



science and policy
for a healthy future

HBM4EU project

A structured approach to the
HBM4EU harmonized study
protocol for reference values

Ulrike Fiddicke

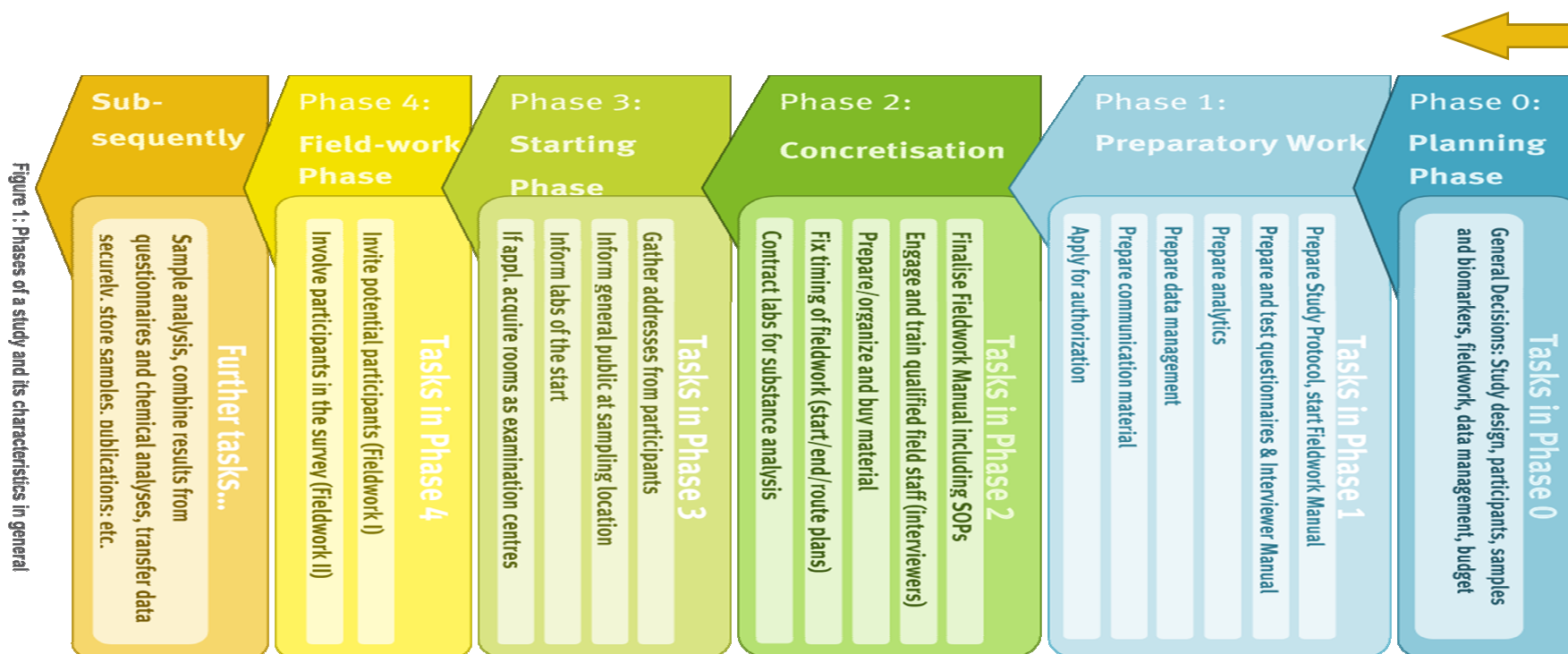


1st HBM4EU Training School 2018

Session 2: Orientation on the design of
HBM4EU studies



Concept for a Study Protocol for HBM studies



Timeframe for a study with 1 year fieldwork



Topics to be decided on in Phase 0

1. Study design and biological samples	<ul style="list-style-type: none"> • Aim for representativeness (sample size) • Type (cohort, case control, cross-sectional?) • Timing, Duration, Follow up? • Substances and their biomarkers • Matrices, sampling time • Sample volume • Biobanking • Ethics and data protection • Data management 	<ul style="list-style-type: none"> • Session 2 • Session 4 • Session 4 • Session 4 • Session 4 • Session 2 • Session 3
2. Selection of participants	<ul style="list-style-type: none"> • Target population • Sampling frame • Geographical distribution • Inclusion / exclusion criteria 	<ul style="list-style-type: none"> • Session 2 • Session 2 • Session 2 • Session 3
3. Recruitment and Fieldwork I (individual recruitment)	<ul style="list-style-type: none"> • Communication • Approach to address holder • Method and frequency to approach participants 	<ul style="list-style-type: none"> • (Session 7)
4. Fieldwork II (investigation of participants)	<ul style="list-style-type: none"> • Instruments to be applied (Questionnaires, Samples (blood, urine, indoor air, drinking water, etc.)) • Place of direct contact to participants • Questionnaire(s) application • Sample collection and further processing including sample conservation and shipment • Selection of the laboratory • Incentives 	<ul style="list-style-type: none"> • Session 3 • Session 3 • Session 4 • Session 4

Phase 0: Decisions to be taken

1. Study design and biological samples

- Type (cohort, case control, cross-sectional?)
- Timing, Duration, Follow up?

Timing Date? Which time of the year? How many seasons?



Source: coco / Fotolia.com



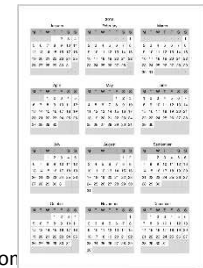
Source: Sunny Studio / Fotolia.com



Source: Stefan Körber / Fotolia.com



Source: Olga Lyubkin / Fotolia.com



Duration Time necessary to conduct the main instrument and all instruments?



Source: UBA



Source: Fotolia.com



Source: angellodeco / Fotolia.com



Source: UBA



<https://dokuwiki.noctri.edu/lib/exe/fetch.php?media=ger:203:2013:spr:uhr.jpg>

Follow-up Will the participants be revisited?



Source: Oksana Kuzmina / Fotolia.com



Source: yanlev / Fotolia.com

<https://catercomm.com/2017/04/10/art-of-follow-up-pitch/>
The Art of the Follow-up Pitch, posted on April 10th 2017 in Journalists on PR & Pitching & PR



Phase 0 - Alternatives Timing/Duration

	Alternatives	Pros	Cons
Timing/ Duration of fieldwork	<i>Within one season</i>	No seasonal bias; early results	Organisational effort in case of many participants and face-to-face interviews
	<i>Covering some seasons</i>	Organisation convenient for field staff	Seasonal bias
	<i>Covering all four seasons</i>	Seasonal bias can be avoided through logistic measures and a long fieldwork phase	Long lasting study; organisational effort to avoid seasonal bias
Time for answering the main questionnaire	<i>Short (30-45 minutes)</i>	Concise questionnaire for small range of topics/substances	Hardly possible with face-to-face (F2F); no details; narrow range of topics
	<i>Medium (60-80 minutes)</i>	Main questions can be asked in sufficient detail	Some details and topics might not be addressed
	<i>Long (90-100 minutes)</i>	Comprehensive inquiry for several topics/substances possible	Patience of not highly interested participants is stressed
Time for whole participant involvement (if not web- based)	<i>Short (45-60 minutes)</i>	Low participant burden	F2F: Limited questionnaire + urine sample specifics only
	<i>Medium (80-100 minutes)</i>	Concise questionnaire + urine sample specifics	Participant burden
	<i>Long (90-120 minutes)</i>	Comprehensive questionnaire + urine sample specifics + other samples	Patience of not highly interested participants is stressed (may evoke refusal: "no time")

Topics to be decided on in Phase 0

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Phase 0: Decisions to be taken

3. Recruitment and Fieldwork I (individual recruitment)

- Communication
- Approach to address holder (Sampling frame)
- Method and frequency to approach participants

Communication: Flyer, Invitation, Reminder, Letter of thanks, Results letter → Task 7.5
WP2 → Website, Newsletter, etc.

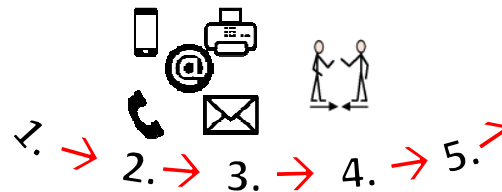
www.hbm4eu.eu



MOH-CY:
Andromachi
Katsonouri;
D7.4

Approach to address holder: public registries, school lists
Telephone directories, households of selected city quarters

Method and frequency
to approach participants:



<https://pixabay.com/nl/juichen-gelukkig-springen-mensen-297420/>

Adapted from: Graphic by [Mathew Callaghan](#) on 23/03/2014 is licensed under a [CC BY 4.0 license](#).



Robert Rexach
www.mkt3000.com



TUBS - Based on [OpenStreetMap Data](#) (© OpenStreetMap and Mitwirkende, CC-BY-SA) Stadt Karlsruhe Hrsg. v. "Stadtgebiet und Flächennutzung, In: Jahrbuch 2009, 2009."



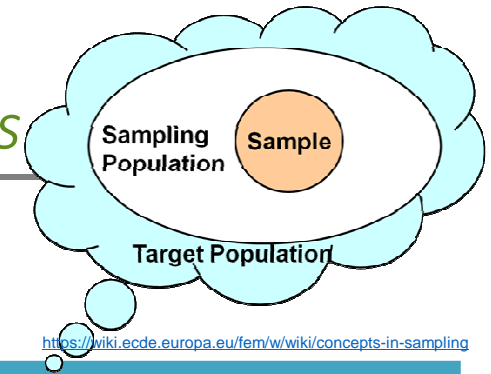
Groksurf's San Diego by George J Janczyn is published under a [Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License](#).

1st HBM4EU Training School, Ljubljana, June 18-22, 2018

Phase 0: Recruitment of participants

→ 1. Approach to participant address holders

Prerequisite: Selection of sampling frame:
„best list of registered units/individuals“



Sampling frame /Address holder	Approach for first contact
Registration offices (population registry)	
Telephone lists (internet, organisations)	Holder of list (contacted via formal letter)
Mail address lists	
Residential telephone numbers	Potential participants
Households (maps)	Potential participants (via visits in selected areas)
Physicians/Doctors/Midwives Hospital/Clinic, etc.	Contact Confidant/ Head of institution via formal letter or personal visit
Kindergarten /School	1. Education authority of the city/county 2. Contact head of institutions via formal letter, call or personal visit
Work place	Contact head of entity (employer) via formal letter, call or personal visit



Phase 0: Recruitment of participants

→ 2. Contact potential participants



<https://pixabay.com/nl/juichen-gelukkig-springen-mensen-297420/>

Sampling frame /Address holder

Registration offices (population registry)

Telephone lists (internet, organisations)

Residential telephone numbers

Households (maps)

Physicians/Doctors/Midwives
Hospital/Clinic, etc.

Kindergarten /School

Work place

Invitation of the potential participant via

Formal letter

Telephone call

Telephone call random digit dialing

Personal visit

Formal letter handed over by trusted person (physician), personal visit, (email ?), (telephone?), information event

Formal letter to parents and or child, information event for parents

Formal letter to employee, information event

Topics to be decided on in Phase 0

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Phase 0 – Fieldwork II

4. Fieldwork II (investigation of participants)

Place of direct contact to participants

Incentives

Place of direct contact to participants: at participants home (“in-home”), in selected examination centres e.g. rooms in schools or in the town hall; in a mobile lab



Source: Kaarsten / Fotolia.com



Source: Bernd Kreuscher / UBA



Source: Christian Schwier / Fotolia.com

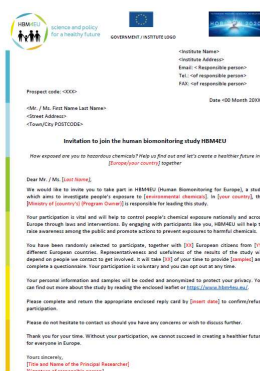


Source: Lars Steffens - Würzburg



Source: UN -Mobile labs to provide HIV/AIDS tests in Abkhazia / flickr.com

Incentives: information, monetary, non-monetary, small gifts, certificates



Source: UBA, GerES V



source: photo 5000 / Fotolia.com

Phase 0: Alternatives for place of direct contact to participants

Alternatives	Pros	Cons	Recommendation for different target groups
At home or work place	Convenient for participants	At home: privacy touched (loss of participants), blood sampling not suitable	Provide always both options if possible
At examination centre/clinic	All equipment at one place, no transport needed	Inconvenience for the participants; in rural areas sometimes long distances / difficulties to reach	
In a mobile lab placed centrally	Good reachability for rural areas, handling of preanalytics on site	Expensive maintenance	Use, if available



Phase 0: Incentives

Type of incentive	Organize incentives and other measures to increase the participation rate
Information	Raise interest and awareness, offer information on study and general results, direct mailing, home visits, provide individual results and advice
Non-/monetary	Reimburse participants for travel costs and/or for spending time and samples
	Offer cash payments or in-kind payments (small gifts)/ certificates tailored to the study (logo!) and to target groups for taking part
Support recruitment	Choose suitable recruitment places (schools, work)
	Reduce the administrative burden of address holder (e. g. GPs) to encourage them to recruit participants
	Link HBM study to ongoing routine surveys etc.
Staff as promotor	Sustain staff commitment to the research through continuous training
Evaluation	Identify barriers to participation, non-responder questionnaires, comparison to target population
	Administer a reduced assessment battery

Phase 0, Summary: Decisions related to Fieldwork II:

the personal involvement of participants

What does the study ask from the participants → Ethics aspects are to be considered!

- samples (matrix, volume, amount),
- questionnaires (self-administered: paper/web-based; face-to-face-interview),
content: substance specific, living conditions and habits, health, nutrition, sociodemographics, occupation; sample specifics, non-responder, satisfaction
- Additionally: medical surgeries (weight, height, blood pressure, etc.)
- Additionally: Physical condition (ECG, lung function, etc.)

How long will the participants be occupied with survey demands? Duration of fieldwork

When will the survey be conducted and the participants involved? Period of fieldwork

Where: At which site will the participant meet the study?

- At participant's home or place of productive hours (workplace, school, kindergarten)
- At an official examination center (in schools, clinics, townhall, etc.)
- At a mobile lab

What will the participants receive to compensate for their burdens?

- Information on study and general results / Individual results and advice
- Money (reimbursement for travel costs and/or for spending time and samples)
- Small gifts /Certificates for taking part

Topics to be decided on in Phase 0

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Phase 1: Preparatory work

Tasks in Phase 1

Prepare Study Protocol, start Fieldwork Manual

Prepare and test questionnaires & Interviewer Manual

Prepare analytics

Prepare data management

Prepare communication material

Apply for authorization

Fieldwork Manual

Describes all steps of fieldwork and provides papers and SOPs for all essential steps: detailed instructions are listed, and check lists for all important steps of the procedures of fieldwork are compiled.



Reference book for every day use to standardize and facilitate the work of the field staff.

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)

Phase 1: Organisation of the study

Organisation/conduct (**Fieldwork I and II**)

Survey Office
(Study centre)



General aspects,
organizational background
study management



<https://luistorodupouy.blogspot.com/2010/10/project-management-drawing-conclusions.html>



Shared responsibility

Field staff
(interviewer,
physicians, etc.)



Topics directly happening at the
sampling location; can be organized
shortly.



<http://www.pngall.com/wp-content/uploads/2016/07/Team-Work-Free-PNG-Image.png>

Phase 2: Concretisation Phase

Tasks in Phase 2

Finalise Fieldwork Manual including SOPs

Engage and train qualified field staff (interviewers)

Prepare/organize and buy material

Fix timing of fieldwork (start/end/route plans)

Contract labs for substance analysis

Phase 3: Starting Phase

Tasks in Phase 3

Gather addresses from participants

Inform general public at sampling location

Inform labs of the start

If appl. acquire rooms as examination centres

Phase 4: Fieldwork Phase












Tasks in Phase 4

Invite potential participants (Fieldwork I)

Involve participants in the survey (Fieldwork II),
Including quality assurance and control measures

Phase 4, Fieldwork I: Individual approach to participants

Example for approach to general population, starting 3 weeks prior to begin of study

Day	
1	Send official personalized invitation   (including the date for proposed appointment and a reply card)
2-9	Waiting for response    
10	1. Reminder
11-15	Waiting for response
16	2. Reminder    
17-20	More reminders if necessary  (personal visit by the field staff)
21	Envisaged participation



Note: sms facilitate the contact –
pledges AND rejections!

Subsequently

Further tasks...

Sample analysis, combine results from questionnaires and chemical analyses, transfer data securely for detailed data analysis, store samples in a biobank, publications; etc.

Quality assurance and control methods for fieldwork

- National study protocol

→describes the study in detail

- Fieldwork Manual

→for training and every-day-use, including SOPs for essential procedures

- Log-books for field staff

→to transmit experiences collected during single participant visits, to learn from each other

- Check lists

→listing all material for one participant

- Field visits

→according to check lists for internal and external field visits



Source:
<https://openclipart.org/detail/169719/checklist>

More information: Deliverable D7.3

Access: <https://www.hbm4eu.eu/deliverables/> scroll down to WP 7: Survey design and fieldwork preparation. Scroll down to **D7.3 1st prioritisation Report on survey design: Study protocols, SOPs and Guidelines, tailored and transferred questionnaires for recruitment and sampling**

Annex 1: Concept for a Study protocol

Annex 2: Fieldwork Manual

Annex 2.1: Documents for the Interview

Annex 2.1.1: Basic Questionnaire

Annex 2.1.2: Interviewer Manual

Annex 2.1.2.1: Additional Annexes to the Interviewer Manual

Annex 2.2: Standard Operating Procedures

Annex 2.2.1: Selection of Participants and Recruitment

Annex 2.2.2: Quality Assurance for Recruitment and Fieldwork

Annex 2.2.3: Procedure for obtaining human samples

The logo of the Umwelt Bundesamt (German Federal Environment Agency) is displayed on a green rectangular background. It features the words "Umwelt" and "Bundesamt" in white, sans-serif font, stacked vertically. To the right of the text is a white circular icon containing a stylized human figure with arms raised, set against a green background.

Umwelt Bundesamt

Co-workers of Task 7.2:

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Thank you for your attention!

Questions?

Contacts

Many thanks to my colleague Kim Pack and the co-workers of Task 7.2!

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Speaker's information

Ulrike Fiddicke has been working for the German Environment Agency, Berlin, Germany, since 2010. She already worked within COPHES and DEMOCOPHES in the area of study design and fieldwork. She received training in nutrition science and public health. In HBM4EU she is responsible for study design and fieldwork preparation, leads WP7 and Task 7.2.