HBM4EU science and policy for a healthy future

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Annex 2 to D7.3

Fieldwork Manual Template

WP7

Task 7.2

D 7.3

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Authors and Acknowledgement

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1 Fieldwork Manual

1.1 Use and Objectives

Within a study, the Fieldwork Manual is the document to refer to during day-to-day business and also for the training of field staff (e.g. interviewers). It includes a detailed description of all steps of fieldwork and provides guidelines, checklists and instructions as well as Standard Operating Procedures (SOPs) to harmonise and facilitate the work of the field staff. It essentially covers all aspects necessary for the conduct of the study as far as they touch the direct involvement of the participants but also informs about the general objectives and procedures to enable the involvement of participants and to collect data and samples of high quality.

As HBM4EU is laid out to include several countries, it is important to note that every country has to develop its own Fieldwork Manual on the basis of the information provided with the documents of HBM4EU work packages. In some countries, adaptations might be necessary in order to account for national specifics, e.g. in some countries it is not allowed to distribute incentives to compensate the participants' burden, so the section on incentives has to be revised according to the national conditions.

However, adaptations should be kept to a minimum as the aim of HBM4EU is to harmonise the fieldwork procedures between countries to the greatest extent possible. All versions will be prepared in English, and have to be translated and adapted to national language(s).

The national Survey Office is in charge of preparing the Fieldwork Manual. It should start preparations at the very beginning of the study but updating whenever decisions have been taken is necessary up to the date the field staff shall be trained (and partly also thereafter). As it serves as a handbook to the study, everyone involved in the study (staff of the survey office, fieldwork team, data management team, etc.) should receive their own edition and everyone involved is responsible for pointing out need for updating to the Survey Office.

1.2 Structure

The idea of the Fieldwork Manual is to deliver a structured composition of the documents most important to the study. It essentially provides a handbook that collates both an in-depth description of how the study is planned out as well as all information necessary for conducting the fieldwork, such as master copies, checklists and questionnaires.

For practical reasons the Fieldwork Manual is structured in two main sections. Section I provides mainly detailed information on the respective study concerning its background and concrete details on ethics, data management and all fieldwork procedures etc. – as elaborated when preparing the Study Protocol but providing sophisticated details to enable the exact repeat of all procedures.

Section I can be structured identically to the Study Protocol (e.g. provided in the Concept for a Study Protocol, Table 4: Topics to be decided in Phase 0 of a study). For the template provided here we chose a slightly different structure to highlight that the focus of the Fieldwork Manual is providing information and documents for the field staff.

The second section (Section II) provides master copies, check lists, questionnaires and detailed SOPs for the procedures mentioned in Section I.

Following table gives an overview of a possible structure of a Fieldwork Manual.

Table 1: Overview of the contents of the Fieldwork Manual

Section I: Basic content of the Fieldwork Manual
1. Background and Benefits
1.1. Background of the study in the scope of HBM4EU
1.2. Objectives
1.3. Thematic Areas
1.4. Benefits for the individual participant
1.5. Benefits for the Public Health Service
1.6. Benefits for research
2. Study design, target population
2.1. Selection, sampling frame, recruitment
2.2. Inclusion and exclusion criteria
2.3. Definition of a case
3. Ethics
3.1. Information
3.2. Informed Consent
3.3. Revocation of participation and deletion of data
3.4. Data Protection
4. Project management and training
4.1. Responsibilities
4.2. Selection and training of field staff
5. Fieldwork
5.1. Time schedule for fieldwork and routes
5.2. Survey methods and instruments, e.g. all questionnaires and samples (types and handling of)
5.3. Plan of procedures for fieldwork, including all communication material, all details of involvement of the participants and provision of incentives
5.4. Quality assurance of fieldwork (training of field staff, field visits, quality assurance of sample handling)
6. Communication
6.1. Public relations
6.2. Activities to raise participation (FAQs, additional incentives)
6.3. Reporting results to participants
7. Data management
7.1. Databank for management and addresses
7.2. Data management system
7.3. Quality assurance of data handling and check
Section II: Annex to the Fieldwork Manual
(including check lists, master copies, pre-formulated letters, questionnaires, SOPs, etc. corresponding to the themes of Section I)

To give an example, the two sections of the Fieldwork Manual are briefly described below. Changes and adaptations for each single study are necessary as already indicated above. A more detailed description is offered in Chapter 2.

1.2.1 Section I: Basic content

The first section of the Fieldwork Manual can be structured e.g. in 7 main points that comprise the essential topics to address when conducting fieldwork (see Table 1 above).

The first topic (Background and Benefits) gives an overview of the study in the scope of the HBM4EU programme, provides details on the objectives and benefits on different levels (individual, public health and research) and elaborates on the thematic areas covered within the study.

Point 2 provides details on the design of the actual study, the target population, and the recruitment of individuals to achieve the desired amount of participants. Inclusion and exclusion criteria as well as the definition of a case, i.e. which data needs to be collected from a participant to involve him or her in the final data file, are to be described in detail here.

Ethics requirements are of utmost importance and an ethics approval is the essential prerequisite for a study including the collection of human data and samples. Therefore, it is appropriate to address these issues in a separate point (point 3). It includes detailed information on how (potential) participants are informed about the study, asked for informed consent, how they can revoke from the participation and if this has implications on them. Measures that have been taken to ensure data protection and accordance with ethics requirements are also described. The approvals of ethics and data protection authorities are mentioned.

The HBM4EU deliverables D1.5 ‘Legal and Ethics Policy paper’ and D10.1 ‘Data Management Plan’ including its annex should be read carefully and taken into account for point 3.

Before details of fieldwork are described, the management of the study is laid down under point 4 to inform about responsibilities for the different tasks. This is especially important if parts of study conduct are subcontracted. It also includes the responsibility and timing of training for the field staff.

The time schedule for fieldwork and routes, survey methods and all instruments (like questionnaires and samples) used as well as a detailed plan of procedure and information on quality assurance are elaborated on under point 5, Fieldwork. Single steps from first contact to fixing an appointment with the participant including all communication material, all details of involvement of the participants including e.g. furnishing of examination centres, provision of incentives and documentation of procedures like questionnaires and sampling are described in single sub-chapters.

Communication with the public (e.g. actions necessary in the different sampling locations) as well as special communication measures to raise the participation rate are reflected under point 6. These can be additional incentives or FAQ-list providing short arguments for participation. Data management including the databank for addresses and a data management system are described under point 7.

Quality assurance can be described in a separate point or detailed under the specific points.

1.2.2 Section II (Annex)

Section II of the Fieldwork Manual can also be called “Annex”. It is foreseen to include templates, master copies, SOPs, check lists and other material created for the conduction of the fieldwork for a daily use. These documents will be elaborated in the process of creating the Fieldwork Manual.

The documents sorted in the Annex simplify the standardization of all processes, e.g. the contact with (potential) participants or the actions the field staff has to take.

Following, some examples for Annex documents are presented:

- Approval of the ethics committee and the data protection authority
- Sheet indicating the duration of the fieldwork
- All communication material for the participants (invitation, information leaflet, reply card, reminder, informed consent, letter of thanks, results letter, incentives)
- Questionnaires –recruitment (inclusion/exclusion criteria)- basic, sample specific, satisfaction, non-responder (paper version in case the electronic version breaks down), Interviewer Manual with background information to the questions
- Drawing and handling of samples (for the participants and the field staff)
- SOPs for: - participant selection and recruitment; - fieldwork and quality assurance, sample reception and registration, sample handling, packing and shipment
- Routine procedures for fieldwork including a detailed process description, check lists for preparing the visit of the participants (at their home or at an examination centre).

2 Template Fieldwork Manual, Section I: Basic content

For each study, a Fieldwork Manual should be developed. The more detailed it is the more it serves the identical repeat of all processes of the study which contributes greatly to the high survey quality necessary for reliable data.

Provided herewith is a short description (partly bullet points) of what could be written in the chapters of Section I of a Fieldwork Manual. The documents for the Annex (Section II) result directly from the described chapters.

2.1 Background and Benefits

In this chapter, the focus should be on briefly introducing the study. This includes explaining what it has to offer in terms of aims and thematic areas, but should also elaborate on how and why this particular study was set up and how it relates to the overall HBM4EU objectives.

In the following chapters some examples are provided in bullet points and have to be elaborated appropriately for each study.

2.1.1 Background of the study in the scope of HBM4EU

- history of the countries studies in which this one is embedded
- relation to HBM4EU
- design and scope, etc.

2.1.2 Objectives

The study has the objective of providing current population representative data on the environmental pollution of people in the country.

The current data collected in the study also serves for:

- the identification and quantification of pollution sources and paths,
- as the basis for the derivation of reference values about the burden of the population to environmental pollutants, which then form the basis for a nationwide uniform assessment and will also be used as a European scale by EU-wide studies,
- the depiction of temporal trends in the burden,
- the identification of especially burdened groups,
- the examination of possible influences of particular environmental factors on the health situation,
- the evaluation of prevention, intervention and minimisation strategies within the scope of health and environmental measures.

2.1.3 Thematic Areas

The study program comprises the following components:

A) Human biomonitoring (HBM) on all participants:

- Whole blood, serum, plasma
- Morning urine samples (total amount of urine that is discharged in the morning); sampling is carried out by the participants themselves.

B) Interview-monitoring with all participants (face-to-face interviews, questionnaires for self-completion)

- The personal and written questioning includes standardised questions for detecting potential burden pathways for interpretation of the measurement results and of exposure-relevant behavioural patterns. Further, topic constellations such as environmental justice and environmental health problems are taken into consideration.

2.1.4 Benefits for the individual participant

- The analyses performed are, in some cases, very cost-intensive and are not a part of the normal analysis program which is offered by private practitioners.
- The study provides valuable information about their personal environmental exposure and their potential risks and information about how to reduce the pollution burdens.
- Participants receive, if they so desire, an environmental-medicinal evaluation of the measurement values
- The participants contribute significantly to a clarification of the individual-related environmental pollution of the population of the country and thus personally make an important contribution to research in the fields of environment and health and in health and exposure monitoring.

2.1.5 Benefits for the Public Health Service

- Results deliver a reliable assessment of the actual exposure situation for people in the country and enable federally uniform ratings of pollution burdens.
- The derived risk mitigation measures and information benefit the general population.
- Reference values for the corporal pollution burden of the general public (overall and stratified by age groups) are derived, indispensable for the assessment of individual situations and in the classification of results from local and time-limited environmental health studies.

2.1.6 Benefits for research

- The study will provide first insights into toxicological or health important substances to which the population may be increasingly exposed.
- The study updated essential basic data for estimation of the environmental pollutant exposure of people in the country.
- The data obtained will support future environmental-epidemiological studies and reinforce the scientific basis of governmental risk assessment.
- The data will be made available to the public and interested scientists as a "public use file".
- These analyses are an important first step to the generation of new hypotheses in environmental-related health protection and for prioritising research questions in longitudinal studies.

2.1.7 Other benefits

- There can also be benefits for institutions beyond the public health services. Other institutions with a focus on chemical regulations, risk assessment, environmental safety and/or food safety could potentially also use data or research conclusions from the study for their tasks.

2.2 Study design, target population

The design of the study and the rationale behind choosing this design should be explained in this paragraph taking the target population and aims of the study into account.

2.2.1 Selection, sampling frame, recruitment

A general overview of the sampling frame (i.e. the list of the target population units from which the sample is drawn) and the envisaged sample size is provided here, and how a random sample will be achieved. For example, a description is provided of the procedures to select 150 males and 150 females between 20-40 years who are envisaged to participate in a pre-selected geographical area. Therefore regional population registers will be approached to provide a list of adults of the selected age-group. The recruitment procedure through the approach via registries is described and additionally how the participants are approached individually (Fieldwork I).

2.2.2 Inclusion and exclusion criteria

This paragraph elaborates briefly on inclusion and exclusion criteria for the participants, e.g. exclusion of hospitalized individuals. It is useful to list these criteria separately to avoid misunderstanding during the recruitment process.

2.2.3 Definition of eligibility

Here it should be defined what data and samples collected are required in order to count a singular participant as eligible for the study case.

2.3 Ethics

In advance to setting up this section concerning ethics, it is required to consider the following HBM4EU ethics documents:

- D1.5 Legal and Ethics Policy Paper,
- D17.1 – D17.6 Ethic requirements (see Grant Agreement number 733032; page 111 of 128),
- First, second and following Ethics reports (see internal webpage work package folder/scientific and administrative management/WP1).

Task 7.5 has developed a template for the informed consent (see Deliverable 7.4).

2.3.1 Information

A short description is offered how participants are informed about the study and its background and objectives, e.g. when they are informed about the study, which (written?) material is provided to enable an informed consent.

This paragraph further includes the addressee of the application of the ethical approval for the study, the date of approval as well as a short description of the content concerning the reporting of results to the participants.

2.3.2 Informed Consent

A more detailed description of the declaration of informed consent for study participation is given, when it is provided, what it consists of, who (e.g. parents or children?) has to sign it. It is important that the participants also consent to that information and that samples are sent to other countries (at least within the EU). This often has to be stated separately.

2.3.3 Revocation of participation and deletion of data

Describe here how participants are informed how they can revoke their participation (complete or partial revocation of participation) and how and which steps need to be taken if such a revocation arrives to the field staff or Survey Office also concerning the deletion of addresses and already collected data. Also a hint to a respective SOP is advisable.

2.3.4 Data Protection

This section elaborates on details regarding data protection such as the addressee of the data protection concept for the study and the date of approval. In short, it should be described how participants were informed about data protection and the main statements. If applicable also describe how subcontractors are dealt with.

2.4 Project management and training

2.4.1 Responsibilities

It is essential to note down the different responsibilities and the names of the involved persons for the management of the different study parts, especially if a study is run by different partner institutions.

2.4.2 Involved personnel, their tasks and training

It is also recommended to describe in detail who is responsible for which single task, to warrant that all responsibilities are laid down. Expertise and criteria for hiring field staff shall be listed and information on training activities provided.

2.5 Fieldwork

2.5.1 Time schedule for fieldwork and routes

In order to provide a precise overview, the total runtime as well as the dates of beginning and end of the fieldwork phase should be named in this section. If there is no defined end date set, an estimation is also sufficient.

Further, it is recommended to list here the time planned in per sampling location.

For people of all age groups, but especially school children, holidays and vacations need to be considered when setting up a time plan. Possible seasonal differences should be balanced out within the time schedule for fieldwork.

2.5.2 Survey methods and instruments, questionnaires and samples

This section goes into detail regarding methods and instruments used to collect data.

If one or more questionnaire is planned to be used, the questionnaire(s) and all its parts and possible annexes are described and explained here. This includes the description of the format (self-administered, CAPI, etc.) and the explanation of the content as well as the most important points regarding handling of the questionnaire done by the interviewer. Additional questionnaires such as satisfaction questionnaires are also elaborated on under this headline.

Further, this section includes a description of all sample types (e. g. urine, blood, drinking water, etc.) taken and gives a rough introduction on how they are taken. Additionally it informs about the further processing of all samples collected, how field staff has to handle them e.g. how they are transported to the lab or another place for storage, etc.

2.5.3 Plan of procedures for fieldwork

The plan of procedures is foreseen to describe in detail every step taken starting with the contact to the participants up until the samples are handed over or send off for analysis. If fieldwork comprises many parts providing a flowchart may facilitate the overview. This allows for an in-depth insight in every step and can often not only promote the comparability within the fieldwork staff but also answer questions arising at the sampling location. It also addresses the incentives provided to the participant directly after being involved in the study.

Such a process could be described with the following chapters:

1) Contact phase, including recruitment of individual participants and transmission of address and contact data, the communication material for the participants (invitation, reply card, reminder (letter and/or call), Appointment confirmation and despatch of sample materials), (Fieldwork I), Procedure with foreign-language participants, contact by the interviewer at the sampling location

2) Prior to the sampling location visit: description of all what has to be done prior to the visit of the location (see Concretisation Phase of the study protocol)
3) Arrival at the location: description of all what has to be done by the field staff when they arrive at the sampling location
4) Before home visits: description of all what has to be done by the field staff the day before the visit of the participant, e.g. a phone call to remember on the visit and preparation of all that is necessary for that visit
5) During home visits: Description of the whole procedure of the visit of the participant home (or at an examination centre), including acceptance of the informed consent, the interview, the sampling, the handing over of incentives
6) After the home visit: description of what has to be done when the visit is finished, like sample transport, transmission of data and return of material that can be reused.

2.5.4 Quality assurance of fieldwork

To assure the quality, systematic observations and assessment if quality standards are upheld can be put into place. An independent assessment of the measures taken for quality assurance shall also be set up. It is highly recommended to keep in mind the guidelines for good epidemiological practice (https://dgepi.de/fileadmin/pdf/GEP_LL_english_f.pdf). Additional information provides SOP 2 Quality Assurance (QA) for Recruitment and Fieldwork (see Deliverable 7.3 Annex .2.2.2)

In here, it is further described how fieldwork is quality assured.

- Will there be field visits from study-internal or external personnel?
- Is extra training of the field staff foreseen, what can be a reason for extra training?
- How is the quality of the samples assured?
  - Frequency of temperature control,
  - Check lists for sample handling.

2.6 Communication

2.6.1 Public relations

Describe here the strategy for public relation and information of the general public in order to communicate the aims and potential output of the study. Describe the aims of these activities and the organisational responsibilities for these activities. Activities could be:

- Publication and continuous updating of a website informing about the survey
- Establishment of a hotline for questions from both participants and the public
- Information of local authorities about the conduct of the study in their area
- Documentation of (local) publications about the study
- Interviews with different types of media (press, radio, TV, etc.)
- Tweets and posts on social media such as Twitter and Facebook
- Scientific publications and representation at conferences

2.6.2 Activities to raise participation

A high participation rate is of utmost importance for representative studies, therefore the field staff has to be able to communicate the objectives of the study to best inform potential participants.

Providing answers to frequently asked questions is a widely used communication tool. Answers should be provided already at the start of the study e.g. for the study web page but can also assist the argumentation for the interviewers.

Examples for such questions can be:

- ‘I don’t have time to participate.’
- ‘What is the purpose of this survey?’

- ‘Why did you choose me?’
- ‘What do I get from participating?’
- ‘How much time do I have to spend on this?’
- ‘What happens to my data?’
- Will I get my individual results – and when?

A frequently used measure to raise participation is the provision of incentives. Which incentives will be offered to potential participants, when and how should be described here.

2.6.3 Reporting results to participants

This section is likely to vary between countries as it is closely interlinked with the ethics approval. Results can be reported as a whole or in parts, they can include commentary and explanations or they can be blank and other fulfil requirements that can be different across country borders.

Here, the process of reporting results to the participants should be elaborated on, including how they are informed (in person, via letter, via phone call, etc.) and what they are presented with.

2.7 Data management

All information and templates regarding HBM4EU Data Management should be considered when setting up this section. They are available via https://www.hbm4eu.eu/data-management/. The helpdesk on data management is available to support and advice you in data management related tasks of WP10 (internal webpage: https://www.hbm4eu.eu/privatehelp-desks__trashedwp10-help-desk/).

2.7.1 Databank for management and addresses

For the control and documentation of all steps of the fieldwork a database should be developed. Its use and functionalities and the rights to access it should shortly be described here.

2.7.2 Data management system

If a study consists of different parts which are in the responsibility of different partners it may be advisable to establish a data management system, this should be described here as well as the main functionalities and access rights. Timing of data transfer between the partners should also be described here.

2.7.3 Quality assurance of data handling and check

Without being thoroughly checked, no data can be reported to anyone or merged with other data. Whenever data is collected it has to be cross-checked for correctness and validity. This section should inform about measures taken to assure data quality.