*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) separate consents must be prepared for each type of participant involved.*

*In case of research with* ***minors****, the consent must make explicit the name of the minor involved in the study and include the following sentence* "I declare to be the parent of /or to hold parental authority on [name of the minor]". Either both parents sign the consent or the one signing the consent ticks the statement "I declare that all who hold parental authority on [nome minore]" agree with the participation of said minor to the study described in the information note preceding this declaration (in Italian: "dichiaro che tutti coloro che condividono la patria potestà sono d’accordo con la partecipazione del bambino allo studio descritto nell'informativa"*,*

*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*

|  |  |
| --- | --- |
|  | **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 principal investigator name].  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 must use simple, straightforward language and be short. No technical terms.  This research is sponsored by [COMPLETION BY PRINCIPAL INVESTIGATOR, including link to website]. The research has/has no commercial purpose. |
| **Procedure** | If you decide to participate, you will be asked by...  The description must contain the following information:  - NAME OF PERSON IN THE RESEARCH TEAM REALATING WTH THE PARTICIPANT; IT CAN BE DIFFERENT FROM THE PRINCIPAL INVESTIGATOR]  - THE DATA COLLECTION TECHNIQUE USED, **THE KIND OF DATA COLLECTED** AS SPECIFICALLY AS POSSIBLE WITHOUT BEING SUGGESTIVE SO THE PROSPECTIVE PARTICIPANT WILL KNOW WHETHER S/HE IS WILLING TO UNDERGO THAT PROCEDURE This must use simple, straightforward language and be short. No technical terms. No task instructions here or bibliographic references.  [IN CASE YOU NEED TO HIDE SOME INFORMATION HERE OR DECEIVE, YOU ALSO NEED A SECOND CONSENT FORM AT THE END OF THE DATA COLLECTION].  The data collection session takes place in [LOCATION] and lasts approximately [COMPLETION BY PRINCIPAL INVESTIGATOR].   To participate, you must [ADD INCLUSION CONDITIONS, e.g. age, ..]. |
| **Compliance statement** | [ONCE YOU ASCERTAIN THIS TO BE TRUE, PLEASE DECLARE THAT: "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)"  “Il proponente dichiara di ottemperare alle misure di contenimenti del contagio da Covid-19 valide al momento della ricerca e di rendere noti al partecipante I rischi di contagio legati alla partecipazione e le misure di contenimento adottate.” /The principal investigator declares to comply with the measures to contain the contagium from Covid-19 in place at the time of the data collection, and to inform the participant about the risks of contagion depending on the participation to the present study, as well as about the measures to prevent them. (attach the description of covid-related risks and measures as an addendum) |
| **Incidental findings** | [THE PURPOSE OF THIS FIELD IS TO INFORM PARTICIPANTS OF THE KIND OF INCIDENTAL FINDINGS THEY CAN EXPECT e.g. position of the participants score with respect to the average - AND TO LET THEM DECIDE WHETHER THEY WANT TO BE INFORMED OR NOT AND HOW THEY CAN EXPRESS THIS DECISION] |
| **Potential Risks and Discomforts and related minimization procedures** | This requires a risk analysis exercise: CLARIFY WHAT OBVIOUS PHYSICAL, LEGAL OR ECONOMIC RISKS ARE ASSOCIATED WITH PARTICIPATING IN THE STUDY, and the related MINIMIZATION PROCEDURES. THEN, EXPLAIN HOW THE PARTICIPANT DISCOMFORT WILL BE DETECTED (e.g. A SIGNAL?) 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, even if you gave consent. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized 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** | The research team has the following components: [NAMES AND AFFILIATION]. All components commit to treat the data collected with confidentiality and have received proper instruction about the specific nature of this commitment and of the project approved by the HIT Ethical Committee.  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. [Explain how long the data will be stored and in which form; if indefinitely, add: Personal data can be kept for statistic or scientific purposes even beyond the time necessary to reach the goals for which they have been collected or subsequently elaborated, according to 5, § 1e of GDPR].  No image collected during the session will be displayed in publications or presentations unless you explicitly agreed in the declaration form below.  [IF THE ANONYMIZED **DATASET WILL BE STORED IN A PUBLIC REPOSITORY OR WILL BE OTHERWISE PUBLICLY ACCESSIBLE**: PARTICIPANTS SHOULD BE INFORMED ON HOW THEIR DATA WILL BE SHARED; FOR EXAMPLE, REPOSITORY TYPE OR NAME, AND ACCESS PROCEDURE] |
| **Data protection rights** | [INFORM THAT THE PARTICIPANT HAS TO EXPRESSELY PROVIDE OR DENY THEIR CONSENT TO THE PROCESSING OF PERSONAL DATA, WHEN THIS CONSENT IS ASKED].  INFORM THAT THE PARTICIPANTS HAS THE RIGHT TO REQUEST FROM THE INSTITUTIONAL PRIVACY REFERENT 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 INSTITUTIONAL PRIVACY REFERENT’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)] |
| **Data controller + institutional privacy referent** | Please specify who holds the responsibility of the whole data processing (Art. 28 GDPR). For research carried out at UNIPD, the data controller ('Titolare del trattamento, in Italian) is the University of Padova and the institutional privacy referent 'Referente organizzativo per la privacy' is a member of the research team who is an employee of UNIPD (i.e. not a PhD student). Provide name and contact of the institutional privacy referent. |
| **Autorizzati al trattamento** | Members of the research team who participate in the data treatment including PhD students, research fellows, trainees, ... |
| **Processor** | Specify if there is any **external** agency or university or research centre processing the data or any external partner ( Art. 28 GDPR). IN CASE THERE IS ONE, ALSO CLARIFY WHAT ARE THE TERMS O F THE AGREEMENT WITH RESPECT TO DATA PROTECTION.- |
| **In case of deceit** | Instructions to the proponent: If some deceit in the procedure makes it necessary to provide full information about the goals of the study after the data collection has taken place, we recommend to ask for the consent to process data both before and after the session and to include in the pre-session consent a statement like this: 'All information that does not compromise the validity of the data collection was provided in this information note. After the data collection you will be asked again for your permission to process the collected data, which will not be elaborated without such permission. ' |
| **ETHICAL APPROVAL** | This study has been reviewed and approved by the HIT Ethical Committee [ADD APPROVAL ID ANDS AND DATE] |

|  |  |  |
| --- | --- | --- |
|  | **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 [NAME OF ETHICAL COMMITTEE]  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. Please keep the one option that is applicable to this research: I know that I have the right to withdraw the consent at any time, I know that I have right to request from the institutional privacy referent access to and rectification or erasure of personal data (Artt. 15, 16, 17 GDPR). OR I am aware that the data erasure from the dataset is not possible, because of 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. Please keep the one option that is applicable to this research: I know that I have the right to withdraw the consent at any time, I know that I have right to request from the institutional privacy referent access to and rectification or erasure of personal data (Artt. 15, 16, 17 GDPR). OR I am aware that the data erasure from publication is not possible, because of 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** |