Education, Audiovisual and Culture Executive Agency

Some ethical considerations

E+ KA3: Initiatives for policy innovation – European Policy experimentations

This document is provided for information only in order to raise awareness among the partnership on the some ethical issues which should be considered in the design and implementation of the policy experimentation:

The policy experimentation projects use a variety of quantitative and qualitative methodologies that range from focus groups to large scale, multi-site randomised field trials (RCTs), difference-in difference (DiD), regression discontinuity design (RDD), national surveys, literature reviews and synthesis, questionnaires and interviews.

Such methodologies may involve observations or the collection of data on individuals, who directly participate or agree to the use of the information about themselves.

The project results will be made public in a variety of formats tailored to different audiences such as policy makers, families, teachers, academics etc.

Gathering data on the participants (institutions or individuals) may involve risks of harming the participants through, for example: unfair treatment, stress, withheld benefits, and discomfort. There is also a risk for the falsification of data, plagiarism, abuse of confidentiality, etc.

Therefore the partnerships are requested to be aware of and respect ethical principles which should govern the design and execution of the experimentation conducted. These principles should be consistent and compliant with the principles and the professional and ethical codes of conduct to which the researchers must adhere in the respective countries and/or institutions.

When designing and implementing field trials all the parties involved are therefore encouraged to protect the values, rights and interests of the participants and to respect basic ethical principles such as *non-maleficence* (acts should not cause avoidable or intentional harm to others), *informed consent* and *fair treatment*. All the parties involved should act consistently with the principles and professional/ethical codes of conduct applicable in the respective institutions and countries.

Non maleficence

The experimentation should promote interventions bringing benefits to the participants. The method should be appropriate to the chosen topic and the target group (age, social/cultural

level/background). Data collection should be justified by the needs of the participants, target the right groups and follow a suitable timeline.

The parties involved should be aware of potential implications for vulnerable individuals or institutions linked to psychological, social or cultural perceptions. Such implications could be mitigated, for example, by explaining the meaning of questions in advance or by emphasising the right not to answer or participate if participants feel uncomfortable.

Informed consent

Participation in field trials is voluntary. Anyone has the right to refuse to participate or to withdraw participation or data at any time without any consequences.

Participation must be free (potential participants should not feel pressured or forced) and based on informed consent[1]. Consent must be requested and obtained in advance in writing[2] (preserving privacy) on the basis of comprehensive information provided in a language and in terms that are understandable to the (potential) participants. A lack of response to a written request may indicate unwillingness to participate.

(Potential) participants should be informed on the project aims and methods and on how data will be collected, protected during the project and either destroyed or subsequently reused. They should be made aware of the nature of their participation and of potential implications, including how unexpected or incidental findings will be handled.

The participation of institutions/organisations (eg schools) in field trials should be formally endorsed by the responsible management body/bodies. The management and staff directly concerned (eg administrators, teachers) should be in agreement with the decision.

When field trials involve direct contacts with minors, beneficiaries should seek written consent on participation from the parents or the persons holding parental responsibility, and assent from the minors themselves through age-appropriate means[3].

Fair treatment

The selection of participants must be based on clear and accessible criteria. These criteria should be equivalent and comparable in all the countries performing the field trials, as far as different systems and structures allow it.

Members of "comparison groups" ("control groups" or equivalent) and not of "treatment groups" (or equivalent) should receive clear explanations on the methodology and on the benefits that they can derive by participating in the trials even if they will not be testing the new measure, in order to prevent feelings of discrimination.

The policy experimentation must comply with:

- ethical principles

[1] This can reduce the risk of withdrawal at a later stage.
[2] In exceptional cases where written consent can be perceived as harmful or offensive, oral consent can be requested
[3] Not necessarily in writing

- applicable international, EU and national law.

This implies that the partnerships must ensure respect for people and for human dignity, fair distribution of research benefits and burden and protecting the values, rights and interests of the research participants.

Choosing an ethical experimentation approach and designing an ethical experimentation protocol

The policy experimentation often involves working with human participants and particular methodological tools (e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and whether these include physical interventions). You must therefore clarify the ethical implications of the chosen methodologies.

An ethical experimentation design would imply the following:

- ✓ the partnership should choose a research methodology that is appropriate to the type of population that will be subject to the experimentation (sample) ; it should anticipate possible positive or negative perceptions by the population and possible implications (eg for minors);
- ✓ the methodology should be appropriate to the topic, to maximise the utility of results. This would mean to collect data from the right stakeholders and promote interventions from which participants can get the greatest benefit;
- ✓ the experiment must have a clearly rationale justifying the collection of information, and must be grounded in the needs of the participants (schools, children adults, etc) to help them and other like them to receive a better service in the future;
- ✓ the participants must understand the rationale of the experimentation, what is expected of their participation, how their specific information will be used and for what purpose;
- ✓ any trial must suit the data collection needs, be appropriate for the age and education level of participants and have an appropriate duration to gather the desired information;
- ✓ given the nature of the experimentations, precautions should be taken in order to protect the participants. These precautions may include: screenings to identify vulnerable institutions/individuals, ensuring that participants understand the nature of questions in advance, emphasising the right not to answer/participate if they feel uncountable etc. When experimentations involve direct contacts with minors it is essential to seek consent on participation directly from the parents or the persons holding parental responsibility, and from the minors themselves.

Identifying the participants

Strategies to identify/ locate the potential participants can include advertising in local media, posters in public spaces, wide –spread mailing of leaflets etc. These strategies should ensure that the potential participants have fair opportunities to participate in the experimentation. Certain types of experimentations may require participants to be contacted personally. These contacts must be made in writing (undertaking all precautions to preserve privacy), explaining the aims and operation of the experimentation and asking the addressees if they would like to participate. A lack of response to the written request may indicate a desire not to participate.

Selection of the participants

The selection of the participants must be based on clear criteria which are defined by the partnership and are accessible to the participants. The selection criteria should be the same for all partners, to the extent that the peculiarities of education and training/youth systems in each partner country allow it. Participants included only in the "control group" (and not in the "treatment group") should obtain clear explanations about the methodology applied and especially on the benefits that they can derive from participating in the experimentation. The inclusion in one or another group might raise a discrimination feeling, therefore the necessary measures should be undertaken to ensure a fair treatment of all participants.

After selection, comprehensive information must be provided to participants so they can still confirm or decline participation based upon informed knowledge ("informed consent"). This information must include all the details of the study, roadmap of activities, must be in the language of the participants and is commensurate with their ages, level of literacy skills etc. This would minimise the risk to withdraw at a later stage. In this context as well it is crucial that awareness and knowledge should be raised at all levels i.e if the principal of a school agrees to participate in the experimentation , the relevant teachers, students, school administrators should be in line with this decision.

During the implementation of the experimentation the following must apply:

- ✓ the necessary ethics approvals (if required)
- ✓ free and fully informed consent of the participants.

Participation of persons must be entirely voluntary and the partnership must obtain (and clearly document) their informed consent in advance. No consent is required if national law provides for an exception (e.g. in the public interest).

Participants must be provided with an ‘informed consent form’ and detailed ‘information sheets’ that:

- ✓ are in a language and in terms fully understandable to them
- ✓ describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might be involved
- ✓ explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- ✓ indicate how the data will be collected, protected during the project and either destroyed or reused subsequently

- ✓ indicate what procedures will be implemented in the event of unexpected or incidental findings (in particular, if the participants have the right to know, or not to know, of any such findings).

The partnership must ensure that the potential participant has fully understood the information and does not feel pressured or forced to give consent.
Consent must normally be given in writing (e.g. by signing the 'informed consent form' and 'information sheets'). If the consent cannot be given in writing, for example because of illiteracy, the non-written consent must be formally documented and independently witnessed.

Specific cases:

- ✓ Research involving children (or other persons unable to give consent, e.g. certain elderly populations, persons judged as lacking mental capacity) — The partnership must obtain informed consent from the legally authorised representative and ensure that they have sufficient information to enable them to provide this on behalf and in the best interests of the participants. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents or legal representatives. If necessary, re-consent must be asked by the participants at the age of maturity. Dissent should be respected.

- ✓ In social sciences and humanities research, there may be situations where standard procedures for obtaining written informed consent are harmful or offensive to the participants (rather than providing them with protection). In such cases, explain how alternative consent will be gained (e.g. orally). If deception is to be used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred by both researchers and participants.

Handling of information

Information gathered from the individuals or from archival sources should be held in secure conditions and destroyed in a timely manner. Therefore:

- ✓ each participant is guaranteed that information he/she provides will be kept confidential;
- ✓ the anonymity of participants is preserved; therefore names are never used and in any report; the data are presented only in aggregate form;
- ✓ the information obtained is stored in a secure manner and ability to retrieve this information is restricted to authorised personnel defined by the partnership (i.e. partners staff, other relevant staff outside the partnership etc.);
- ✓ in case confidential information is gained form a third party the same guarantees of confidentiality and safe storage should apply;
- ✓ participants in the experimentation may at some point in the future wish to access the information they provided, and the information should be released to them only upon written request;
- ✓ the destruction of the information after the completion of the experimentation should be discussed and the partnership should agree on the timing ;
- ✓ partner institutions must ensure that the manner in which research outcomes are reported does not contravene the right to privacy and data protection (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals

with regard to the processing of personal data and on the free movement of such data, Official Journal of the European Communities (23.11.95) No. L 281/31 – 39) ;

- ✓ partner institutions must comply with the Data Protection legislation applicable in the country where the research is carried out.

Dissemination of results

The partnership has the obligation to distribute the results in languages and formats which are accessible to policy makers, stakeholders, participants etc. The results of the projects should be published as stipulated in the relevant EACEA Call for proposals.

The data collection instruments designed by the projects could be made publicly available to encourage mutual learning and the dissemination of good practice.