easily available

II. WHO CAN APPLY FOR ACCESS TO DATA?

Researchers who have an interest in using data for research purposes can apply for access to data. Any delivery of data will be considered as a sub-project in INMA Project. The applicant has to be affiliated with an institution with competence in conducting research projects that is willing to be responsible for a sub-project. Inexperienced researchers must have a scientific supervisor belonging to such an institution. All sub-projects must have a principal investigator with scientific responsibility for the project. For each sub-project, a contract will be signed.

III. HOW TO APPLY FOR ACCESS TO DATA

To apply for access to data in INMA Project, the electronic application system for this project should be used. Our "*Application for external collaboration. Data analysis request form*" should be used. All applications should be sent to inma@proyectoinma.org. More information about access to the data can be found on our website (www.proyectoinma.org/en/) under "Publish with us" section (bottom of the website).

IV. WHAT KIND OF ACCESS IS GRANTED

Access is granted to data from the INMA Project database. For detailed information about the content of the database please study the project design (http://www.proyectoinma.org/presentacion-inma/en_diseno.html) and check the general summary of the data available from the INMA Project (www.proyectoinma.org/en/inma-project/inma-collaboration-policy/). The INMA Project database contains questionnaire data filled out by the participants in the study as well as additional data from sub-projects and linkages. Only data without personal identifiers are handed out. No exclusive rights to the data are given. However, exclusive rights to publish on specific research questions for a limited period of time are granted.

Decisions on applications for access to quality-assured data that already exists in the database can be made without delay. Applications for data that are not yet collected or not in a quality-

assured state will, as the main rule, only be registered as an interest, and any application will be handled at a later point in time.

V. WHAT SHOULD BE INCLUDED IN THE APPLICATION?

This is thoroughly described in the application form. The applicant should specify the objectives, institution, responsible person, co-workers, title and purpose, and include a short description of the sub-project. This description should be brief and start with the background for the project and the reasons for the choice of research question. Each research question should be formulated in one sentence with individual sentences for sub-questions if necessary. The application should also contain a time schedule, a publication plan, and a budget.

The dataset to be analyzed should be described. The specific dependent variables (outcome) applied for should be stated, as well as the independent variables (main exposure) and confounders (covariates).

Necessary attachments:

- Scientific project proposal (protocol)
- Description of variables
- CV of the principal investigator for the last 5 years
- List of planned publications with a short description of their objectives
- Copies of permissions from regulatory bodies

The application should be written in English. Uncompleted applications will not be processed.

INMA Project must be informed of all changes in approved projects (inma@proyectoinma.org), and the changes must be approved by the INMA Executive Committee before any manuscript is submitted.

VI. CONSIDERATIONS TO BE TAKEN INTO ACCOUNT WHEN ACCESS TO DATA IS GRANTED

The research question(s) must follow the purpose of INMA Project as described in the protocol. In addition, the following criteria apply:

- Scientific quality and originality
- Scientific environment surrounding the applicant
- Usefulness for preventive or curative medicine
- Scientific, administrative, practical, and economical contributions to the planning and/or the collection of data in INMA Project

VII. WHO DECIDES?

The applications are received and controlled by the staff of the INMA Project, and are processed and approved by the INMA Executive Committee (in contact with INMA subcohort). In specific cases, outside experts can be consulted. The decision to accept or reject a proposal for a sub-project is taken by the INMA Executive Committee.

In situations where more than one researcher are interested in the same research question, the researchers will be encouraged to collaborate, either on analysis and publication or by dividing the area of interest between each other. In cases where these solutions are difficult, the application that meets most of the conditions mentioned above will be chosen. As part of the coordination process, open scientific meetings around research questions of general interest will be held. These meetings are to be announced widely.

VIII. APPROVALS FROM REGULATORY BODIES

It is important that all research based on data from INMA Project meets requirements of privacy and research ethics, and all approvals must be available for the INMA Executive Committee before any delivery of data occurs.

IX. FINANCIAL CONDITIONS

All sub-projects have to pay a fee to get access to services reflecting true costs to the INMA Project in providing the requested resources. Costs are decided on a project to project basis in agreement with the INMA Executive Committee.
Document: "INMA Project services"

X. RULES FOR PUBLICATION

All manuscripts and abstracts must be sent to INMA Project (inma@proyectoinma.org) for reviewing before they are submitted for publication. The INMA Executive Committee will assess if scientific articles based on the INMA Project data is according to conditions in signed contracts on rights to analyses.
Regarding authorship, INMA proposes that each INMA subcohort participating in the manuscript is represented by 2 co-authors, if possible, and that according to the ICMJE (International Committee of Medical Journals Editors) guidelines, each co-auhtor will review critically its intellectual content and provide relevant contributions to both the proposal and the manuscript.

XI. ROUTINES IN CASE OF VIOLATION OF ACCORDANCE BETWEEN MANUSCRIPTS AND APPROVED PROJECT DESCRIPTION

In case of suspicion of violation of accordance between manuscripts and approved research questions from the project descriptions an INMA Project adviser will contact project investigator/manuscript author for clarification. If agreement between partners can not be achieved, and the case is considered as a break in the agreement the following reactions will be considered:

- A written notification will be sent to project responsible institute informing that the project investigator has overstepped the agreement of rights to analysis.
- A written notification will be sent to editors of journals where the manuscript has been submitted informing about the situation.
- Rights of analysis will be withdrawn from the project.

XII. CONFLICT OF INTEREST BETWEEN APPROVED SUB PROJECTS

In case of possible conflicts between approved sub projects, project investigators will be contacted and asked to inform the INMA Executive Committee about the situation. Project investigator will be responsible of contacting the projects where the conflicts on specific study objectives occur. Possible collaboration should be considered between sub projects. If agreement is not achieved the case will be sent to the INMA Executive Committee for further consideration.