*This template applies to studies in which participants are adult healthy individuals. In other cases as well as in cases in which additional permission must be granted by other bodies (caregivers, school, employer) different versions of this document are to be added*

*If the study includes deceit, then a separate consent to use the data collected must be obtained after the debriefing on the actual goals of the study has taken place*

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|  | **INFORMATION NOTE** |
| **Project Title** | [COMPLETION BY PRINCIPAL INVESTIGATOR] |
| **Purpose of the Study** | This research is being conducted by [INSTITUTION NAME, including link to website] and is supervised by [NAME OF PRINCIPAL INVESTIGATOR AND HIS/HER EMAIL ADDRESS]. The purpose of this research project is [COMPLETION BY PRINCIPAL INVESTIGATOR] and its larger implications are [RELEVANCE OF THIS RESEARCH FOR SOCIETY, IF ANY]. This research is sponsored by [COMPLETION BY PRINCIPAL INVESTIGATOR, including link to website]. The research has no commercial purpose. |
| **Compliance statement** | This project complies with the current pertinent regulations related to research ethics and professional deontology, such as: The European Convention on Human Rights (1950), The Oviedo Convention (1997), the Protocol on Biomedical Research (2007), the EU Charter on Fundamental Rights (2000), The General Data Protection Regulation (EU) 2016/679 ("GDPR") and [DELETE NON RELEVANT ONES] World Medical Association (WMA), Declaration of Helsinki (2008), The UNESCO Universal Declaration on Bioethics and Human Rights (2005), ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice (1997) |
| **Procedures** | If you decide to participate, you will be asked by [NAME OF PERSON IN TH ERESEARCH TEAM REALATING WTH THE PARTICIPANT; IT CAN BE DIFFERENT FROM THE PRINCIPAL INVESTIGATOR] to [CLARIFY IN A FEW WORDS THE DATA COLLECTION TECHNIQUE USED OR TASK] about [CLARIFY TOPIC AS SPECIFICALLY AS POSSIBLE WITHOUT BEING SUGGESTIVE]. The data collection session take place in [COMPLETION BY PRINCIPAL INVESTIGATOR] and lasts approximately [COMPLETION BY PRINCIPAL INVESTIGATOR].   To participate, you must [ADD INCLUSION CONDITIONS, e.g. age, ..]. |
| **Incidental findings** | [INFORM PARTICIPANTS OF THE KIND OF INCIDENTAL FINDINGS YOU CAN GET AND LET THEM DECIDE WHETHER THEY WANT TO BE INFORMED OR NOT OF THEM] |
| **ETHICAL APPROVAL** | This study has been reviewed and approved by the HIT Ethical Committee [ADD APPROVAL ID ANDS AND DATE] |
| **Potential Risks and Discomforts** | [CLARIFY WHAT OBVIOUS PHYSICAL, LEGAL OR ECONOMIC RISKS ARE ASSOCIATED WITH PARTICIPATING IN THE STUDY, IF ANY MINIMIZATION PROCEDURES ARE IN PLACE AND HOW CAN THE PARTICIPANT SIGNAL DISCOMFORT AND STOP THE SESSION] |
| **Potential Benefits** | [CLARIFY WHAT SPECIFIC OR GENERAL BENEFITS DERIVE FROM PARTICIPATING IN THE RESEARCH; IF TREATMENT IS TESTED, BE CLEAR ABOUT THE EXPECTED IMPROVEMENTS AND IF THERE IS GOING TO BE ANY] |
| **Compensation** | [CLARIFY IF ANY COMPENSATION HAS TO BE EXPECTED AND WHEN] |
| **Right to Withdraw and Questions** | Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalised or lose any benefits to which you otherwise qualify. [PLEASE ADD WHAT IS APPROPRIATE: IN CASE OF WITHDRAWAL THE DATA COLLECTED UP TO THAT MOMENT WILL/WILL NOT BE SAVED/PROCESSED FOR ANALYSIS].  If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the principal investigator. |
| **Confidentiality** | Your privacy will be protected to the maximum extent allowable by law. No personally identifiable information will be reported in any research product. All data will be stored and processed in anonymous form; identification information will be destroyed after the data collection. Data are stored in a secure location in the researchers’ offices or on the researchers password-protected computers only trained research staff will have access to your responses.  No image collected during the session will be displayed in publications or presentations unless you explicitly agreed in the declaration form below.  [IF THE **DATASET WILL BE STORED IN A PUBLIC REPOSITORY OR OTHERWISE PUBLICLY ACCESSIBLE**: PARTICIPANTS SHOULD BE INFORMED ON HOW THEIR DATA WILL BE SHARED; FOR EXAMPLE, IT SHOULD BE CLEAR IF DATA WILL BE AVAILABLE ON PUBLIC REPOSITORIES OR RESTRICTED ACCESS PROCEDURES WILL BE IN PLACE] |
| **Consent to data processing** | [INFORM THAT THE PARTICIPANT HAS TO CONSENT TO THE PROCESSING OF PERSONAL DATA, WHEN THIS CONSENT WILL BE ASKED (WHETHER BEFORE OR AFTER PARTICIPATION).  INFORM THAT THE PARTICIPANTS HAS THE RIGHT TO REQUEST FROM THE CONTROLLER ACCESS TO AND RECTIFICATION OR ERASURE OF PERSONAL DATA (ARTT. 15, 16, 17 GDPR). IF DATA ERASURE IS NOT POSSIBLE, EXPLAIN WHY THIS IS THE CASE (E.G. THE IMPOSSIBILITY OF IDENTIFYING THE DATA SUBJECT DUE TO A PROCESS OF ANONYMIZATION – ART. 11 GDPR). PROVIDE CONTROLLER’S CONTACT INFORMATION.]  [IF THE PROJECT SEEMS TO INVOLVE PROFILING (E.G. "ANY FORM OF AUTOMATED PROCESSING OF PERSONAL DATA EVALUATING THE PERSONAL ASPECTS RELATING TO A NATURAL PERSON, IN PARTICULAR TO ANALYSE OR PREDICT ASPECTS CONCERNING THE DATA SUBJECT'S PERFORMANCE AT WORK, ECONOMIC SITUATION, HEALTH, PERSONAL PREFERENCES OR INTERESTS, RELIABILITY OR BEHAVIOUR, LOCATION OR MOVEMENTS, WHERE IT PRODUCES LEGAL EFFECTS CONCERNING HIM OR HER OR SIMILARLY SIGNIFICANTLY AFFECTS HIM OR HER"), THE RESEARCHERS NEEDS TO DESCRIBE THE NECESSARY PROVISIONS TO MEET GDPR REQUIREMENTS IN THIS CASE, AND IN PARTICULAR: THE RIGHT TO OBJECT (ART 21), THE RIGHT NOT TO BE SUBJECT TO A DECISION BASED SOLELY ON AUTOMATED PROCESSING (ART 22) AND THE DESCRIPTION OF THE CONSEQUENCES OF PROFILING (PRINCIPLE OF FAIR AND TRANSPARENT PROCESSING)] |
| **Controller** | Please specify who holds the responsibility of the whole data processing (the "controller" – Art. 28 GDPR). It can be the principal investigator. |
| **Processor** | Specify who is the representative of the controller who carries out the processing on behalf of the controller – the processor Art. 28 GDPR) |

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|  | **CONSENT STATEMENTS** | |
| **Statement of Consent to participate** | I agree to participate in the research project described in the information note attached here and led by [COMPLETION BY PRINCIPAL INVESTIGATOR].  1. I have been given sufficient information about this research project and my questions has been answered to my satisfaction. The purpose of my participation has been explained to me and is clear.  2. My participation is voluntary. There is no explicit or implicit coercion whatsoever to participate.  3. I am at least 18 years of age. | |
|  | 4. I have the right not to answer any of the questions. If I feel uncomfortable in any way during the interview session, I have the right to withdraw from the interview.  5. I have been given the explicit guarantee that the researcher will not identify me by name or function in any reports based on this study, and that my confidentiality as a participant in this study will remain secure. In all cases subsequent uses of records and data will be subject to standard data use policies at the EU (Data Protection Policy).  6. I have been given the guarantee that this research project has been reviewed and approved by [COMPLETION BY PRINCIPAL INVESTIGATOR]  7. I have been given a copy of this consent form co-signed by the interviewer. | |
| **Signature and Date** | **NAME PARTICIPANT** | **NAME PRINCIPAL INVESTIGATOR** |
| **SIGNATURE** | **SIGNATURE** |
| **DATE** | **DATE** |
| **Consent to data processing** | 1. I was explained and I understood the full goal of the study.  2. I consent to the processing of the personal data collected during the session in which I participated for the project led by[COMPLETION BY PRINCIPAL INVESTIGATOR].  3. I know that I have the right to withdraw the consent at any time. I also know that I have right to request from the controller access to and rectification or erasure of personal data (Artt. 15, 16, 17 GDPR). I am aware that where the data erasure is not possible, the controller will explain why this is the case (e.g. the impossibility of identifying the data subject due to a process of anonymization – Art. 11 GDPR) | |
| **Signature and Date** | **NAME PARTICIPANT** | **NAME PRINCIPAL INVESTIGATOR** |
| **SIGNATURE** | **SIGNATURE** |
| **DATE** | **DATE** |
| **Consent to publishing images** | 1. I consent that images taken from photo or video recordings collected during the session can be used when presenting the study and publishing its results. (optional) .  2. I know that I have the right to withdraw the consent at any time, I know that I have right to request from the controller access to and rectification or erasure of personal data (Artt. 15, 16, 17 GDPR). I am aware that where the data erasure is not possible, the controller will explain why this is the case (e.g. the impossibility of identifying the data subject due to a process of anonymization – Art. 11 GDPR) | |
| **Signature and Date** | **NAME PARTICIPANT** | **NAME PRINCIPAL INVESTIGATOR** |
| **SIGNATURE** | **SIGNATURE** |
| **DATE** | **DATE** |