**Sample of an Informed Consent Form for Participation in the Research**

We invite you to participate in the research [*research title*], conducted by [*research institution, researcher*]. [*If applicable, mention the source of funding, e.g., research project, industry funding, etc.*]. We would like to introduce you to the purpose, process, and content of the study. Please read all the information carefully before signing this document! Before signing, you have the right to ask questions about the study and receive answers.

**Purpose of the Study:** [*Describe the purpose of the study in a way that is understandable to participants and explain how the study results will be used*].

**Process of the Study:** [*Describe the planned process of the study in a way that is understandable to the participants. Where will the study take place? What will the participants need to do? How much time will participation in the study take? What methods will be used in the study? Will there be randomization, invasive procedures, invasive or non-invasive biological sample collection, or data collection from medical records? What tests will be conducted as part of the study, what questionnaires will need to be completed, and how much time will participation take? If biological samples are collected, how large will they be (e.g., how many ml of blood will be taken for the study)? How will the treatment of patients involved in the study differ from those not involved? Will participants/the treating physician have access to any individual results obtained during the study?*]

**Benefits and Risks** [*Describe the potential benefits for study participants (if any) and for society as a whole. Explain all potential risks, including psychological risks that may arise during the study. Will any questions cause discomfort, bring up unpleasant memories, or create stress? Describe the physical risks from study procedures, psychological risks, potential side effects, or risks posed by randomization. Could the study pose risks to pregnant women or breastfeeding mothers? Are there specific risks for certain patient groups? How will these risks be mitigated?]*

**Confidentiality and Personal Data Protection:** [*Confirm that personal data processing will be done according to the Personal Data Processing Law. In understandable language, describe how personal data security and confidentiality will be ensured. List all personal data to be collected and processed (e.g., name, surname, date of birth, photographs, video or audio recordings, specific measurements, test results, geo-location data, information from social networks, medical test results, information from medical records). How long will the personal data be stored, and where and how will they be stored? What happens to personal data if the participant withdraws from the study? If the data will be pseudonymized (coded), how will that be done? Keep in mind that pseudonymized data are still considered personal data according to regulations. If the data are coded, in what circumstances can they be decoded? How will the study results be published?
Current regulations require specifying the personal data controller and their contact information.*

*Could a healthcare professional, such as the participant’s general practitioner, receive study data (this could happen if the study yields results important for treatment, but the participant should be able to indicate whether they wish this?*]

**Voluntary Participation:** Participation in this study is voluntary. You have the right to decline participation or withdraw from the study at any time. Declining to participate or withdrawing from the study will not have any adverse effects on the quality of the healthcare you receive. We will inform you of any changes in the study that might affect your decision to continue participating. [*Are there any cases where the researcher may decide to terminate the participant’s involvement prematurely? What are the reasons for this?]*

If you have any questions about this study, please contact [*researcher's contact information*].

This study has been approved by the [*name*] ethics committee: ethics committee contact information.

This document is provided in two copies, one for the researcher and one for the participant.

**Consent to Participate in [Study Title]**

By signing below, I confirm that:

1. I have read and understood the information about the study provided in this document, including its purpose, process, risks, and benefits;
2. I had the opportunity to ask questions about the study, and my questions were answered;
3. I understand that my participation in this study is voluntary, and my decision not to participate or to withdraw will not have any negative consequences;
4. I am informed about the purpose and extent of personal data processing;
5. I agree that my personal data, as mentioned in the study information, will be collected, stored, and processed according to legal requirements during the study;
6. **I consent to participate in this study**.

|  |  |
| --- | --- |
| Participant’s Name |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
| Researcher’s Name |  |
| Signature |  |
| Date |  |