**HREC template for an Information Sheet for research participants**

*(Please note that the final version of this form must contain the EPFL logo and the PI/lab header/footer).*

**INFORMATION SHEET FOR RESEARCH PARTICIPANTS**

**Introduction:**

The information provided to participants is a very important part of your project. It explains to participants what is expected of them, gives them an idea of the risks and benefits of their participation, and how their data will be used and protected.

Below is a sample participant information sheet for projects that fall under the HREC mandate. These projects are not covered by the Federal Act on Research involving Human Beings (LRH, or Human Research Act, [HRA](https://www.fedlex.admin.ch/eli/cc/2013/617/en)).

This template must be adapted to the specific research project. When drafting the information sheet, please keep in mind the points described below. The participant information sheet should mention only the essential information for the participants, be formulated in simple and clear language and focus on the participants' point of view.

**Introduction - invitation:**

In the first paragraph, potential participants are invited to take part in your research and indicate that participation is on a voluntary basis.

Example:

*Dear Sir or Madam,*

*We would like to invite you to participate in our research study. Before you decide, it is important that you understand why this research is being carried out and what it means for you.*

*Your participation is completely voluntary.*

*In this information sheet you will find important and detailed information about participating in the research project.*

*All data collected in this project is subject to strict data protection rules.*

*Please take the time to read this information. If you have any questions or require further information, please do not hesitate to contact us.*

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| **Information sheet for research participants**  **A copy of this information sheet should be given to you**  Name of the project:  This research project has been approved by the EPFL Human Research Ethics Committee (HREC No.......).  The research project is conducted by: (Contact Principal Investigator)  Institution / Professional address: |

**1. General information about the project**

This section should present the most important elements the participants need to know in a clear and concise way. Give a brief overview of the purpose of your study in layman's terms. Do not use jargon and specialised language.

* Give background information/summary of the project;
* Describe the design of the study; it is recommended NOT to use technical terms;
* Indicate the total duration of the project;
* National / international project;
* Indicate the approximate number of participants to be included locally and globally;
* Indicate the source of funding for this study.

**2. Objectives of the research project (Why this research project?)**

Describe why this research project is being conducted.

*(We want to know if / to what extent ... / our research project aims to study ....)*

**3. Selection of potential participants (Who has been invited to participate in this study?)**

Please describe the participants who can take part in the study with the inclusion criteria.

*(Participation is open to all people who have / are ... have not / are not ...)*

*We are carrying out this project in accordance with the requirements of Swiss law.*

**4. Procedure for participants (What do I have to do / what is expected of me if I decide to participate?)**

Describe the course of the project and what is expected of the participants (filling in questionnaires, observations, etc.);

Indicate the location, number of experiences and duration of the project for the participant (if possible in the form of a table, diagram or scheme).

**5. Benefits for participants (What are the possible benefits of my participation?)**

Sometimes a participation to a research project can come with direct benefits. If so, please describe them. If not, be equally clear that there is no direct benefit. If applicable, make sure that potential participants are aware that you do not know what the outcome will be, and that is why you are conducting this research.

Examples:

[Option 1]: *There will be no direct benefit coming from your participation in the project. The results of this study may lead to greater knowledge...*

[Option 2]: *If you participate in the project, it may eventually bring you... / it may eventually help you to...*

**6. Risks (What are the possible risks and constraints of my participation?)**

What are the possible disadvantages or risks of my participation? Provide a fair and honest assessment of the possible risks. Describe the nature of the risk, its degree and likelihood. Also, describe what you will do to mitigate these risks. For example: discomfort that may be felt, questionnaires/interview questions that may cause distress or stress, etc.

Examples:

[Option 1]: *By participating in the project you will not be exposed to any particular risks.*

[Option 2]: *By participating in the project you will only be exposed to minor inconveniences (such as being observed, wearing or carrying special clothing or equipment, being asked personal questions, or feeling slightly stressed) (please state any other minor risks).*

[Option 3]: *Only if you have consented, you are aware that the principal investigator may use any static or dynamic recording of you, including any recording of your voice, reproduction of your image, for the purposes of this research project, for any subsequent research project (if applicable). (Option 1 - In the event of withdrawal of consent, the principal investigator will communicate your choice to those who may have obtained such recordings and will anonymise such recordings or delete them from its databases. (Option 2 - During the course of the study the principal investigator will anonymise your image/video/audio).*

**7. Discoveries during the project (What happens if the researchers discover something unexpected about me?)**

Could the analysis of certain data, images or questionnaire responses produce results of clinical importance to the participants? If so, please specify how these 'incidental findings' will be managed. This will usually involve clinical verification and/or referral to the participant's doctor.

Example:

*Unless we are working with anonymised personal data from the outset, the Principal Investigator will inform you of any incidental findings, which may contribute to the prevention, diagnosis or treatment of existing or likely future diseases, and advise you to consult a specialist. If you do not wish to be informed, please inform the principal investigator. It is your responsibility to decide whether the finding warrants an appointment with your doctor.*

**8. Participants' rights (What are my rights?)**

This section details the rights of participants.

Example:

*Your participation is entirely voluntary. You are free to accept or refuse to participate in the project. If you choose not to participate, or if you choose to change your mind during the course of the project, you will not have to justify your decision. This will not change your usual care and will not put you at a disadvantage in any way. You can ask any questions about the study at any time. Please contact the person listed at the end of this information sheet.*

*Finally, you can exercise the following rights with the Principal Investigator:*

* ***Right to withdraw your consent****: (see section 11 for more information)*
* ***Right to be informed****: you may at any time request further information about the project, about the use of your personal data, and about any future project that uses your personal data (Please adapt the last part of this sentence as appropriate to the project);*
* ***Right of access****: you have the right to know what personal data we hold about you;*
* ***Right to object****: in certain circumstances you can also object to the processing of personal data at any time;*
* ***Right to modify or delete****: your personal data may be modified or deleted, unless otherwise provided by law;*
* ***Right to portability****: in certain circumstances, you can ask us to provide you with your personal data in a suitable format for transfer to another data controller;*
* ***Right to lodge a complaint****: if you consider that we have made improper use of your personal data, you have the right to lodge a complaint with the Swiss Federal Data Protection and Information Commissioner or with the supervisory authority in your country or residence.*

**9. Information about the results of the research (Will I be informed about the results of the research?)**

You should inform potential participants of your intentions regarding the communication of the results of your research. For example, it would be useful to mention how the results will be published or communicated. It would also be useful to mention whether participants will receive a copy of the publication, a summary of the publication, or a link to the communication of the results. On the other hand, it should also be mentioned if the results will not be communicated directly to the participants.

Example:

[Option 1]: *At the end of the research project, we will provide you with a link to the publication of the results, the press release, or to a summary of the results obtained. Of course, you can always request more information by sending an email to the principal investigator:* [*xxx@epfl.ch*](mailto:xxx@epfl.ch) *(e-mail address of the PI).*

[Option 2]: *You will not normally be informed of the results of research projects using your personal data, unless you specifically request this from the principal investigator at the following email:* [*xxx@epfl.ch*](mailto:xxx@epfl.ch) *(e-mail address of the PI).*

**10. Protection of personal data (How is my data protected?)**

Describe in this section the type of data you will collect (whether it includes personal data or not) and how the data will be protected (anonymisation/pseudonymisation procedures).

Participants cannot withdraw their data if it is anonymised during the course of the study and they must be specifically informed of this (either in this section or in the section on withdrawing their participation, section 11).

What will happen to personal data from this study? Potential participants should be reassured that their personal data will not be publicly available (via scientific publications or sharing on a public register). If personal data will be published (e.g. with images of faces), specific consent will be required for this.

Examples:

*Personal data collected. For the purposes of the study, we will record the following personal data: (Name the category(ies) of personal data involved.)*

*[Option: This personal data has been collected from the databases of : ...]*

*Purpose of the data processing. By law, EPFL may collect and use personal data for research purposes (art. 36c of the Federal Law on the Federal Institutes of Technology of 4 October 1991) and we rely on this legal basis to legitimise our processing of personal data.*

*Security measures. Your personal data will be encrypted or anonymised after collection. It will be encrypted when used by researchers and will in principle be anonymised in any scientific publication (unless you have consented to publication of your personal data).*

*The term "coded" means that your identifying information (surname, first name, date of birth) will be replaced by a code. The key to your identity is kept secure. People who do not have the key are generally not able to identify you. Only a limited number of people can see your personal data in unencrypted form.*

*The term "anonymised" means that your personal information has been sufficiently aggregated and protected, preventing anyone from re-identifying you. This means that no one can re-identify you unless they go to great lengths to do so. It should be noted, however, that absolute anonymity cannot be guaranteed.*

*Finally, we take appropriate technical and organisational measures to protect your personal data as much as possible. Your personal data will be stored for a maximum of ... years before being deleted or anonymised.*

2 options to choose from:

[Option 1]*: Publication. In the case of publication, personal data is anonymised and it is not possible for third parties to re-identify you. Your name will never appear on the Internet or in a publication.*

[Option 2]*: Publication. If you have consented to the publication of your personal data (other than medical or intimate data), we will publish your personal data on a public register which is generally used for scientific research purposes. If they have a legitimate reason to do so, third parties may then re-use your personal data and publish it in other media or on other websites.*

*Communication and transfer. We may transfer your personal data to the following recipients for the purposes of this project only:*

* *Other research partners located in Switzerland or abroad; and*
* *Subcontractors; and*
* *Scientific journals; and*
* *Authorities responsible for monitoring research projects (such as Swiss or foreign ethics committees or Swiss or foreign authorities responsible for protecting your personal data).*

*If raw data is to be transmitted, it will always be coded and will therefore not identify you as an individual. If data is sent abroad, the foreign institution receiving the data must comply with standards or clauses that are at least equivalent to those in Switzerland. If necessary, a contract will be drawn up with the partner or subcontractor.*

**11. (Optional, if applicable - Re-use of your personal data in future projects)**

*Your personal data may be re-used in scientific research projects, not yet defined, in Switzerland and abroad. The recipient of your data will, however, have to comply with the same standards and requirements as those required for the present project, in particular with regard to the period of retention. The research projects will be carried out by researchers at EPFL, as well as at other research institutions (e.g. other hospitals, universities, research institutes, start-ups or research companies) in Switzerland and abroad. Your personal data will only be transmitted in coded or anonymised form and a contract will be concluded with the institutions concerned.*

*You can always contact us to receive information about the further use of your personal data by sending an email to the following address:* [xxx@epfl.ch](mailto:xxx@epfl.ch) *(Please add the IP's email address).*

**12. Withdrawal from the project (What if I want to stop participating? What will be the consequences?)**

What will happen if the participant does not want to continue the study? Make it clear that: participation is voluntary and participants can change their mind later and that withdrawal will not affect them negatively. What is the procedure in case of withdrawal? Will the participant data collected so far be kept for the study, withdrawn, or will the participant have a choice? This should be clearly explained to participants.

Examples:

*Your participation is entirely voluntary. You can withdraw from the study at any time if you wish. If you choose not to participate, or if you choose to participate and withdraw during the course of the study, you do not have to explain your decision.*

[Option 1]*: If you withdraw, we will delete (or anonymise) all your personal data and we will not collect any further personal data about you. Your personal data will no longer be part of this research project and will not be used in the future (if applicable).*

[Option 2]*: If you withdraw, we will not collect any further personal data about you, but we will retain and use the personal data already collected (at the time of your withdrawal) until the end of the project. If applicable, your data will therefore not be used in any further research projects - it will be deleted at the end of the project. However, if you specifically request it, we will delete (or anonymise) all your personal data.*

[Option 3]*: If you withdraw, we will not collect any further personal data about you, but we will retain and use the personal data already collected (at the time of your withdrawal) until the end of the project. If applicable, your personal data obtained up to that point may however be used in other subsequent research projects. If you nevertheless expressly request it, we will delete (or anonymise) all your personal data.*

**13. Compensation for participants (Will I be reimbursed for my participation?)**

Will participants be compensated for their participation? Specify whether participants will be compensated for their time/effort. Specify whether participants will be reimbursed for expenses such as travel, meals, etc. Their participation should not result in costs to them, but at the same time, any compensation should not be an undue incentive to participate in the research project (e.g. it is doubtful that compensation of more than CHF 25.- per hour is acceptable).

Examples:

[Option 1]: *If you participate in this project, you will not receive any remuneration for it.*

[Option 2]: *If you participate in this project, you will receive the following remuneration: ...*

[*Variant]: You will be reimbursed for expenses, such as transport costs, which arise directly from your participation in the study.*

**14. Compensation for damage**

*Damages caused as a result of this study will be covered if EPFL is held responsible for the occurrence of such damages. If you have suffered any damage, please contact the principal investigator immediately.*

*You are nevertheless required to obtain accident and health insurance (in general, compulsory in Switzerland).*

*N.B.: Text highlighted in yellow will be added only for participants in Switzerland.*

**15. Contact person(s)**

*If you have any doubts, concerns or emergencies during or after the study, you can contact one of the following people at any time:*

*Project manager: (Full business address of the PI followed by a telephone number and e-mail address)*