UNIVERSITÀ DEGLI STUDI DI PALERMO

Department of Psychology, Educational Science and Human Movement

CHILDREN'S PROTECTION IN RESEARCH ACTIVITIES

Approved by the Director of Department

Table of Contents

1. Abbreviations and Notions

For the purposes of these guidelines, we consider the following abbreviations and notions.

CRC: United Nations Convention on the Rights of the Child Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989 entry into force 2 September 1990, in accordance with article 49.
CFR: Charter of Fundamental Rights of the European Union 2012/C 326/02
GDPR: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
Declaration of Helsinki: The World Medical Association (WMA) Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975 35th WMA General Assembly, Venice, Italy, October 1983 41st WMA General Assembly, Hong Kong, September 1989 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added) 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added) 59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
Children: persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. In general, the law considers any person under 18 years old to be a child. However specific exceptions may be identified under the law (e.g. Article 8 GDPR).
Research Subjects: individuals that participates in research either as a recipient or as a control of a given participatory activity and they can be either patients or healthy persons.
Regole Deontologiche: Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica pubblicate ai sensi dell'art. 20, comma 4, del d.lgs. 10 agosto 2018, n. 101 - 19 dicembre 2018" issued by the Italian Data Protection Authority.

2. Background and principles

The involvement of human participants in research activities entails the ethical-legal issues arising from those risks that may attempt to their dignity and fundamental rights protection.

Especially, where children are engaged as research subjects, there is the necessity to ensure the effective implementation of existing binding European and international instruments protecting fundamental rights within the research activities.

The Department of Psychology, Educational Science and Human Movement (DSPPEFF) takes seriously into account possible emerging individual and groups vulnerabilities at every steps of their development. In particular, applicable ethical requirements and legal obligations impacting on research activities result in a complex system of checks and balances.

Considering the rights of children as stated by Article 24 CFR, namely, "the right to such protection and care as is necessary for their well-being", and to "express their views freely. Such views shall be taken into consideration on matters which concern them in accordance with their age and maturity", their engagement as research subjects shall be considered as a sensitive activity for the DSPPEFF. While, in fact, the law requires the consent to be given by the adult being the legal representative of the child, ethical considerations impose to give primary relevance to the child's opinion.

In this regard, the right of all children to be heard and have their views taken seriously in accordance with their age and maturity is laid down also in Article 12 CRC. Such a general principle is connected to all other articles of the Convention and in particular to Article 2 (the right to non-discrimination), Article 3 (primary consideration of the best interests of the child), Article 5 (guidance by parents and evolving capacities of the child), Article 6 (the right to life, survival and development), Article 13 (the right to freedom of expression), Article 15 (the right to freedom of association) and Article 17 (the right to information).

These principles find, therefore, application both when a legal representative is involved and when the child is able to personally participate.

An assessment on the balance between the level of vulnerability experienced by the participant and the need to respect and give way to his/her actual capability to exercise his/her own rights shall be performed in case of children engagement.

Through these guidelines, the DSPPEFF provides its strategy towards children's protection in all institutional activities, as a full commitment to implement any possible safeguards that might be required to ensure a fair, transparent, and responsible approach towards children's wellbeing and best interests.

3. Identified risks

The DSPPEFF considers extremely low the risk either to attempt or to infringe children's fundamentalrights within its institutional activities. In particular:

- Didactical activities are mainly addressed to adults. Exceptions might be identified for outreaching activities and in case a 17 years old candidate is selected as an *Allieva/Allievo.* In these cases, the whole selection process ensures the proper level of child's maturity to undertake the DSPPEFF's activities. Legal representatives consent the enrolment. Other activities (like training ones) developed in collaboration with high schools are framed within specific programs following the pre-determined protocols.

- Third mission activities are mainly addressed to adults. Children could be unknown addresses of communication, dissemination, and exploitation activities, without any risk of direct engagement.
- Research activities. Whereas children are research subjects a risk-based approach will drive our activities in order to assess possible arising risks. The impact of our research on fundamental rights shall be considered as acceptable. To this end, the DSPPEFF is fully committed to implement the needed actions to facilitate the compliance activities and ensuring that the best interests of the involved children are pursued.

The DSPPEFF has a pioneering role in social as well as in experimental sciences. It undertakes research in crucial areas addressing the current societal challenges emerging from Internet Addiction, Cyberbulling, Shame from videophone. Many of our projects deal with applications based on the educational, social and psychological implications of using Artificial Intelligence techniques, etc. processing and mapping the area of risks.

In these scenarios, the DSPPEFF is fully committed to proactively address the ethical-legal challenges emerging from any possible children engagement as research subjects, addressees, stakeholders, data subjects etc. in order to identify and mitigate any possible risks emerging from the use of new technologies

4. Organizational and technical measures

The DSPPEFF is committed to preventing, protecting, and responding to any harm to children engaged in the research activities through the following technical and organizational measures that are implemented considering our operational capacity in promoting fundamental rights protection in every research activity and adopting a proactive approach towards any ethical and legal issue that our impactful research may arise.

In case that the research is funded by an external body, the ethics assessment on the ethical-legal issues emerging from the involvement of the children will be provided according to the specific requirements of the call/granting procedure. Otherwise, an internal self-assessment is performed by the principal investigator.

The results of such an assessment will be included in the project documentation and stored together with the informed consent templates for the time required by the *Regole Deontologiche*.

Research activities may either directly engage children under i) clinical trials and ii) non-clinical trials, or indirectly engage them by iii) processing their personal data.

i) For clinical trials involving children, research protocols shall be submitted to the competent ethical committee of University of Palermo, following the applicable regulatory framework identifying specifictechnical and organizational measures aimed at protecting children that are research subjects because of their specific condition of patients.

ii) For non-clinical trials involving children, research protocols could be submitted to the competent ethics committee(s) of Department SPPEFF.

iii) In case the research includes the processing of children's personal data, GDPR and national

implementations find application.

Under *sub* i) and ii) research protocols shall address the following issues: recruitment procedures, taking into account the level of vulnerability of the participants in order to ensure the enhancement of their fundamental rights (i.e. dignity, health, data protection and privacy, non-discrimination related to all grounds like age, sexual orientation, gender, disability etc.).

Information sheets and informed consent templates will be submitted for approval as well. The information sheet will include a transparent and exhaustive information regarding the project and its purposes, partners involved in the trials and funding bodies, tasks and activities, benefits, possible risks, incidental findings procedures, insurance details, information privacy, including privacy governance and data retention policy. These issues will be addressed both to the research subjects and their legal representatives (guardians, parents, etc.). Language will be adapted to the age of the minors in order to make them aware and able to express their opinion on their participation.

In case of teenagers who can express consent on their own on a given research activity, the recruitment procedures and provided information shall employ a less technical and simpler language to describe the features of the study and of the data processing activities, with the aim to vehiculate in a more effective way the information and collect child's consent to participate to the study. In case the child cannot express his/her consent, his/her maturity will be in any case assessed in order to make him/her aware of the activity and give the opportunity to express his/her own idea.

The same balance will be performed in case the child shall exercise his/her rights to access the results of the research, receive more information, express the desire to withdraw from the study. Any opinion will be taken into account under the legal obligation to pursuing the best interest of the child.

If geographically competent, non-clinical research protocols can be submitted for approval before the Joint Ethics Committee for Research Activities established by University of Palermo, under its regulation (https://www.unipa.it/strutture/comitato-bioetica/).

Under iii) personal data processing is regulated by the GDPR. Therefore, all the compliance activities will be undertaken considering the vulnerability of the data subjects as an element to be assessed in the data protection impact assessment.

In this regard, the DSPPEFF is aware that Article 8 GDPR refers to children as data subjects. In particular,16 years old children can express the consent to get access to information society services. According to the same provision, Member States may provide by law for a lower age, not below 13 years: for example, the article 2-*quinques* of the Italian D. Lgs. 196/2003 enables a 14 years old child to express his/her consent, under the condition that privacy information will be structured in a simple, concise, and exhaustive language adapted to the maturity of the data subjects.

5. Roles and responsibilities

The principal investigator / project coordinator for the DSPPEFF is responsible to ensure that research activities including children will be undertaken in compliance with the applicable ethical-legal framework.

The principal investigator/project coordinator for the DSPPEFF is responsible to train and instruct

internal/external collaborators to ensure the implementation of the identified safeguards aimed at ensuring the compliance of the project as well.

Authorized non-clinical research staff that processes personal data for research purposes is committed to specific confidentiality obligations, pursuing the *Regole Deontologiche*. Possible clinical staff is committed to confidentiality obligations also in case of data processing for research purposes.

The data protection officer can be involved to provide advice on issues related to personal data protection including children as data subjects, and the GDPR compliance-related activities

Specific expertise may be engaged for advice, especially for research involving new technologies.

6. Accountability

The DSPPEFF is committed to ensuring the full compliance of its institutional activities through its internal organization activities.

In addition, considering the pioneering role that the DSPPEFF has within the scientific community, the diffusion of a responsible attitude *by design* and *by default* towards children's protection and wellbeing is promoted by the following activities in order to create awareness, share good practices, and enhance children's rights.

i. Training activities and seminars are organized to share best practises on children's protection among administrative and research staff.
ii. A dedicated webpage on the intranet of the DSPPEFF will include information, templates, materials on children's protection within research activities.
iii. These guidelines will be available on the institutional website of the DSPPEFF.

Palermo, 16 maggio 2022

Director
prof. Gioacchino Lavanco

Firmato digitalmente da: Gioacchino Lavanco
Data: 16/05/2022 10:10:25