

## **Erasmus + KA 201 "NEMO - NEw MONitoring guidelines to develop innovative ECEC teachers curricula"**

### **Ethics self-assessment**

Every research activity of NEMO project will be conducted with respect for all the persons involved, for their rights and interests, as well as for their dignity, freedom, and privacy.

Our ethical guidelines have been coordinated with the Privacy Office of the Alma Mater Studiorum-University of Bologna and with the DPO of AIAS Bologna Onlus, according to widely recognized international codes of practices and texts, including but not limited to:

- The United Nations Universal Declaration of Human Rights
- The Charter of Fundamental Rights of the EU and its Supplementary Protocols
- The Declaration of Helsinki in its latest version
- The European Human Rights Convention
- The principles enshrined in the Oviedo Bioethics Convention
- EU Regulation No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC
- EU Regulation No. 2016/679 of the European Parliament and of the Council of 27 April 2016, concerning the protection of natural persons with regard to the processing of personal data and the free movement of such data.

#### **1. Research on infants-caregivers interaction**

NEMO project involves the analysis of videos of caregivers-children interactions for the realization of IO1 (Teacher Training Course on Pre-linguistic observation and early ASD evaluation). The children represented in the videos are between 9 and 18-months-old of age. The children involved are divided into two groups: 1) Neurotypical children 2) Children who were later diagnosed with Autism Spectrum Disorders.

Due to the sensitivity of the data processed, the project refers to a series of storing, processing, and analyzing procedures, based on the European directives mentioned above.

#### **2. Confidentiality and Protection of recorded data**

The Alma Mater Studiorum- University of Bologna has an established, robust procedure for the approval of any research involving human participation before the study can start.

In particular, the Privacy Office of the University of Bologna and the DPO of AIAS Bologna Onlus are responsible for the evaluation and the approval of all researches. Every scheduled procedure has been agreed with the Privacy Office, after the explicit discussion on how to deal with the following points:

1. Informed consent;
2. Right to withdraw;
3. Openness and honesty;
4. Data storage and protection;
5. Confidentiality;
6. Ethical principles.

To successfully carry out project activities, it is necessary to store information concerning volunteers. This information deal with the health situation of the participant. The project involves minors, and among them, there are subjects with physical and mental disabilities. Therefore, we need the explicit authorisation of their guardians (information and consent Form for children).

Any other kind of data (sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction) is not collected.

None of the participants is in a position of dependence on the researcher or his/her associates, and there is no economic incentive for them to participate, so the participation of the subjects is entirely based on free will and free from any kind of pressure.

An Information and Consent Form will be submitted to the participants in order to store their information correctly. Once aware of all the needed information, the participants can fill out the Form providing their voluntary consent.

All information about the research participants and the recorded data will be kept confidential. We are committed to maintain strict rules of privacy and prevent all personal data from being abused or leaked. Under no circumstances will we provide, give, or sell any information on the involved subjects to any third party. The collected personal data will not be used for any kind of commercial purpose. Personal data will be collected and used only for the aims of the project and will be processed while protecting personal identities. The anonymity of information will be preserved, and no information will be used for any different reason from the ones for which permission has been obtained.

### **3. Informed Consent procedure**

We recognize and feel the need to carry out all the work of the NEMO project to the highest ethical standards, committed to full respect for the relevant national, international, and local regulations and codes of conduct.

All studies conducted with human participants within this project comply with the ethical guidelines of the Italian Association of Psychology (AIP) and are approved beforehand by the DPO of the University of Bologna (Italy) and the DPO of AIAS Bologna Onlus.

Therefore, it is necessary to collect a signed informed consent from all participants or from their parents, guardians, or legal tutors when minors are concerned.

People involved in our studies will be informed - at the beginning, at any other stage of the research and whenever needed or asked - of our research topics, and both the theoretical and the applicative objectives will be clearly communicated. Every activity will follow standard procedures.

The University of Bologna is a very experienced institution as far as this type of research is concerned. Ethical approval to conduct such experiments by our local Privacy Committee has already been obtained.

For each analysis and observation, we need an Informed Consent Form subscribed. The purpose of this Form is to explain to participants the procedures of their data treatment if they consent to take part in our research. It provides them with the information they need in order to decide to participate. It will be written in lay language, avoiding technical terms and abbreviations.

Participants may read the Informed Consent Form and request further information from researchers where they deem it necessary. The Informed Consent Form states that the participants have read the information sheet, have had the opportunity to discuss the research and ask questions, have received satisfactory answers to those questions, understanding that they are free to withdraw from the research, and they agree to participate.

The Information and Consent Form allows the participants to:

- Provide their consent to the processing of their personal data and their children's data (see paragraph 2.1. of the attached Information and Consent Form, which is mandatory in order to accomplish the project research).
- Provide their consent to the dissemination of the data, if these are found to be particularly significant for the aims of the project (see paragraph 2.2 of the Information and Consent form attached, which is optional).
- Provide their consent to the storing of the data after the conclusion of the project, for future reuse of the data in similar projects with the same aims and purposes (see paragraph 2.3 of the Information and Consent form attached, which is optional).

#### **4. Research on infants**

We are observing and analyzing home videos with infants between 9 and 18-month-old. In these video recordings, usually shot for family or memory purposes, infants are filmed during natural interactions with their caregivers. Therefore, in all our observations and studies, minors will be included.

For this reason, we consider the informative stage even more important. The aim and every procedure of the project will always be outlined in the Informative Form. Parents of the children and caregivers will be informed about the observational procedures at play. Parents will always be able to make informed decisions about their participation in the research. Consent from both parents and all legal guardians is always needed.

#### **5. Details of the participation procedures and the security measures to prevent Personal Data Breach**

As far as data gathering is concerned, we will follow the following steps:

- 1- Widespread dissemination of the research project's objectives thanks to the University of Bologna, to our associated partners, to social networks, and to the official website of the project.
- 2- Volunteers may contact us in order to provide their consent both in person or by sending an email to the official project address, enclosing a signed Consent Form and ID card.
- 3- Participants have access to a shared encrypted webspace created by the University of Bologna to protect their personal data and hosted on the University of Bologna web servers.
- 4- The researchers of the NEMO team will associate the videos and the informed consent with an encrypted code. In this way, videos will not be directly linked to the names of the participants. This operation also allows the recovery of the names for the cancellation of the data, if requested by the participants.
- 5- At this point, videos will be moved to an encrypted database provided by the University of Bologna, granting access only to the project team.

Data will be stored until the end of the project. Since participants are asked about their will to provide their videos also for further research on the subject, the videos of the participants who answered "yes" to paragraph 2.3 of the consent form will be kept. All other videos and data will be destroyed.

The security measures to maintain the confidentiality of recorded data comply with national regulations and relevant EC directives, as the EU Regulation No. 2016/679 of the European Parliament and of the Council of 27 April 2016.

#### **6. Data protection for research outputs**

Given the sensitivity of the data processed and the processing methodology, the only risk associated with participation in the NEMO project is the disclosure of private data.

Therefore, we are committed to limit this risk as much as it is possible through efficient anonymization and encryption tools provided by Alma Mater Studiorum.

During the publications of the scientific results of the project, we will take care of the anonymization or pseudonymization of the participants who have given their consent to the conditions in paragraph 2.2 of the Information and Consent Form (attached). No identity will possibly be traced back to the real participants of the project. This objective will be achieved through appropriate secure video editing programs approved by the Privacy Office of the University of Bologna.