**HIT Ethical committee**

**List of items contained in the online form**

**(updated Feb 2020)**

* Project title
* Principal investigator
* Project proponent
* The proponent is (BMCS PhD student/HIT member/none of the above - the committee will check for eligibility)
* The project is (a BMCS student project/HIT is the beneficiary of the grant or the party in an agreement/none of the above - the committee will check for eligibility)
* Proponents’ role
* Proponents' affiliation
* Proponents’ e-mail
* Proponents’ research area
* Researchers participating in the project and accessing the data (Name, Surname, Affiliation, Job position and Role in the project)
* 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 by the funding agency, please specify the exact deadline (this cannot be shorter than 15 working days from the date of your submission)

**Project description**

* Projects description and goals
* Keywords
* Methods and equipment
* Please describe any prototype still not in the market and interfacing the user in this project
* 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 controller (person in charge of data protection who shall maintain a record of processing activities under its responsibility)
* Referente privacy (must be a UNIPD employee, not a student)
* Will bodies other than UNIPD share the collected data (including cloud services storing the data, other universities, sponsors, ..)?
* If you answered yes, please clarify who is the data processor and what are the basis of the agreement with them
* Will data be shared with extra-European bodies?
* 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?
* 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

**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**

* Is this project a slight variation of previously approved project?
* If you answered yes please list the changes to the previously approved project
* Has this same 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?