HBM4EU science and policy for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Inserm
La science pour la santé
From science to health

Additional Feasibility Studies for Combining HBM and Health studies

First Internal Call for WP3

2018

This internal call is organised by INSERM along with the members of the managing board of HBM4EU

https://www.hbm4eu.eu/about-hbm4eu/

The documents for the call can be downloaded from

https://sp2013.inserm.fr/sites/eva/appels-a-projets/Pages/HBM4EU-WP3-%E2%80%93-Call-1-2018-.aspx

Online Submissions: https://www.eva3.inserm.fr/login from January 22th 2018

Deadline: March 2nd 2018

For further information, please contact: HBM4EU-WP3.desp@inserm.fr

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CONTEXT

HBM4EU is a joint effort of 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020.

The main aim of the initiative is to coordinate and advance human biomonitoring in Europe. HBM4EU will provide better evidence of the actual exposure of citizens to chemicals and the possible health effects to support policy making.

This internal call is part of the Annual Work Plan (AWP) of WP3 2017-2018 of HBM4EU. The organisational part of this internal call is entrusted to INSERM. The aim of this call is to establish feasibility studies, that assess the **opportunities and obstacles** encountered when combining two similar but still in some respect different survey types. Opportunities and obstacles are expected to include **practical/logistic, financial and scientific** benefits and shortcomings for many areas of survey organization such as:

- Sampling: including definition of sample size, selection of sampling frame and sampling scheme;
- Recruitment of invitees;
- Research ethics and data protection including obtaining ethics approval and informed consent;
- Data management; and
- Questionnaire design and administration;

For other areas such as requirements related for the collection and storage of biological samples, contents of the questionnaires, or included physical examination, differences exist. When requirements and/or protocols of two studies differ, decisions have to be made to find a balance between requirements. These decisions have to be justified and support the aims of the combined study. Feasibility studies are expected to be carried out in connection of already planned HBM studies or health examination survey (HES)/nutrition surveys to reduce costs related to establishment of survey infrastructure. It is expected that 4-5 studies will be carried out.

Sample size should be at least 200 persons and ideally 400 if feasible due to the available funds. HBM and health/nutrition studies are using very similar methods, which could be easily combined. Also for many quality assurance/control measures similarities can be seen between HBM and health/nutrition studies.

For HBM components, Standard Operating Procedures prepared by HBM4EU should be followed. For health components, especially physical measurements, European Health Examination Survey (EHES) protocols should be followed. Included questionnaire modules are:

- Socio-demographic status,
- Occupation and occupational exposure,
- Self-reported height and weight,
- Lifestyle questions on smoking,
- General health status,
- Use of medications,
- Minimum European Health Module,
- Dietary consumption,
- Home and household environment,
- Chemical specific questions.

The biological samples collected depend on the biomarkers to be measured, but at least blood and urine samples are collected. For physical health measurements at least anthropometric measurement and blood pressure should be included and some chemical specific measurements such as cognitive tests. More details about these will be provided in the AD11.2. “Criteria for feasibility studies”.

SCIENTIFIC ISSUES

Since this call is more focused on evaluation of a feasibility of data collection in different settings, scientific issues are more related to survey methodology than human biomonitoring. These feasibility studies will be designed so that they will, whenever possible, provide also data and samples which can be used for other WPs in their scientific questions.

OBJECTIVES

These feasibility studies will address following specific objectives of the HBM4EU:

- Harmonising and optimising the practices of national HMB programmes, including sample collection, quality assurance and data management through promotion of use of the HBM SOPs in the feasibility studies.
- Including new HBM data in the European Commission's Information Platform for Chemical Monitoring (IPCheM) through providing HBM data generated in the feasibility studies to the IPCheM.
- Promoting capacity building at national level through training and exchange programmes through training provided for organizers of the feasibility studies and support/coordination given to them.

Feasibility studies will also find out opportunities and obstacles for combing HBM studies and HES. If these two studies are combined, it should bring cost savings for survey organizers through common infrastructure and at the same time, more extensive dataset on health and health determinants to work on.

ELIGIBILITY

Countries with different previous experience and available infrastructures should be included to feasibility studies to ensure that as extensive experiences as possible will be obtained. In general, countries could be classified to following three categories:

- Country that has experience in organizing health studies with clinical measurements but has not conducted HBM studies previously.
- Country that has experience in organizing HBM studies but has not conducted health studies with clinical measurements previously.
- Country that has no experience in health studies with clinical measurements or HBM studies.

The fieldwork of feasibility studies should take place in 2019. This means that feasibility studies should be planned as part of the studies/surveys already under planning/preparation.

To obtain new information about opportunities and obstacles in combining HBM and HES in different infrastructures and national settings, **partners who have already conducted national studies/have national programmes combining these two modules will not participate**. All other consortium partners are eligible to participate if they have planned a HBM study or HES into which additional module could be included.

INDICATIVE DURATION

The planning of the studies should start at the end of 2018 and the actual field work should take place in 2019. The analyses of the biological samples for HBM and health biomarkers are expected to start already in 2019 and finalized in 2020.

INDICATIVE BUDGET AND COST COVERAGE

The indicative budget for this internal call is about 500 000 Euros. The feasibility studies is to run as part of already planned HBM or HES/nutrition surveys, **only additional costs related to incorporation of HBM or HES module will be covered by HBM4EU**. This would mean additional personnel costs related to collection of samples, administration of questionnaires, preparation of data etc., preparation (including translation) of questionnaires, obtaining required measurement devices/sample collection material, etc. **The costs related to the analysis of the biological samples for HBM biomarkers are not included to this call.**

CALENDAR

Diffusion of the call to HBMEU consortium	January 9th 2018
Opening of the submission platform (EVA3)	January 22th 2018
Deadline	**March 2nd 2018**
Results	July 2018

PROJECT SUBMISSION PROCEDURE

CONFIDENTIALITY

Inserm undertakes to preserve the confidentiality of all information acquired in the course of execution of the project notably that contained in the Activity Report, hereafter referred to as the "Information". Inserm is not allowed to disclose anything at all in any form to any third party (apart from the Cancer Plan Steering Committee) without written permission from the Coordinator.

Nevertheless, Inserm will not be bound to secrecy for a specific point of information if it can prove that:

- The information is in the public domain without there having been infraction of the grant agreement or the Rules;
- The information was already known to Inserm on the date of signing of the agreement;
- The information becomes freely available from some other source which has the right to it.

CHECKLIST FOR SUBMISSION

Before the coordinator (or single applicant) officially submits the proposal, the following points should be verified:

- the proposal fulfils the conditions set out in the call;
- the proposal (both the administrative form and Scientific file) is complete, legible, accessible and printable;
- the requested declarations have been made;
- all consortium members have signed the consent form which is in page 7 of the scientific file

SUBMISSION

Your proposal consists of an online administrative form and a scientific file. The scientific files need to be downloaded from our **EVA application** and filled. The filled in application shall be uploaded on our EVA3 submission platform. All applicants shall receive a confirmation by e-mail failing which the applicants are suggested to verify their submission as the submission was unsuccessful. If you have problems in submitting your proposal, please contact our our helpdesk at : **HBM4EU-WP3.desp@inserm.fr**.

The deadline for submission is 2nd March 2018.

WITHDRAWING A PROPOSAL

The coordinator can withdraw the proposal at any time before the call deadline, **2nd March 2018.**

ADMISSIBILITY CHECK

The proposals will be verified for their admissibility in terms of their compatibility with the framework of the call and general submission procedures. The work plan gives the standard admissibility conditions.

A proposal is considered administratively admissible if:

- Submitted online on our Electronic Submission System before the deadline, **22th January 2018**;
- Legible, accessible and printable.

Incomplete proposals shall be considered ineligible. This includes the requested administrative data, the proposal description, and any supporting documents specified in the call.

EVALUATION OF PROPOSALS

The proposals shall be evaluated with the help of independent external experts. The main criteria of our evaluation procedure are:

- **Excellence:** The projects proposed should be of high quality in terms of the topic and the call
- **Transparency:** Funding decisions are based on clearly described rules and procedures, applicants shall receive adequate feedback on the outcome of the evaluation
- **Fairness and Impartiality**: All proposals submitted are treated equally and evaluated impartially based on their merits, irrespective of their origin or identity of the applicants
- **Efficiency and Speed:** Evaluation, award and grant establishing procedures shall be done as quickly possible without compromising quality or neglecting the rules.

In order to ensure that proposals of high quality are selected for funding, we rely on **independent experts** for the evaluation of proposals. The experts are proposed by the HBM4EU Scientific advisory board (Experts with conflict of interests will be excluded).

We consider that a conflict of interest exists, if an expert:

- Was involved in the preparation of a proposal;
- Benefits directly or indirectly from the proposal if accepted;
- Has a close family or personal relationship with any person representing an applicant;
- Is a director, trustee or partner or is in any way involved in the management of an applicant;
- Is employed or contracted by one of the applicants.

Experts will receive your project title, abstract, the name of the participants and keywords in order to ensure their level of expertise and check their potential conflict of interest.

AWARD CRITERIA — SCORING — THRESHOLDS

Your proposal for the following award criteria:

- Excellence
- Impact
- Quality and Efficiency of implementation

For each criterion, your proposal will be given scores of 0 to 5 (half marks are possible),

- The proposal cannot be assessed due to missing or incomplete information;
- **Poor:** there are serious inherent weaknesses;
- **Fair**: the proposal broadly addresses the criterion but there are significant weaknesses;
- **Good**: the proposal addresses the criterion well but with a number of shortcomings;
- **Very good**: the proposal addresses the criterion very well but with a small number of shortcomings;
- **Excellen**t: the proposal successfully addresses all relevant aspects of the criterion; any shortcomings are minor

The evaluation process has **two phases**:

- Phase 1 — Individual evaluation by experts
- Phase 2 — Consensus of HBM4EU Scientific advisory board meeting

HBM4EU Scientific advisory board will rank the proposals that passed the threshold based on the expert's evaluation results. The grants will be awarded based on this ranking and the available funds for the year.