Example letters and forms to consider ethical aspects in preparing the EU Menu survey based on the PANCAKE and PILOT-PANEU projects\(^1\)

\(^1\) The content of this Appendix is used with permission of the PANCAKE consortium and of the PILOT-PANEU project (Ocké et al., 2012), (Ambrus et al., 2013).
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Appendix 2.2

Invitation of the subjects included in the sample – adults, adolescents

Insert letterhead of the institute sending out the letter

Address

Place and date

Dear Mr. / Ms. (name)……………………….. ,

The safety of our food is one of the primary concerns for all of us. In order to assess the potential risk caused by different food contaminants, reliable information on the kinds and amounts of food we consume is required. The European Food Safety Authority (EFSA) is planning a European-wide food consumption survey for building up a suitable data base for food safety assessment.

You have been selected to be part of a representative sample based on statistical procedures and you are invited to participate in the dietary survey which covers the age groups of [specify].

If you kindly agree to participate, you will be interviewed by a nutrition specialist about the food you have eaten at two different occasions, one of which would be a weekend day. The approximate duration of the whole interview is 1.5 hours on the first occasion. The second interview will be shorter. You will be requested to reply to questions related to usually eaten food, physical activity, food choices and social background, and, in addition, your weight and height will be measured. The questionnaires are enclosed in this invitation letter for your information. If needed, you will be assisted in filling in the questionnaires during the first interview. Please take your identity card with you for the interview.

Your personal data will be handled with strict confidentiality, similar to that required in the case of medical treatment and in accordance with the Personal Data Protection Act. Even the researchers evaluating the results later on will not have access to them.

We will send you the result based on your replies after the survey has been evaluated. In addition, you will receive a small present as a reward for your contribution.3

The place and time of the two interviews depend on your choice. The first interview will be conducted face-to-face. It can be organised either in your home where two dietician specialists would visit you or in4 ……..

If the interview is away from your home, the travel expenses between the place of interview and your residence (home) will be covered by the organisers upon receiving the tickets used5. You may choose a telephone interview for the second interview.

We suggest that the first interview should take place on ……. [date] and …….. [time].

2 This text is an example, and it may be altered according to the country practices and requirements.

3 Whether the information on the nature of the reward is included in the invitation letter or whether the subject will be told after the first interview, as foreseen in the Manual, shall be decided by the study organiser taking into account prior national practices.

4 The suitable option, e.g. health centre should be inserted for each subject specifically.

5 The organisers shall decide if they offer this option.
If the above date and time do not suit you, please feel free to suggest another suitable date and time\(^6\) on the enclosed consent form.

The name, address and telephone number of the interviewer for future contact in relation to the interview is: ______________________________________________________________

If you have any questions concerning the procedure or need some clarification regarding the consent form, please feel free to contact ........... [insert name, address and telephone number of interviewer].

Detailed consumption data are required to assess the safety of the food we eat, therefore your participation and your feedback is very important to us and it would be greatly appreciated. We hope that you are willing to contribute to this important programme. Please confirm your intention by filling in, signing and returning one copy of the enclosed consent form using the prepaid envelope. Please keep the other copy of the consent form for personal use.

<table>
<thead>
<tr>
<th>Alternative text for inviting adolescents:</th>
</tr>
</thead>
<tbody>
<tr>
<td>We hope that you are willing to contribute to this important programme and that your parent(s) or adult caretaker give permission. They are welcome to accompany you for the interview. If you agree, please confirm your intention by filling in and returning the enclosed consent form using the enclosed prepaid envelope.</td>
</tr>
</tbody>
</table>

Upon receiving your agreement we will confirm the date and place of the first interview.

In the unlikely event that you cannot participate in the survey please fill in and return the questionnaire for non-responders. It is also important to know your reasons and under what conditions you would take part in a future dietary survey.

Your contribution is very much appreciated, thank you very much for your cooperation.

Sincerely yours,

<table>
<thead>
<tr>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
</tbody>
</table>

Enclosures:
- Consent form (two copies)
- Background and lifestyle questionnaire
- Physical activity questionnaire
- Food propensity questionnaire
- Food choice questionnaire
- Non-responder’s questionnaire

\(^6\) The subject can change the time by telephone.
Informed consent form, children 1

Name of the study:
PANCAKE (Pilot study for the Assessment of Nutrient intake and food Consumption Among Kids in Europe)

Child's name: .............................................................................................................

Parents name (or the proxy): ......................................................................................

1. I, the undersigned, agree with the participation of myself and my child in the study. I am over 18 years.

2. I was informed about the study objectives, the procedure and about what am I expected to do. I acknowledge that the study is a research activity.

3. I understand that I can discontinue or withdraw the participation anytime during the study. Participation in the study is voluntary.

4. Once enrolled in the study the personal data (mine and my child) will be stored with full protection in accordance with valid laws of the Czech Republic. During the study the personal data without identity (anonymous data only with code number) might be provided to other than the above mentioned bodies. Also, the data might be provided for experimental or scientific purpose, but only anonymous or with my permission.

5. The reward for completing the study is 20 € (twenty Euros).

6. I understand that my name or my child’s name will never appear in the papers about this study. I will have no objections against the use of anonymous results from this study.

................................................. .................................................
Signature of parents Signature of representative of NIPH

Date: .................................... Date: ...........................................

Please, write down your contact details:

................................................. .................................................
Telephone number E-mail
Informed consent form – children 2

Parents:

- We declare to be informed about the kind of study, the objectives of the study, the duration of the study, the eventual adverse effects and what is expected from us
- We did have sufficient time to think about it and to talk about it with the person(s) of our choice (doctor, family member)
- We did have the opportunity to ask all questions that came up and we received a decent answer
- We understood that our participation to the study is completely voluntary
- We understood that we are free to quit from the study at every possible moment without having to justify this
- We understood that data concerning us and our child will be collected during the study and that the researchers guarantee complete confidentiality of these data
- We understood that our data will be made anonymous. This means that the researchers will not be able to link the data collected during the study to our personal data
- We received a copy of the information to the participant and the informed consent form

Date, name and signature of both parents:

(In case this is impossible, see attachment for who should sign this form. Don’t forget to mention the relationship of this person with the child and in addition the reason why it was impossible for both parents to sign this form):

The interviewer, named _______________________________ declares on date __________, that she/he gave sufficient and necessary explanations about the study to the parents.

Signature of interviewer:
The sequence of persons who can give informed consent as representative of a person younger than 18 years is as follows:

1) In case the child has two parents:
   * Informed consent is necessary from both parents
   * Informed consent from one parent is sufficient in case
     - the other parent cannot be reached in a reasonable manner
     - it is impossible for the other parent to inform about his/her consent
     - the other parent does not have the responsibility of parent anymore

2) In case the child only has one parent anymore:
   * Informed consent of this parent is sufficient, unless this parent does not have responsibility of parent anymore

3) In case the child does not have parents anymore or both of them are not in the possibility to inform about their consent or both of them do not have the responsibility of parent anymore:
   * Informed consent of custody is necessary

4) In case it is impossible in a reasonable way to reach the parents and in situations were there is not appointed custody (yet):
   * For urgent experiments it is possible to ask to the family members where the child currently resides
   * In not urgent cases, custody needs to be appointed first

In case of children older than 12 years, it is always necessary to also obtain their personal consent, in addition to the consent of the above mentioned persons.
Consent form – adults, adolescents/parents

Information leaflet of the study to be included here.\(^7\)

Identification code ______

**The aim of this study** is to collect information on the kind and amount of food and drink consumed by people living in [country]. This programme is part of a European Food Consumption survey coordinated by the European Food Safety Authority (EFSA). The person in charge of this part is ……… [insert name of study coordinator]. The personal interview will be conducted by ……… [insert name(s) of interviewers]. The contact details of the interviewers are as follows: …………………………………………………

**STATEMENT OF CONSENT**\(^8\)

I have read the invitation letter I received, as well as the consent form, and I am familiar with and fully understood the purpose and procedures of the study, the methods and the use of the data. I am aware that my participation is voluntary and that I may discontinue it either during the study or later if I so decide.

The condition for my consent is that the information thus gathered will be handled with the confidentiality required of health care personnel and in accordance with the Personal Data Act. The result of the survey will be provided to me after the information collected in the survey has been evaluated.

By signing this statement I give my consent that the information I provide during the survey and the results of the measurements taken from me may be used for the purpose of the study.

Preferred place and time of the first interview: ______________________________

Name of the subject (print): ____________________________________________

Address of the subject: ________________________________________________

Phone

Date

_________________________

signature

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\(^7\) Age-specific version for children of 10-14 years of age can be attached as well, if it is required by country legislation.

\(^8\) Please return one signed copy and keep the other for personal use.
Consent form for parents of adolescents

Identification code _____

The aim of this study is to collect information on the kind and amount of food and drink consumed by people living in [country]. This programme is part of a European Food Consumption survey coordinated by the European Food Safety Authority (EFSA). The person in charge of this part is ……. [insert name of study coordinator]. The personal interview will be conducted by ……. [insert name(s) of interviewers]. The contact details of the interviewers are as follows: …………………………………………………

STATEMENT OF CONSENT

I have read the invitation letter sent to my adolescent child, as well as the consent form and I am familiar with the purpose and procedures of the study, and the methods and the use of the data are fully understood. I am aware that the participation of my child is voluntary and that he/she may discontinue it either during the study or later if he/she or I so decide.

The condition for my consent is that the information thus gathered will be handled with the confidentiality required of health care personnel and in accordance with the Personal Data Act. The result of the survey will be provided to me after the information collected in the survey has been evaluated.

By signing this statement I give my consent for that the information my child provides during the survey and the results of the measurements taken from him/her may be used for the purpose of the study.

Preferred place and time of the first interview: ______________________________

Name of the subject (print): _____________________________________________

Address of the subject: _________________________________________________

Phone

Date

__________________________  ____________________________

signature of parent  signature of child

9 Please return one signed copy and keep the other for personal use.

10 At least one of the parents has to agree for the child to participate in the study.
Confirmation letter – adults, adolescents

Insert letterhead of the institute sending out the letter

Address

Place and date

Dear Mr./Ms. (name)……………………….. ,

We are very pleased to receive your reply to our invitation letter confirming your intention to participate in the food consumption survey. We confirm that the interview will take place at …………… [place] on ……………………. [date, time].

Please bring with you the completed questionnaires sent with our invitation letter. If you have any doubt about the correct answer leave the relevant part empty, we will assist you during the personal interview.

Furthermore, please bring with you your identification document and the tickets used to travel to the interview.

We would like to measure your weight in light indoor clothing, without shoes. Please dress accordingly.

If for any unforeseen reason you cannot take part in the interview on the above date and time, please contact …………………………… [name, address and telephone number of the interviewer] to make alternative arrangements.

Your contribution is greatly appreciated, thank you very much for your cooperation.

Sincerely yours,

Signature

Name
Study plan of the EU Menu dietary survey

The safety of our food is one of the primary concerns for all of us. In order to assess the potential risk caused by different food contaminants reliable information on the kinds and amounts of food we consume is required. The European Food Safety Authority (EFSA) is coordinating a European-wide food consumption survey for building up a suitable data base for food safety assessment.

About [targeted number] individuals representing the age groups of [specify] will be invited to take part in the study which comprises of recalling the food eaten during the previous day at two occasions. During the interview, trained nutritionists or dieticians will collect information on the amount and kind of food and drinks eaten or drunk during the previous day. In addition the weight and height of the participants will be measured.

The information provided by the invited individuals will be recorded applying a computer based methodology developed by [database provider]. In addition, the invited persons will be asked to fill in the enclosed questionnaires.

The whole interview is planned to last about 1.5 hours, and it will be conducted at a suitable public place (e.g. medical centre, school) or at the home of the selected persons depending on their preference.

The personal data will be handled strictly confidentially as required in case of medical treatment. The personal data will be coded. Even the researchers evaluating the results later on will not have access to them.

The randomly selected individuals shall sign the enclosed Consent Form verifying their voluntary participation and agreement to using their replies for the evaluation of the dietary survey methodology. The interviews will be conducted during the period of [insert].

Enclosures:

- Questionnaires:
  - Background questionnaire
  - International physical activity questionnaire
  - Food propensity questionnaire
  - Non-respondents questionnaire

- Protocol on anthropometric measurements
- Invitation letter of the participants
- Information leaflet and consent letter

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11 To be submitted with the application for permission of Ethics Committee

12 Insert details of the software to be used.
References
