HIT Ethical committee

List of items contained in the online form

- Project title
- Principal investigator
- Project proponent
- Proponents’ role
- Proponents’ affiliation
- Proponents’ e-mail
- Proponents’ research area
- Details of researchers participating in the project and accessing the data (Name, Surname, Role, Affiliation)
- If - according to current law - any specific professional is needed for the project (nurse, psychologist, ... ) please explain who they are
- Project type
- Is the project funded or is the proponent going to apply for funding?
- If you answered yes: Please specify what funding agency is/will be involved and the name of the call/funding program
- If the ethical approval is required for an application, please specify the exact deadline (this cannot be shorter than 15 working days from the date of your submission)
- Projects description and goals
- Keywords
- Methods and equipment
- Number of participants
- Participants' gender
- Participants' age range
- Are there underage participants?
- Are there participants belonging to vulnerable categories?
- If you answered yes - Measures to protect and respect vulnerable participants and address their special needs
- Other participants' characteristics (inclusion/exclusion criteria during recruitment)
- Compensation measures in case of lack of treatment (if applicable)
- Does the project involve any kind of deceit?
- Participants’ risks - Please assess if participants can incur any psychological or physical damage due to participation in the study (except privacy risks, which is deal with in a separate section of this form).
- Provisions to face/minimize the risks listed above
- Will the project lead to straightforward incidental findings? (relevant findings falling outside the primary purpose of the project, such as anomalies of clinical relevance)
- Could some participants be in a situation of dependency from the principal investigator making their consent to participate not voluntary?
- If you answered yes: what measures are taken to prevent the prospective participant from feeling obliged to participate?
• Reward - will participants receive any sort of reward from participating in the study (monetary, course credits, vouchers, ...)
• Reward conditions - If you answered yes, what are the necessary steps in order for the participant to receive the reward (session completion? signature of informed consent? data check?)

Data protection
• Data collected (the committee will check for compliance with the data minimization principle)
• Does the project involve the collection and/or processing of sensitive personal data (e.g., health, sexual habits, ethnicity, political opinions, religion, worldview, personal data relating to criminal convictions and offences)?
• Does the project involve the analysis of genetic information (Art. 9 GDPR)?
• Does the project involve tracking or observing participants?
• Expected duration of data collection process
• Protocol (briefly describe the steps of the data collection)
• Type of data analysis method
• Does the project involve the elaboration of personal data previously collected (secondary use)?
• If you answered yes: Please specify which database is used and whose permission is obtained
• Does the project involve automated individual decision-making including profiling (Art. 22 GDPR)?
• Dissemination of pictures - will project dissemination include the pictures of some participants?
• Will bodies other than the one to which the data controller is affiliated share the collected data (including cloud services storing the data, other universities, sponsors, ..)?
• Will data be shared with extra-European bodies?
• Identification information - will identification information be kept even after the end of the study (including in case of pseudonymized data)?
• Data protection risks - Please, assess the impact of the envisaged processing operations on the protection of personal data
• Data anonymization/pseudonymization procedure
• Please describe other privacy protection procedures to face the risks described above and related to collecting, archiving, elaborating and destroying data
• Data controller (person in charge of data protection who shall maintain a record of processing activities under its responsibility)

Consent acquisition
• To whom will the consent be asked? - (in case it is impossible to ask each participant please explain why)
• If the complete information is delayed please explain why and when it is provided
• Contact information - How will participants be given contact information in case they need clarifications?
• Please, upload your informed consent form(s) collated as one PDF file; refer to the template on HIT website http://hit.psy.unipd.it/sites/dipartimenti.it/files/HITEthicalCom_ConsentTemplate.docx
• If the authorization of a third party is needed in order to collect the data please upload their authorization (school, hospital,...)

Final statements and submission
• Has this project been previously submitted to HIT Ethical committee?
• If you answered yes, can you please provide the reference number contained in our decision letter?
• Has this project been previously submitted to other ethical committees than HIT?
• If that other committee did not provide a favorable opinion, what were the controversial issues that you were not able to solve?