HUMAN INSPIRED TECHNOLOGY
Research Centre

HIT Ethical committee

List of items contained in the online form

(updated on April 16nd, 2024)

This list of items has the purpose of helping the proponent prepare the information for the submission. It is not meant for offline submission.

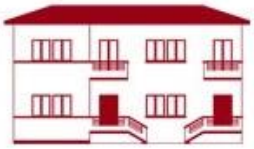
- **Do not prepare a separate informed consent.** The informed consent for your project will be automatically generated with the information inputted in the "**$**" fields in the form. It will be sent to the email of the principal investigator entered in the form.
- Fields marked with the **asterisk (*) are mandatory**.
- Depending on your project, you might need to prepare and upload in the form two documents:
    1. *if a team member is external to UNIPD* ->decide whether it is a data processor or a data controller along with UNIPD; accordingly, prepare the **agreement using the appropriate one among the following templates (the links are on the** website**);**

        - joint data controller (in Italian)
        - joint data controller (in English)
        - data processor (in Italian)
        - data processor (in English)

    2. *if you are collecting data in an online survey or experiment*->**a short version of the informed consent form** to be posted on the first page of the survey, containing:
        - name and contact information of the data controller and project-specific referent for data protection
        - sponsor's name
        - why and which data are collected,
        - whether any automated operations or profiling is used
        - whether the data will be transferred to a third-party / data processor,
        - whether the data will be transferred to third countries (i.e., outside the EU),
        - format of data storage
        - participant's rights (withdrawal, being forgotten, data accuracy) and how to exercise them
        - link to the extended information note
        - declaration of consent

Eligibility

1. The principal investigator is (select the option that better applies- the committee will check for eligibility):
    a) BMCs PhD student
    b) HIT member
    c) authorized non-member



d) none of the above

2. Does the project involve the voluntary or involuntary collection of participants' personal data (opinions, behaviors, responses, physiological state, etc.)
   a) Yes
   b) No
3. Does the project involve the analysis of genetic information (Art. 9 GDPR)?
   a) Yes
   b) No

Project info

3. $- Project title
   [editing box]
4. $ - Principal investigator
   [editing box]
5. $ - Principal investigator's institution
   [editing box]
6. $ - Principal investigator's affiliation (Department)
   [editing box]
7. $- Principal investigators' e-mail (will be used as contact email for the participants in the information note)
   [editing box]
8. Confirm e-mail
   [editing box]
9. E-mail of person filling in this submission (to receive the informed consent file and complete the submission process)
   [editing box]
10. Confirm e-mail
   [editing box]
11. Is the principal investigator a tenured/tenure-tracked UNIPD employee?
   a) Yes
   b) No
12. Is the project funded or is the principal investigator going to apply for funding?
   a) The project is already funded
   b) The principal investigator is going to apply for funding
   c) The project has not been funded yet nor the principal investigator is going to apply for funding

12.1. *If a or b is yes then $*: Please specify what funding agency is/will be involved and the name of the call/funding program
   [editing box]

13. Will you store some data from this project on a public repository? (Open Data; please check carefully: your funding body might mandate an open data policy)
   a) Yes
   b) No

   13.1 *If a, then $:* (Open Data statement) Please select the following info for inclusion in the information note:
   According to an Open Data policy in science, some data from this project will be stored on a public repository
   13.2 *If a, then : $*In which format will be the data stored in the public repository?

a) in anonymous format
b) some anonymized, some not

13.3 *If a, then: $* - (Repository's name) What is the name of the public repository? (leave it blank if you do not know it yet)
[editing box]

13.4 *If a, then*: $ - How can the data be accessed in the repository?
a) The repository data will be accessible to anybody
b) The repository data will be accessible to anybody with a registered account
c) The repository data will be accessible after submitting a justified request to the principal investigator
d) Other [editing box]

14. According to current law, is any specific professional needed in your project (nurse, physician, etc.)?
a) Yes
b) No

14.1 *If a) then*: Please, explain which professional this is, specify their name, and clarify how they are involved in the project (phase, whether in the data processing,...)
[editing box]

15. $ - Does the research have a commercial purpose?
a) The research has a commercial purpose
b) The research does NOT have a commercial purpose

16. Does the project involve any kind of deceit?
a) Yes
b) No

16.1 *If b) then $*: Project's goals (one sentence)
[editing box]

16.2 *If a) then:* (NOTICE): Since the study involves deceit, two distinct informed consent forms will be produced:
1. a **pre-data collection** consent form with the "deceitful" goal of the research;
2. a **post-data collection** consent form with the actual goal of the research.

16.3 *If a) then:* $ - Project's goal (pre-data collection: this answer will show on the PRE-data collection informed consent; one sentence)
[editing box]

16.4 *If a) then:* $ - Project's goal (post-data collection: this answer will show on the POST-data collection informed consent; one sentence)
[editing box]

16.5 *If a) then:* Please explain what kind of deceit is involved
[editing box]

16.6 *If a) then:* $ 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.

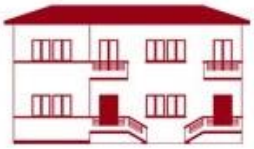
16.7 *If a) then* If the complete information is delayed, please explain why and when it is provided
[editing box]

17. $ - (Optional) Project's background
[editing box]

18. Keywords
[editing box]

19. Study protocol (PROTOCOL: a step-by-step description of the study's sequential phases, including any preliminary steps if needed. Use bullet points to make it as schematic as possible.)
[editing box]

Data collection



20. $ - What data collection procedure is used?
    The participant will be asked to...[editing box]
21. $ - The legal ground for the collection of data is
    a) consent
    b) contract
    c) legitimate interest
    d) Other: [editing box]
22. $ - Expected duration of the data collection session for each individual participant
    Data collection lasts approximately... (please estimate it realistically, based on simulations) [editing box]
23. $ - Location of data collection
    The data collection session takes place in ...(if more than one, then please provide a list of options to be selected at the time of the actual data collection)
    [editing box]
24. Is any special category of personal data collected and/or processed in the project (e.g., health, sexual habits, ethnicity, political opinions, religion, worldview, personal data relating to criminal convictions and offenses)?
    a) Yes
    b) no

24.1 *If a, then* $ - What special category of personal data is collected and/or processed in the project (please list as bullet points)
    [editing box]

25. Is any behavioral/observational data processed in the project?
    a) Yes
    b) no

25.1 *If a, then* $ - What behavioral/observational data is processed in the project (please list as bullet points)
    [editing box]

26. $ - Other types of data collected (bullet points) (Provide a clear and specific description of the data that will be collected, so the prospective participant will know whether they are willing to undergo that procedure. Use simple and concise language without any technical terms. Avoid being suggestive and do not include any instructions or references. If you need to hide some information or deceive the participant, you will also need to hand out a second consent form at the end of the data collection.
    [editing box]

27. For each category of data listed above, including special categories and behavioral, please BRIEFLY explain its instrumentality to the goal of the study (the committee will check for compliance with the data minimization principle. "Any data collected from participants must be appropriate, pertinent, and limited to the specific purposes for which it will be processed"- GDPR, Art 5)
    [editing box]

28. $ - What is the practical way in which the participant can interrupt/withdraw their participation in the study (e.g., signal to the researcher present in the room, specific button on the screen, etc.)?
    To interrupt your participation...
    [editing box]

29. Equipment and material
    [editing box]

30. $ - Name(s) of researcher(s) relating with the participant; they can be different from the principal investigator
    [editing box]

31. Please describe any prototype equipment still not in the market and interfacing with the participants in this project

[editing box]

Participants

32. Number of participants
[editing box]
33. Participants' gender
[editing box]
34. Participants'age
[editing box]
35. Are there underage participants?
a) Yes
b) No
36. Are there participants belonging to vulnerable categories?
a) Yes
b) No

36.1 *If a) then:* Describe the measures to protect and respect vulnerable participants and address their special needs
[editing box]

37. Are participants able to express their consent to participate without a caregiver doing it on their behalf?
a) Yes
b) No
38. $ - Other participants' characteristics (inclusion criteria during recruitment)
[editing box]
39. $ - What are the exclusion criteria during recruitment?
[editing box]
40. Is any pre-screening needed to assess the participant's compliance with the criteria?
a) Yes
b) No

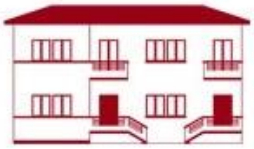
40.1 *If a) then:* Please describe the pre-screening (who does it? How? When?)
[editing box]

41. Is any data collected for the pre-screening?
a) Yes
b) No

41.1 *If a) then:* $ - Please list which data is collected from the pre-screening (Please, provide a clear and specific description)
[editing box]

Risks - Incidental Findings - Rewards - Potential Benefits

42. $ - Risk analysis - Please assess if the equipment/tasks/manipulations in the study can produce, in principle, any psychological or physical inconvenience or discomfort to the participants (except privacy risks, which are dealt with in a separate section of this form)
[editing box]
43. $ - Please, describe the provisions you will take to minimize the risks listed above and explain how the participant's discomfort will be detected (e.g., agreeing on a signal)
[editing box]
44. Will the project lead to straightforward incidental findings?



a) Incidental findings are expected
b) No incidental finding is expected

44.1 *If a) then* $ - Describe the nature of the incidental findings
[editing box]

44.2 *If a) then* $ How will the incidental findings be communicated to the interested participants?
a) Incidental findings will be communicated to participants before they leave the session
b) Interested participants will be contacted via e-mail

45. Could some participants find themselves in a situation of dependency on the principal investigator (which would make their consent to participate not voluntary)?
a) Yes
b) No

45.1 *If a) then* What measures are taken to prevent the prospective participant from feeling obliged to participate?
[editing box]

46. Reward - Will participants receive any sort of reward for participating in the study (monetary, course credits, vouchers, etc.)?
a) Participants will receive a reward for participating in the study
b) Participants will NOT receive any reward for participating in the study

46.1 *If a) then* $ - Please describe what kind of reward will the participants receive
[editing box]

46.2 *If a) then* $ - Reward conditions - Please describe the necessary steps for the participant to receive the reward (session completion, signature of informed consent, data check).
[editing box]

46.3 *If a) then* Reward conditions - Please describe the criteria used to define the amount of the reward
[editing box]

47. $ - Clarify what specific or general benefits derive from participating in the research (e.g., to contribute to the advancement of the knowledge in …; individual feedback about some aspects of the study)
[editing box]

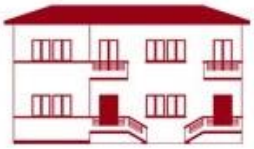
48. Lack of treatment - Does your design involve one subgroup of the recruited participants being excluded from treatment? (including recruiting a preexisting groups, e.g., a class, and then excluding some of the pupils)
a) No
b) Yes

48.1 *If b) then* $ - Compensation measures in case of lack of treatment/lack of compliance with inclusion criteria (if applicable)
[editing box]

Participants' contact info

49. Will you keep the participants' contact information to contact them again?
a) Yes
b) No

49.1 *If a) then*: Logic$ - Explain why and for how long you will keep participants's contact information and who will have access to it
[editing box]



49.2 *If a) then*: Logic$ - What is the practical way in which participants can ask to be deleted from the mailing list?

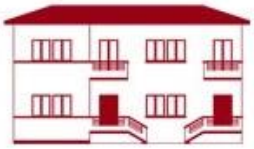
Privacy and data protection

50. $ - Data controller (titolare del trattamento) (DATA CONTROLLER: who determines the reasons and methods for processing personal data in the study. In the case of projects conducted by the University of Padua, UNIPD is by default the data controller.)
[editing box]
51. $ - Project-specific referent for data protection (referente organizzativo per la privacy)
[editing box]
52. $ - Project-specific referent for data protection (referente organizzativo per la privacy)'s e-mail
[editing box]
53. Confirm e-mail
[editing box]
54. Are there any non-UNIPD data processors/controllers (responsabili /contitolari del trattamento)? (DATA PROCESSOR: an individual or organization, including a public authority or agency, that processes personal data on behalf of the data controller. The term "processing" refers to any action (or series of actions) carried out on personal data (or groups of personal data), regardless of whether it is done by automated means. It includes: collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. Even the storage of information, without consultation, qualifies as processing.)
a) Yes, there are non-UNIPD data processors/controllers.
b) No, all data processors/controllers are with UNIPD.

54.1 *If a) then* Logic$ - $ - Please specify who the non-UNIPD data processor/controller is
[editing box]
54.2 *If a) then* Logic$ - Please specify the purpose of the non-UNIPD processing/controller
The data will be transferred to the data processor in order to... [editing box]
55. $ - Members of the UNIPD research team and related affiliation (Please include every member of the research team who participates in the data processing processing. This includes: PhD students, research fellows, trainees, etc.)
[editing box]
56. $ - Will the data collected be re-used?
a) The data collected will be used exclusively to fulfill the scientific purpose described above.
b) The data collected here can be used to fulfill scientific purposes compatible with the ones declared here

57. Dissemination of pictures - will the project’s dissemination material include pictures/videofooting where the participant is recognizable?
a) Yes
b) No

57.1 *If a) then* $ - Please select the following option:
No image collected during the session will be displayed in publications or presentations in which you are recognizable unless you explicitly agree in the declaration form below
57.2 *If a) then* $ - Since you said you collect participant's image, if they agree, then please select the following option to be inserted in the information note
Except for the images of the participants who gave consent to use them for dissemination
58. $ - Participation withdrawal during data collection
a) in case of withdrawal, the data collected up to that moment will be deleted



b) in case of withdrawal, the data collected up to that moment will be retained unless you [the participant] ask for their erasure
c) in case of withdrawal, the data collected up to that moment will be retained because it is technically impossible to delete

59. Does the project involve elaborating personal data previously collected (secondary use)?
a) Yes
b) No

59.1 *If a) then* Please specify which dataset is used and whose permission is obtained
[editing box]

60. $ - What kind of data analysis is conducted (e.g., statistical analysis on aggregated data)?
[editing box]

61. $ - Does the project involve automated processing, including profiling (Art. 22 GDPR)?(PROFILING: the automated processing of personal data related to an individual in order to evaluate and predict their abilities in a particular field, or to assist in categorizing groups of people. This includes data about work performance, economic status, health, personal preferences or interests, reliability or behavior, location or movement, which may have legal implications or significantly impact them.)
a) The project involves automated processing
b) The project does not involve processing -making

61.1 *If a) then* $ - Please specify the profiling theme (e.g., personality, ethnicity, etc.).
[editing box]

62. Will the data be analyzed by web-based services? (e.g., Code Interpreter)
a) Web-based services will analyze data
b) Web-based services will analyze no data

63. $ - In which format will the data be processed (except for participants' image, if any)? (Data is considered ANONYMOUS when it cannot be linked to an identified or identifiable individual. This can be achieved by avoiding the collection of identifying information or by employing anonymization techniques. PSEUDONYMIZATION: replacing identifying information with a pseudonym (i.e., an alias, a code number or any other artificial identifier), storing elsewhere the information that allows individuals to be re-identified. Such additional information must be kept separately and is subject to technical and organizational measures to prevent personal data from being linked to an identifiable natural person.)
a) Data will be processed anonymously.
b) Data will be processed pseudonymously.
c) Data will be processed pseudonymously, and anonymized sometime after the collection
d) Data will be processed confidentially, but without any anonymization procedure.

63.1 *If a) then* $ - When will identification data be deleted?
a) after the post-session informed consent.
b) after incidental findings are communicated.
c) Other: [editing box]

63.2 *If a) then*: $ - [id erasure anonym.] Please select the following option:
Data erasure is not possible because of the impossibility of identifying the data subject due to a process of anonymization (art. 11 GDPR)

63.3 *If a) then:* $ - [id erasure anonym.] Statement - Please select the following option
I (the participant) 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).

63.4 *If b), d) then* $ - [id erasure pseud. + confid.] Please select the following option:
You have the right to request from the project-specific referent for data protection (referente organizzativo per la privacy) access to and rectification or erasure of personal data (artt. 15, 16, 17 GDPR). The published works based on data that have been used under the terms you authorized so far cannot be deleted.

63.5 *If b), d) then* $ - [id erasure pseud. + confid.] statement - please select the following option
I (the participant) know I have the right to request from the institutional privacy referent access to and rectification or erasure of personal data (Art. 15, 16, 17 GDPR). The published works based on data that have been used under the terms I authorized so far cannot be deleted.

63.7 *If c) then $* - [id erasure pseud2] Please select the following option
You have the right to request from the project-specific referent for data protection (referente organizzativo per la privacy) access to and rectification or erasure of personal data (Art. 15, 16, 17 GDPR). The published works based on data that have been used under the terms you authorized so far cannot be deleted. This right can be exerted before the data are anonymized, hence UNTIL

63.8 *If c), then* $ - [id erasure pseud2] statement - please select the following option
I (the participant) know that I have the right to request from the institutional privacy referent access to and rectification or erasure of personal data (Art. 15, 16, 17 GDPR). The published works based on data that have been used under the terms I authorized so far cannot be deleted. This right can be exerted before the data are anonymized, hence UNTIL

63.9 *If d), then* $ - If the data will be stored indefinitely, please select the following option: "Personal data can be kept for statistics 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"

64. *If 62.1a and 62a and 63b,c,d) then $*: Please explain how you are going to guarantee the following: 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)
[editing box]

65. $ - Please provide more details about: 1. Identification data (which one will be stored, reasons for keeping it) 2. Anonymization procedure or pseudonymization procedure for EACH kind of data (it might be different for images and text).
[editing box]

66. Data protection risks - Please, assess the impact of the envisaged processing operations on the protection of personal data
[editing box]

67. Please describe other privacy protection procedures to face the risks described above and related to collecting, archiving, elaborating and destroying data
[editing box]

68. To whom will the consent be asked? - (in case it is not possible to ask each participant please explain why)
[editing box]

Non-UNIPD Data processing/Joint controller

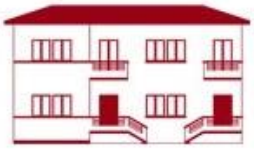
This section refers to the agreement that needs to be stipulated when data are processed/jointly controlled by a non-UNIPD party. In such research partnerships, whether to be a data controller, alone or jointly with other parties, or "just" a data processor depends on their role in determining the goal of treatment and in taking on the data protection obligations of the controller.

69. $ - Please specify who is the referent in the non-UNIPD party
[editing box]

70. $ - Specify in which countries the non-UNIPD research team members are based

71. $ - Are all of the States involved EU members? (For the updated list of EU member states visit https://tinyurl.com/ymcp3t8y)
a) All of the States involved are EU members.
b) Not all of the States involved are EU members.

71.1 *If b), then* $ - If they are not EU members, has the EU already made an adequacy decision? (The European Commission determines if a non-EU country provides sufficient data protection. For an up-to-date list of



adequacy decisions, please visit https://tinyurl.com/4k3xx2tv. When exchanging data with the U.S., the adequacy decision is not sufficient. The American organization must also be part of the Data Privacy Framework. For an up-to-date list of organizations belonging to the Data Privacy Framework, please visit https://tinyurl.com/y5cw2mr3)

a) The EU has already made an adequacy decision.
b) The EU has not made an adequacy decision yet.

71.1 *If b), then*: What are the non-EU members' adaptations to GDPR standards?

72. $ - Please specify the format in which data are accessed by the data processor

73. $ - Explain what the object, nature, purpose and duration of the processing are

74. $ - What are the rights and obligations of both the data controller and the data processor?
Please, state the terms of the agreement with the data processors regarding data protection, in particular clarify whether the data is shared in an anonymous format (recommended). If the data processor is (a) not an EU member state and (b) the EU has not made an adequacy decision about it, the agreement must also ensure that the general rights granted to EU citizens by GDPR are granted to the EU study participants

- Please, upload the text of the agreement with the data processors/joint controller; templates were linked to at the beginning of this form. In particular, please clarify whether the data is shared in an anonymous format (recommended). If the data processor is (a) not an EU member state and (b) the EU has not made an adequacy decision about it, the agreement must also ensure that the general rights granted to EU citizens by GDPR are granted to the EU study participants. In particular please clarify whether the data is shared in an anonymous format (recommended). If the data processor is (a) not an EU member state and (b) the EU has not made an adequacy decision about it, the agreement must also ensure that the general rights granted to EU citizens by GDPR are granted to the EU study participants [file upload]

Regulations and compliance statements

75. $ - 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 World Medical Association (WMA)
- the Declaration of Helsinki (2008)
- the UNESCO Universal Declaration on Bioethics and Human Rights (2005)
- the ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice (1997)
- Other: (Only relevant ones)

76. Do you use a short-form informed consent where you link the complete version of the informed consent itself?(In the short-form informed consent, provide the following details: name and contact information of the data controller, contact information of the data protection officer (DPO), motives for processing the data, how the data will be processed, the legal ground for collecting data (e.g., consent, contract, or legitimate interest), which personal data will be processed, whether any automated operations (e.g., Code Interpreter) will be used whether the data will be transferred to a third-party / data processors, whether the data will be transferred to third countries (i.e., outside the EU), duration of data storage, participant's rights and how to exercise them, link to access the extended informed consent, link to the full information note, declaration of consent)

a) Yes
b) No

76.1 *If a) then*: Please upload the short informed consent

[file upload]

77. Is this project a slight variation of a previous project approved by this committee?
    a) Yes
    b) No

77.1 *If a) then*: Please provide the submission ID or any other way to identify that project
Has this project been previously submitted to other ethical committees than HIT?
    a) Yes
    b) No

77.2 *If a) then*: If that other committee did not provide a favorable opinion, what were the controversial issues that you were not able to solve?
[editing box]

The undersigned declares that all the information provided to the Ethics Committee through this form is truthful pursuant to the articles 46 and 47 of the Presidential Decree 445/2000, aware of the criminal sanctions provided for by art. 76 of Presidential Decree 445/2000, for cases of falsity in documents and false declarations