



CropBooster-P

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Title: Ethics requirements for studies involving human participants in CropBooster-P

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Ethics requirements for data collection

This is a general description to develop studies adhering to ethics requirements to be carried out by researchers of CropBooster-P.

CropBooster-P plans only studies where the opinion of individuals is asked for. Although CropBooster-P has not planned studies that fall outside this general description, a check whether individual studies meet the inclusion and exclusion criteria must be done before engaging in data collection to make ensure the studies fall within this scope and conform to requirements outlined in the protocol. If a study does not fall within the description below, the study should be amended or additional action needs to be taken to argue the deviations are essential and how additional action is taken to safeguard ethical data collection

It is the responsibility of the task-leader of a specific task within CropBooster-P to safeguard ethical and data protection aspects in the task in and agreement with other involved researchers, to ascertain that all ethical requirements specified below are met. The task-leader may appoint a replacement, but will remain first point of contact.

Note that these requirements only refer to participants in CropBooster-P studies and not to individual working on behalf of partners within CropBooster-P itself.

Research team and research context

CropBooster-P studies fall within this protocol is the study is led or carried out by scientific staff of CropBooster-P partners and it is carried out in EU/EEA countries, USA, Canada, Australia or New Zealand. Studies carried out in other (non-Western cultural) contexts will require individual prior review of a Research Ethics Committee approached through the task leader. The reason for this distinction is that there is sufficient overlap in Western cultures and public moralities about what sorts of (observing) activities are deemed acceptable in public contexts. In other cultural contexts these assumptions might sometimes be misplaced.

CropBooster-P partners with an appointed DPO refer to their institutional data protection policies. CropBooster-P partner who do not have an appointed DPO have to develop a description how they will deal with ethics in data protection, prior to data collection. This description has to be kept on file by the partner for the EU agency to review on request.

Research participants/groups

CropBooster-P anticipates to collect data from healthy volunteers. CropBooster-P does not anticipate to collect data from vulnerable groups which entail:

Vulnerable groups constitute out of participants with an age below 16, who are cognitively impaired, or otherwise vulnerable, are in circumstances of distress, pressure, dependence or suppression that make them vulnerable for exploitation or to other risks

Specific approval by an ethics committee must be obtained if data from vulnerable participants is collected.

Types of data collected and analysed

Three types of data are distinguished. Within CropBooster-P it is likely most data will contain personal data.

Collected data types

Anonymous data: Data where from the moment of collection it is impossible (including to members of the research team) to identify the participants and where the data does not give enough information to reconstruct the identity of a participant. Note that highly specific information about a person may allow reconstruction of identity. For example if a function is held by a single person (the mayor of Wageningen), if a photo that allows facial recognition is stored, etc. On the other hand, generic demographics like age, gender etc. can be anonymous as long as they are not sufficiently specific to allow identification of the participant.

Data protection is not about this – no specific safety procedures need to be applied. However this type of data is fairly rare.

Personal information included: Data includes information that allows identification of a specific person. Email address, name, most photo, video and audio footage or any other information that allows identification.

Data protection is about this, so following the rules is needed.

Such data needs to be stored by the task leader at a secured location, with limited access to named CropBooster-P individuals. Temporary files created during data collection are kept confidential and copies to local devices are removed as soon as the data is stored at the secured location.

This data can only be used for purposes a participant has given prior agreement to (including use of photos in presentations, transfer of this information to other studies within CropBooster-P, etc.). Usage agreement can be outlined in the informed consent form (see appendix).

Note: Visible E-mail addresses in mailings can be seen as personal data (use BCC instead of CC), as can be information about the editor of a document stored in document history.

Sensitive information included: Data that can cause discomfort or problems if associated with an individual (e.g. religion, health status)

Data protection is strict. CropBooster-P studies do not need this kind of data so in principle do not collect this kind of information.

Although CropBooster-P does not anticipate the collection of sensitive personal data, in the unforeseen circumstance sensitive data is needed the task-leader of the study will submit a justification for the need to collect sensitive data for approval to CropBooster-P management. This justification will be added as a deliverable to the commission.

In a justification to need sensitive data, the beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation' principle). Recruitment of participants for a study collecting sensitive data can only start after approval is given.

Data types for analysis

For data containing personal and/or sensitive information care must be taken that during analysis no such information is leaked.

Non-anonymized data: The data contains personal or sensitive information

This data must be securely stored (limited access, password protected), and is therefore generally not the best data for analyses on a local machine.

Pseudonymised data: Before analysis all references allowing identification are replaced with a key that has no meaning but allows reconnecting to personal data

This data can be more broadly shared among partners for analysis, but the key connecting the data to identifying information needs to be securely stored. This allows reconnecting the research data to personal information to allow for follow up studies using the same participants.

Anonymised data: Before analysis all references allowing identification are removed in such a way the data can no longer be connected to an individual

This data can be more broadly shared among partners for analysis, but follow up with the same participants is no longer possible.

Permission/ consent

Prior to the start of the research, participants are asked to sign an informed consent form in the local language (see appendix for English language template).

Participant will not be pressured to sign the consent form.

In the informed consent form it should be clearly stated that the participants will not have negative effects or leaving the study at any time, how they can review their own data. In the informed consent form pre-agreement for the use of personal data can also be requested – including agreement to publicly communicate identifiable quotes, photo or video materials, or the request to use the data to approach participants for follow up studies.

Recruitment of research subjects

Research subjects will be volunteers. Recruitment of expert participants will be conducted through publicly available contact data and personal networks of CropBooster-P staff. Recruitment of non-expert participants will be through advertising, or through research platforms where participants explicitly agreed to be willing to be approached for participation in research.

Methods and research activities

Studies in CropBooster-P employ regular social sciences methods for observing individuals or groups; such as focus groups, workshop discussion and citizen juries.

The following measurements and situations are excluded:

- Study setups that, for participants, involve medical/psychological/social risks that are higher than in normal daily activities.
- Collection of information that as such is generally considered sensitive (e.g. illegal, asocial, private behaviour).
- Observations or other forms of data-collection in sensitive spaces or contexts (for reasons of, e.g. privacy, illegality, etc.)
- Social/societal interventions that might cause conflict, unrest, or disrespect between people, and /or unfair treatment of minorities.
- In addition if pictures are to be taken, or audio/videos recorded in which individuals are recognizable; this should be (1) mentioned explicitly in the informed consent form (2) these materials should not be used in presentation of the research unless the recognizable participant explicitly agrees to such use of the data.

If any of the above applies, the task-leader has to acquire approval of a relevant ethics committee and file approval of such ethics committee for review, before starting recruitment.

Information disclosure after completion of the study

At the end of the study, information about the study and its results will be made available to the target groups. The study plan specifies how and when this is done.

Explanation: Informing the target groups about the study and its results can be done by mailing a summary but also, for example, through newspapers or other media. This can be considered as a matter of trustworthiness and respect.

Data management / confidentiality

CropBooster-P task-leaders are responsible to manage data in their task in a way that ensures privacy protection, secure storage of data, and access for future use.

Personal data retrieved by researchers are kept confidential and stored in a secured data storage, with limited access. The task-leader will identify the storage and keeps a file with named persons that have access to the data. Data will not be shared with others than the research subject herself (anonymity) unless specified otherwise in the informed consent, or required by law.

Communicated data in e.g. presentations, reports, scientific papers, will only present anonymised and/or aggregated accounts of participant input; which are presented in such a way that it is impossible to identify individuals based on the provided information, unless explicit agreement by an individual is given that (s)he may be recognisable in a specific report.

Procedure

Before participants recruitment for any study starts, the task-leader will store all materials of the study and will allow review on request. Before starting participants, the task-leader ensures that the study satisfies all requirements and criteria as specified above.

Appendix 1: Template Informed consent form

Adapt the highlighted sections to provide information about the specific study.

Informed Consent

This research is conducted by [task-leader institute NAME (or other partner is so agreed)] as part of the EU-funded research project CropBooster-P. The research is about developing the next generation of plants to increase yields, and consists of [TYPE OF STUDY] which take [TIME ESTIMATE]. [ABOUT 2 LINES OF DETAILS WHAT IS EXPECTED OF PARTICIPANTS IN THE STUDY]

Please read the text, and sign the form when you agree to participate.

Your informed consent

You will be asked to answer questions regarding:

[specify additional bullet points for study as needed]

Personal details (age, gender, and email address) [adapt to study specifics]

Your decision to be in this research is voluntary. You can stop at any time.

Data we process when you answer this questionnaire

We only process information about the information that you provide. [In case a multiple stage study is needed mention here something like: We link the three workshops responses together based on your assigned participant number and your e-mail address.] Before analysis, your e-mail address will be removed from the dataset so that the data is anonymized. Age and gender [adapt personal data to match those included] will remain in the dataset, but can no longer be linked to you personally.

Why we process it

With the data collected with this study, we will:

Conduct analyses and measurement to understand how people think about [adapt to study].

Answer applied and scientific questions for research purposes.

Improve the quality of our research methods

[add requests for other uses, including communication here if applicable]

Personal data

Personal data such as age and gender will be asked to provide a description of the sample only and will not be provided to third parties. You may choose to not answer a question and skip it. Your participation in this research is confidential. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared or stored. The data will be stored for at least 10 years and possibly longer.

Security measures

CropBooster-P will ensure an appropriate level of security for the data, which will be stored on a server of [task-leader for specific study]. Only persons designated for such purpose within the framework of this project will be able to access the anonymized data. Data will be used solely for the purposes described above and in accordance with the General Data Protection Regulation (GDPR).

Informed consent

By giving your consent you declare to have given your personal information voluntarily. The data you provide will only be used for the purposes as described above. You have the right to object to process and share your data. Until the data has been anonymised you have the right to see your own data, correct it or request deletion. The anonymization will take place after we have received the final online questionnaire. In case you have a complaint you can file this complaint by contacting [contact data DPO of task leader, or relevant contact information for partners without DPO].

Name:

Signature:

Appendix 2: Checklists

Before data collection:

- **Do all involved partners have the right to access human data by either having (up to data contact data for a DPO on file, or having provided a detailed data-protection plan (according to D7.2).**
 - If not, partners lacking this should not be granted access to personal data, until resolved.
- Protocol is ready and stored – taking account of the requirements in this document.
- *Only if needed:* Ethical approval of a relevant ethics committee is obtained
- Informed consent form are prepared and stored
 - Pre-agreement for future use, including agreement to use quotes, photos, etc. and to use personal data to approach participant for follow up is included if needed,
- Only anonymous data will be collected → No further action, data protection not needed [END OF CHECKLIST]
- Sensitive data will also be included → Approval of study must be obtained before recruitment, and the argumentation why collection of sensitive data must be submitted as additional CropBooster-P deliverable.
- Task-leader (or other named gatekeeper) appointed who is responsible for
 - Ensuring secure storage
 - Keeping track of persons with access to the securely stored data
 - Providing anonymised or pseudonymised data files for analyse
 - Liaising with other task-leaders who have access to personal data (as stipulated in the informed consent form)

Do's and Don'ts

Do:

- Be decent to participants
- Ask for agreement to use personal data in informed consent form, but only if you expect to use it that way
- Be aware that many electronic documents and services may contain personal information
- Aware that working documents on which participants respond electronically may contain personal information who did the edit.

Don't:

- Do not retain copies of non-anonymised or non-pseudonymised data on local devices (including laptops, external drives, USB stick, etc.).
- Do not send personal data by e-mail.
- Collect sensitive data unless it is absolutely unavoidable
- Do not use CC when mailing groups of participants as e-mail addresses are personal information that should not be shared (use BCC instead)
- Do not share electronic document with identifying information of participants
- Do not use photos, videos, etc. without agreement of the recognisable participant

Glossary

- Anonymous data: Data that in no way, by nobody can be traced back to an individual.
- Anonymised data: Data from which each identifiable information is lastingly removed.
- Pseudonymised: Data in which all identifiable information is replaced by a meaningless key that allows reconnection to personal data.
- Personal data: Data that allows identification of a living person. Includes e.g. photo footage
- Sensitive data: Data that can cause harm or discomfort if associated with a living person. Includes e.g. religion, health status etc.
- DPO: Data protection officer