IUSS
Scuola Universitaria Superiore Pavia

RESEARCH PROJECT

Risk analysis sheet for research projects

According to art. 3 of the 'Ethics Rules for Processing for Statistical or Scientific Research Purposes' of the italian Garante per la Protezione dei dati personali (G. U. no. 11 of 14 January 2019) and Art. 89 of EU Regulation 2016/679

1 Project presentation

1.1 Project title

……

……

1.2 Scientific project manager

Name and Surname	
Role or position in Scuola IUSS	
Afferent structure	
E-mail address	
Phone number	

1.3 Other involved researchers

Name and Surname	
Institution of affiliation	
Role or position in Scuola IUSS	
Role or function in the project	

Name and Surname	
Institution of affiliation	
Role or position in Scuola IUSS	
Role or function in the project	

1.3 Is any authorisation of other bodies/third parties required for access to data o or involvment of the partecipants?
❑ Yes (please attach a copy of the letter of authorisation/data request from third parties) ❑ No

1.4 SAre interventions requiring specific professional skills (doctor, psychologists, nurses, etc.) planned?
❑ No ❑ Yes (specify the instructions provided concerning data processing)

1.5 Are there any partners, organisations, sponsors or funders who might become aware of the personal data?
❑ No ❑ Yes (indicate the subjects and their role in the project)

2. Project details

2.1 Scheduled start date
2.2 Scheduled end date
2.3 Research programme summary

2.4 Project description

[content may be modified according to the project and the scientific disciplinary field

2.4.1 Objectives and expected results

2.4.2 Methodology (used tools)

2.4.3 Procedure description (attach a copy of any documentation used/compile process description)

Methods and procedures

- ❑ questionnaires
- ❑ structured or semi-structured interviews
- ❑ in-depth interviews
- ❑ focus group
- ❑ diary keeping
- ❑ observation of the behaviour of subjects without their knowledge
- ❑ observation of subjects' behaviour
- ❑ audio or video recordings of subjects
- ❑ provision of stimuli, tasks or procedures and recording of behavioural responses, opinions or judgements
- ❑ provision of stimuli, tasks or procedures that the subject might find annoying, stressful, physically or psychologically painful, either during or after the conduct of the study
- ❑ movements recording
- ❑ immersion in virtual reality environments
- ❑ recording of evoked potentials
- ❑ provision of tests, questionnaires or experimental protocols via the internet (web, email)
- ❑ use of neuropsychological tests and neuroimaging techniques
- ❑ provision of substances or agents (e.g., drugs, alcohol)
- ❑ partecipation in a clinical trial
- ❑ other (please specify)…….

2.4.4 Project participants

Typology:

- ❑ Adults
- ❑ Minors

- ❑ Students
- ❑ Workers
- ❑ Physically and mentally disabled persons or persons with restricted capacity
- ❑ Members, associates or adherents of religious, political, philosophical or trade union organisations
- ❑ Convicts, detainees, defendants, suspects or those subject to security or preventive measures
- ❑ Healthy volunteers
- ❑ Patients
- ❑ Others

Approximate number of participants_____

Characteristics of the group of research participants:

- ❑ Homogeneous groups by sexual habits
- ❑ Homogeneous groups by racial or ethnic background
- ❑ Homogeneous groups by geographical area
- ❑ Homogeneous groups by physical characteristics
- ❑ Homogeneous groups by consanguinity
- ❑ Homogeneous groups by risk factors
- ❑ Homogeneous groups by religious, philosophical, political or trade union beliefs
- ❑ Specify any additional inclusion/exclusion criteria .....

2.4.5 Is it possible that some of the subjects may be in a position of dependency vis-à-vis the researcher or his collaborators, such that the expression of consent to participate in the study may not be entirely free and unencumbered?

- ❑ Yes

If yes, please indicate how you intend to minimise the possibility of the subject feeling obliged to take part in the research (e.g. student/professor, patient/ physician, employee/employer relationship) Example: The subject evaluates without any hurry or psychological pressure the information received through the forms and decides to take part in the research, giving consent to treatment only after the treatment itself or information meeting

- ❑ No

2.4.6 How will the information/invitation to participate in the research be disseminated?

2.4.7 Is there any form of incentive for study participants?

- ❑ Yes (which)

- ❑ No

2.4.8 Risks for participants

- ❑ None
- ❑ Social, legal or economic risks
- ❑ Discomfort or risks to physical and psychological well-being
- ❑ Others

2.4.9 Benefits for partecipants

- ❑ None
- ❑ Social benefits obtained through improved scientific knowledge
- ❑ Fee
- ❑ Others

2.4.10 Is there a specific liability insurance policy in addition to the University's policy?

- ❑ Yes, an insurance policy has been taken out covering all damages strictly related to participation in the study. Insurance cover has been taken out with the following insurance company:

Name
phone
email address
Insurance number

- ❑ The study is non-profit, observational and the University insurance is used
- ❑ The study is non-profit, interventional and an insurance premium is added
- ❑ No insurance is provided

2.4.11 How do you plan to deal with the case that the person concerned intends not to join the search (even at a later stage)?

- ❑ The data subject may withdraw consent at any time and without giving any reasons, resulting in the destruction of the data

- ❑ The data subject may request that all previously collected data be destroyed or definitively anonymised only in the stages preceding irreversible anonymisation or aggregation
- ❑ other (specify)…….

3. Personal data processing and security measures

3.1 Indicate the reasons/purpose of the research justifying the processing of personal data

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3.2 Select the type of data processed

- ❑ **Personal data** shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, by reference in particular to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to his physical, physiological, genetic, mental, economic, cultural or social identity.
  Personal data in particular include:
  - Identification data: personal data allowing direct identification
- ❑ **Special categories of data (Sensitive data)**: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data intended to uniquely identify a natural person, data concerning a person's health or sex life or sexual orientation;
  - **Genetic data:** personal data relating to hereditary or acquired genetic characteristics of a natural person which provide unambiguous information on the physiology or health of that natural person, and which result in particular from the analysis of a biological sample of that natural person;
  - **Biometric data:** personal data obtained by specific technical processing relating to physical, physiological or behavioural characteristics of a natural person which enable or confirm their unambiguous identification, such as facial image or dactyloscopic data;

- **Healt-related data**: personal data relating to the physical or mental health of a natural person, including the provision of services, health care that reveal information relating to his or her state of health.

- ❑ **Jiudicial data:** personal data that may reveal the existence of certain judicial measures subject to entry in the criminal record or the status of accused persons or suspects;
- ❑ **Anonymous data:** information that does not relate to an identified or identifiable natural person or personal data rendered sufficiently anonymous so that the data subject cannot or no longer can be identified.

3.3 Personal data collection methods

- ❑ **Direct**: participant data is provided by the participant (e.g. use of questionnaires, audio or video recording of subjects, interviews, observation of subject behaviour, administration of tests, etc.; please specify)

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- ❑ **Indirect**: the participant's data is provided by others (e.g. through a request for disclosure of data to another body, questionnaires submitted to family members and/or other third parties; please specify)

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3.4 Information and consent

3.4.1 How will the privacy policy be provided to project participants according to Art. 13 of EU Regulation 2016/679? (please attach copy of the policy)

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3.4.2 (If applicable) Indicate the specific aims and modalities of the project for which it is necessary to postpone the information from the beginning of the project

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3.4.3 (Eventual) If the processing for research purposes concerns data collected for other purposes or even if the data are collected from third parties, and the provision of the information would entail a disproportionate effort, select the forms of advertising to be adopted:

- ❑ Insertion in at least one newspaper with a wide national circulation or advertisement on a radio or television station with a national circulation (for large groups of subjects distributed throughout the entire national territory);
- ❑ Insertion in a daily newspaper with a wide regional (or provincial) circulation or advertisement on a radio or television station with a regional (or provincial) circulation (for groups of subjects spread over a regional or provincial area);
- ❑ Insertion in information tools of which the interested parties are normally the recipients (for groups of specific categories of subjects);
- ❑ Other appropriate forms of publicity to be communicated to the Garante Privacy.

3.4.4 (If applicable) How will consent to the processing of personal data be acquired? (The data of minors or of persons incapable of giving consent will be used only if the consent of the parents or of the other parent in the absence of one of them or of the legal representative is obtained)

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3.4.5 What arrangements will be made to receive expressions of concern and respond to requests for clarification from subjects during the course of the study?

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3.4.6 (In the case of health data) *How will participants be informed of the possibility of receiving, directly or indirectly, any other data relating to their psychophysical condition that may become available during the research? (information)*

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3.4.7 Is the disclosure of personal data (not in anonymous and/or aggregate form) envisaged and in what manner?

- ❑ No
- ❑ Yes

If yes, please specify the modality (Internet, multimedia tools, scientific journals, conferences, databases, etc.) .....

3.5 Data communication and diffusion

3.5.1 The disclosure of personal data (not in anonymous and/or aggregate form) is envisaged and in what manner:

- ❑ No
- ❑ Yes

If yes, please specify to which recipient (Public Administration, project partners, other public or private entities, etc.) and by which means.....

3.5.2 The transfer of personal data (not in anonymous and/or aggregate form) outside the EU is envisaged and according to which modality:

- ❑ No
- ❑ Yes

If yes, please specify to which country and what safeguards are adopted for international transfer .....

3.6 Risk assessment and management, security measures

[The researcher should identify the assets and instruments through which personal data are processed and/or stored (hardware, software, networks, people, paper transmission channels, etc.) as well as describe the protection measures adopted].

3.6.1 Indicate whether the processing presents risks for the rights and freedoms of data subjects under Article 35 of the GDPR, also on the basis of the characteristics of the data (e.g,

profiling and automated decisions; systematic monitoring; processing of special categories of data; data relating to vulnerable persons such as minors, the disabled, the elderly, persons with pathologies; application of new technological solutions)[1]

- ❑ No
- ❑ Yes

if yes, state the specific risk and indicate the measures envisaged to address it

……

3.6.2 Indicate the technical and organisational measures that will be adopted in the processing and storage of personal data (e.g.: pseudonymisation2 , encryption techniques, back-up copies, authentication systems, authorisation systems, specific safeguards in the case of sensitive data, use of unique codes for each participant -only the research manager or other authorised parties can link the codes to the identity of the participants- elimination of personal data after collection, storage of aggregated data only, sample extraction procedures, imputation, correction and statistical protection adopted for data production..etc.). Indicate the measures taken that contribute to the proportionality and necessity of the data processing.

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[1] https://www.garanteprivacy.it/regolamentoue/DPIA/gestione-del-rischio e https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/9058979

[2] This is the processing of personal data in such a way that personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is stored separately and subject to technical and organisational measures to ensure that such personal data is not attributed to an identified or identifiable natural person (Art. 4(5) GDPR).

3.7 Data storage period

3.7.1 Indicate the retention period of the data collected in the research (specify the possible retention of data beyond the realisation of the Project)

Data will be stored for:_____

At the end of this period data will be:

- ❑ *destroyed*
- ❑ *anonymously stored*

……

3.7.2 Indicate how the data will be stored

- ❑ In hard copy
- ❑ In digital format
- ❑ Other

Place and date

……

Project manager signature

……

This Research Project is deposited with the General Affairs Office of the IUSS School, which will keep it confidential for five years from the planned date of completion of the research activity.

Declaration of commitment to comply with the provisions of the Code of Ethics and Good Conduct for the processing of personal data for statistical and scientific purposes and EU Regulation 679/2016

Research project title:
“_____”

This declaration, attached to the above-mentioned Project, will be deposited with the General Affairs Office of the IUSS School, which will take care of its preservation, in a confidential form (since consultation of the project is only possible for the purposes of the application of the legislation on personal data), for five years from the planned conclusion of the research.

The undersigned declare

- that for the purposes of the Research Project data processing is carried out for

  - ❑ personal data
    - identificational
  - ❑ particular categories of data (sensitive data)
    - genetic
    - biometric
    - healt-related
  - ❑ judicial

- that in carrying out the Project all the measures required for the processing of data are adopted in order to guarantee compliance with the regulations in force on the protection of personal data;

- that by signing this declaration they comply with the provisions of the Code of ethics and good conduct for the processing of personal data for statistical and scientific purposes.

Privacy Role	Name	Signature	Place and date
Project manager/ Authorised for processing			
Authorised for processing			
Authorised for processing			
Authorised for processing			

Any changes in the composition of the research team during the continuation of the Project (this declaration must be signed by any additional persons involved in the continuation of the research):

Privacy Role	Name	Start date	End date	Signature for new entrances
Project manager				
Authorised for processing				
Authorised for processing				
.....				