



science and policy  
for a healthy future

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## **Annex 2.2.2 to D7.3**

### **SOP 2:**

### **Quality Assurance for Recruitment and Fieldwork**

#### **WP 7**

#### **Task 7.2**

#### **D 7.3**

**Version 2.0**

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# 1 Introduction

This guideline is intended to be used in the framework of the Human Biomonitoring Initiative (HBM4EU). HBM4EU has the aim to establish a European human biomonitoring platform and to fill knowledge gaps in representative exposure data. HBM4EU supports the countries with several documents heading for a harmonisation of study conduct to facilitate generating European reference values. This SOP, together with other documents, is part of the Deliverable 7.3 on study design focussing on recruitment, fieldwork and sampling and is complemented by deliverables focussing on other parts of study conduct like ethics, analytics and data management provided by other work packages.

This SOP provides a short overview on actions and documents that serve quality assurance in HBM studies.

Fieldwork of high quality is essential for receiving results that can be used for international comparisons between studies and over time. An improved instrument for such documentation is a so called **Fieldwork Manual**. It includes a detailed description of all steps of fieldwork and provides guidelines, checklists and instructions as well as Standard Operating Procedures (SOPs) during day-to-day business.

High quality of fieldwork is also closely connected with the ability of the interviewers to perform the interviews in an appropriate way. To put emphasis on this, the training of the interviewers is addressed in the second part of this SOP. Special background information to facilitate the interviewers' work is provided in the **Interviewer Manual**.

Another important part of quality assurance is quality control. **Quality control measures** encompass internal and external quality control, which are both necessary as it is the interest of all partners involved that fieldwork is performed in a harmonised and correct way. To warrant this, fieldwork has to be controlled and checked: the way to do this is described in the third part of this SOP.

Additional to the three above mentioned guidelines, SOPs for the Selection of Participants and Recruitment and specimen sampling are provided in the Annex 2.2 to Deliverable 7.3, an SOP for the exchange of biobanked samples is provided in Annex 1 to Deliverable 7.2. Any other SOP necessary for a proper conduct of a study in a selected country can be added to the Fieldwork Manual by the specific country.

## 1.1 Fieldwork Manual

The Fieldwork Manual is the most important document for the quality assurance of a study. Typically, the Fieldwork Manual for each study is prepared by the Survey Office at the very start of the study and is then used as a handbook throughout the phases of a survey. Because of its importance, a template for a Fieldwork Manual is included as Annex 2 in Deliverable 7.3. This template provides an overview about the most important points of fieldwork which should be described exhaustively to enable a repetition of the single tasks in exactly the same way. This template can only be an example as each study is different and requires individually prepared documents.

It is recommended that the unit responsible for each study starts preparing a Fieldwork Manual as soon as main decisions on the way the study shall be conducted are taken. A Fieldwork Manual is a "living document" until all procedures, steps and material are fixed. When it is finished, it is the main background document for all persons who have to be trained on the study. Feedback of the trainees should be integrated to update the Fieldwork Manual in the course of the study.

A well-elaborated Fieldwork Manual can also serve for regular quality checks of all procedures and builds the background for a subsequent study.

## 1.2 Training of the interviewers - Interviewer Manual

If a face-to-face interview is foreseen to be one of the instruments of the study it is important that the interviewers (it is advisable to employ more than one interviewer) all act equally as they are the ones who generate the requested data. To avoid an interviewer bias interviewers have to be trained on the content of the study. It is an asset if experienced interviewers can be engaged but still they have to be trained especially for each planned study. Basis for this is the Fieldwork Manual and training with fieldwork experts. It is important that the interviewers practise the conduct of the questionnaires and all parts of the home visit and sample taking (if applicable). Conducting test interviews is a perfect way to become familiar with the questionnaires. These test interviews should follow the exact procedure of the real interview, including the acceptance of the informed consent as the very first action when they meet the participant, the interview itself, the acceptance or taking of samples and the successful ending of the meeting, e.g. with a letter of thanks or a certificate and other incentives. It shall also be trained how to perform the interviews and on the demeanour of the interviewers.

Additionally to training on the interview situation directly, interviewers also need to understand the background of each question and memorise a way to react in case the participant does not understand a question. To this end, an Interviewer Manual to accompany the basic questionnaire developed for HBM4EU's first priority substances was created and can be found in the Annex 2.1.2.

To maintain quality during fieldwork it is advisable to compare once in a while the answers given to the different interviewers to some questions susceptible for interviewer bias. If a bias can be detected, another training and/or a different way of questioning has to be considered. In addition, interviewers are asked to keep a log-book. Positive and negative experiences shall be written down in the log-books and be exchanged with the other interviewers and with the members of the survey office to allow learning from each other.

At the beginning of the study already, criteria for quality targets have to be set and also include a guideline how to deal with potential errors. Both aspects are required to be part of the interviewer training.

If a study does not use a face-to-face interview there still will be a field team. Also these personnel has to be trained on all the procedures of the study – this can also be done with the Fieldwork Manual as background document for main study procedures and the Interviewer Manual as background document for the questionnaire.

## 1.3 Quality control measures

Quality control measures have to accompany all steps of study conduct. The main aim is to avoid and reduce mistakes. For this purpose, strategies to find mistakes in advance have to be applied. Fieldwork Manual, Interviewer Manual and SOPs shall be developed to avoid and reduce mistakes. These guidelines can also support to find mistakes if the correct performance is analysed on basis of these documents. Check lists to facilitate the control of the fieldwork can be developed, but they have to be adapted to the study in question. Internal quality control is done by the interviewers themselves, for the external quality control external controllers (e.g. from the survey office or especially hired ones) are necessary.

As already mentioned, proper handling of mistakes is important. Every error that has been detected in the process of control has to be documented and corrected immediately. Reasons for mistakes have to be evaluated by the survey office, a viable solution has to be found and the problem and its solution have to be communicated. If necessary, the respective parts (pages) of the Fieldwork Manual have to be updated.

### 1.3.1 Internal quality control

The goal of internal quality control is to ensure that every step of fieldwork is overseen (mostly) by the staff member in charge of performing the fieldwork her- or himself. Checklists are used to support training of the field teams.

These internal checklists should i.a. include:

1. Before start of field work check
  - of the transferred material/equipment necessary for conducting fieldwork
  - if all appointments for the sampling location have been fixed in advance and are compiled in the visit schedule
2. Before a home visit (resp. at centre) check:
  - the necessary documents to bring along
  - if everything required for a home visit has been adequately prepared
3. After a home visit (resp. at centre) check:
  - all documents: has everything been filled out and have all samples been taken, labelled and handled correctly?
  - have experiences been written down in the log-book?
4. Between home visits (resp. at centre) check:
  - function of the hot line, handling of last minute cancels, handling of the samples, data management etc.
5. At the examination centre check:
  - rooms and equipment of the examination centre

### 1.3.2 External quality control

External quality control is usually performed by institutions without involvement in the survey, e.g. other universities or private institutes to control the procedures. Especially for large population studies such an external control is essential. In smaller studies “external” quality control (or field visits) include the control of work of the field team members by researchers from the Survey Office responsible for the survey.

External quality control refers mainly to the conduct of the interview or the whole procedure in the context of a home visit. All steps laid down in the Interviewer and Fieldwork Manual can be used for a check, including the correct appearance and demeanour of the interviewer.

## 2 Related documents

Fieldwork Manual (see Annex 2 of Deliverable 7.3)

Interviewer Manual (see Annex 2.1.2 of Deliverable 7.3)

Other SOPs (see Annex 2.2 of Deliverable 7.3 and Annex 1 of Deliverable 7.2)