**HIT Ethical committee**

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

**(updated July 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
* 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; UNIPD for projects carried out by UNIPD)
* Referente organizzativo per la privacy (the UNIPD employee in charge of data protection for the specific research project)
* Autorizzati al trattamento (Members of the research team who participate in the data treatment including PhD students, research fellows, trainees, ...)
* 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 the research team at UNIPD about data protection
* 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 a previous project approved by this committee?
* 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?

**Declaration**

By submitting this form, I (the proponent) declare that if the data collection has not started yet; if the data collection will start before the committee has reached its decisions, I will promptly inform the committee. I also declare to be aware of the content of the American Psychological Association (APA) code of ethics, the Declaration of Helsinki, the Association for Computing Machinery (ACM) code of ethics, the EU Data protection Law (the Directive 95/46/EC and the Directive 2002/58/EC on privacy and electronic communications. I moreover declare that the present project is designed and conducted in compliance with the content of the abovementioned regulations.