Deliverable: D1.1

Ethical clearances

Consortium

University of Twente (UT)
Imperial College London (ICL)
University of Passau (UP)
Institute of Mathematics of the Romanian Academy (IMAR)
University College London (UCL)
Serbian Society of Autism (SSA)
Autism Europe (AE)
IDMind (IDM)

Grant agreement no. 688835

Research and Innovation Action
## Document Information

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<td>Work Package number and title:</td>
<td>WP1 - DE-ENIGMA DB collection, annotation and release</td>
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<td>Lead partner:</td>
<td>ICL</td>
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<td>Participating beneficiaries:</td>
<td>UT, ICL, UP, IMAR, UCL, SSA</td>
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<td>Authors:</td>
<td>UT, UCL, SSA</td>
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<td>Reviewers:</td>
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1. Summary

Dr. Liz Pellicano from UCL and Sunčica Petrović from SSA submitted ethical Approval documents and presented the DE-ENIGMA project to their Ethical Committees. In both cases full ethical approval was granted for the work in work package WP1 of the project. The principal investigators from all DE-ENIGMA beneficiaries are named in the application forms.

In the following pages you will find copies of both ethical clearances for the collection and annotation of facial, bodily, vocal and verbal recordings of interactions between autistic children and a) the robot, b) the researcher and c) their parent made in structured teaching settings. An official translation of the Serbian clearance for SSA is included.

A copy of a letter of support from the Serbian Ministry of Social Policy and an official translation of the letter are also included.
2. UCL clearance: Full ethical approval for REC 796 DE-ENIGMA – letter and application form

From: research.ethics@ucl.ac.uk
Subject: Ethical approval for REC 796 DE-ENIGMA: Multi-Modal HRI for Expanding Social Imagination in Autistic Children
Date: 5 March 2016 08:46:08 GMT
To: Liz Pollicano <l.pollicano@ucl.ac.uk>

Dear Liz,

Approval for REC 796 DE-ENIGMA: Multi-Modal HRI for Expanding Social Imagination in Autistic Children

Please find attached your letter of approval from the UCL IOE Research Ethics Committee.

Best wishes,
Hamnah

Hamnah Pope
Research Ethics and Governance Administrator
Research and Consultancy Services
UCL Institute of Education
Tel: 020 7911 5386
Dear Liz,

Full ethical approval for REC 796 DE-ENIGMA: Multi - Modal HRI for Expanding Social Imagination in Autistic Children

Thank you for your application to the UCL IOE Research Ethics Committee for ethics approval of the above named project. I am pleased to inform you that following a panel review, your application has been approved.

As part of the continued process of monitoring ethics at the Institute, the committee would be interested to hear if you encounter any ethical challenges throughout the course of your project. This will help us to develop our policies and training in line with the needs of researchers. If certain issues are raised during your research, a short summary of how these challenges were addressed can be submitted upon completion of the project.

The UCL IOE Research Ethics Committee’s consideration of all ethics applications are dependent upon the information supplied by the researcher. This information is expected to be truthful, accurate and is based on an expert assessment of ethical issues. This does not detract in any way from the ultimate responsibility which researchers themselves must have for all research which they carry out, including its effects on all those involved.

It is your responsibility to notify the Research Ethics Committee if any of the following occur:

- A complaint of any kind from any person involved or affected by your research. These may include parents/carers, gatekeepers, junior researchers and also members of the group being researched who may be adversely affected by the research reports.

- Changes in the research design, instruments, setting or participants.

- Any other events during the course of the research which give rise to ethical concerns.

If there are any queries, please contact researchethics@ioe.ac.uk

I would like to wish you every success with the project. Please do not hesitate to contact me if you have any queries.

Yours sincerely,

Hannah Pope

(On behalf of UCL IOE Research Ethics Committee)

Hannah Pope
Research Ethics and Governance Administrator
UCL Institute of Education
Staff Ethics Application Form

Anyone conducting research under the auspices of the Institute (staff, students or visitors) where the research involves human participants or the use of data collected from human participants, is required to gain ethical approval before starting. This includes preliminary and pilot studies. Please answer all relevant questions in terms that can be understood by a lay person and note that your form may be returned if incomplete.

The accompanying guidelines provide support and advice http://www.ioe.ac.uk/ethics. You can also contact researchethics@ioe.ac.uk.

Section 1. Project details

<table>
<thead>
<tr>
<th>a. Project title</th>
<th>DE-ENIGMA: Multi-Modal HRI for Expanding Social Imagination in Autistic Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>b. Principal Investigator (PI)</td>
<td>Prof. Liz Pellicano</td>
</tr>
<tr>
<td>c. Co-Investigators/Partners/Collaborators</td>
<td>Prof. Vanessa Evers (Universiteit Twente, Netherlands), Prof. Maja Pantic (Imperial College London), Prof. Bjoern Schuller (Universitat Passau, Germany), Prof. Cristian Sminchisescu (Institutul de Matematica al Academii, Romania), Suncica Petrovic (Serbian Society for Autism), Aurelie Baranger (Autism Europe) and Paulo Alvito (IDMind, Portugal)</td>
</tr>
<tr>
<td>d. Department</td>
<td>Centre for Research in Autism and Education (CRAE), Department of Psychology and Human Development</td>
</tr>
<tr>
<td>e. Start date</td>
<td>1st March 2016</td>
</tr>
<tr>
<td>f. End date</td>
<td>31st July 2019</td>
</tr>
<tr>
<td>g. Funder</td>
<td>European Commission Horizon 2020</td>
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<tr>
<td>h. Funding confirmed?</td>
<td>Yes</td>
</tr>
<tr>
<td>i. Expedited review requested?</td>
<td>Yes ☒ No ☐ NECT go to j.</td>
</tr>
</tbody>
</table>

**If yes**, please give your reason for expedited review. **Note**: Expedited reviews are for exceptional circumstances only.

Our first deliverable to the European Commission is very early in the grant. We need to pilot our procedure with children and make modifications to the robot before the study for Work Package 1 can begin by the beginning of April.

| j. Specifying which professional code of ethics will be adhered to for this research: British Psychological Society |

| k. Is this application a continuation of a research project that has already received ethical approval? | Yes ☐ No ☒ |

**If yes**, provide details below (see guidelines) including the ethics reference number.

March 2015
Country fieldwork will be conducted in UK and Serbia.

If research to be conducted abroad please check [www.fco.gov.uk](http://www.fco.gov.uk) and submit a travel insurance form to Serena Ezra (s.ezra@ucl.ac.uk) in UCL Finance (see application guidelines for more details). This can be accessed here: [https://www.ucl.ac.uk/finance/secure/fin_acc/insurance.htm](https://www.ucl.ac.uk/finance/secure/fin_acc/insurance.htm)

(You will need your UCL login details.)

Has this project been considered by another (external) Research Ethics Committee?

<table>
<thead>
<tr>
<th>Yes</th>
<th>External Committee Name:</th>
</tr>
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<tbody>
<tr>
<td>No</td>
<td>go to Section 2</td>
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</table>

**If yes:**
- Submit a copy of the approval letter with this application.
- Proceed to Section 9 Attachments.

### Section 2 Research methods summary (tick all that apply)

- Interviews
- Focus groups
- Questionnaires
- Action research
- Observation
- Literature review
- Controlled trial/other intervention study
- Use of personal records
- Systematic review → if only method used go to Section 5.
- Secondary data analysis → if secondary analysis used go to Section 6.
- Advisory/consultation/collaborative groups
- Other, give details:

Please provide an overview of the project, focusing on your methodology. This should include some or all of the following: purpose of the research, aims, main research questions, research design, participants, sampling, data collection (including justifications for methods chosen and description of topics/questions to be asked), reporting and dissemination. Please focus on your methodology; the theory, policy, or literary background of your work can be provided in an attached document (i.e. a full research proposal or case for support document). **Minimum 150 words required.**

**BACKGROUND AND AIMS**

Autism affects the way that a person interacts with and experiences the world around them. Difficulties in using and understanding verbal and non-verbal cues (facial expressions, gestures, tone of voice), recognising, understanding and responding to other people’s social and emotional cues and then responding to them appropriately are all core characteristics of autism. These difficulties can have a huge impact on a person’s life – at home, school, work and out-and-about in the community – as they try to navigate the social world.

There are a variety of interventions and teaching methods designed to enhance autistic children’s social and emotional skills. Interventions incorporating computer-based technology are held as particularly beneficial because they appeal to autistic children’s need for regularity, repetitiveness and predictability. Robots, especially life-like ones, have also been used as part of teaching interventions for autistic children with some success. For example, one robot (‘Milo’) was used to promote children’s ability to recognise happiness, sadness, anger, and fear. Milo would portray these facial expressions and the child would be asked to identify the correct emotion by selecting the answer from multiple choices on an iPad. So far, however, all of the available robot interventions like this one have been fairly limited in nature, such that they (1) have focused solely on children...
recognizing the target emotion, not responding to it appropriately and (2) are implemented in such a way that a person remotely controls the behaviour of the robot through a wireless remote-control based system. What is missing is a dynamic, context-sensitive approach, in which the robot behaves in accordance with the child’s reactions.

This large-scale European project (‘DE-ENIGMA’) seeks to address these concerns. DE-ENIGMA seeks to build robot technologies that can robustly and accurately track and recognise children’s facial, bodily, and vocal behaviour and naturalistic interactions ‘in the wild’, and react appropriately based on the observed child’s behaviour – with the ultimate goal of helping autistic children and young people to enhance their social communication skills in structured teaching with a therapist and in everyday interactions.

Specifically, it will develop multimodal human-robot-interaction (HRI) technology that learns from interactions to:

I. model the child’s behaviour,
II. map multimodal input to estimate the child’s affect, interest, physical response and rapport, and
III. adapt the interaction to the current context (the child, her culture, her task, and her level of interest and stress) in order to maximise the effectiveness of teaching socio-emotional skills and social imagination to autistic children.

The robot will learn to understand the child’s vocalisations, their choice of words, facial gestures, head and body gestures and postures and how these modalities are combined to convey meaning. It will also examine the best ways of changing the robot’s interactive behaviours in cases where there is lack of engagement, lack of rapport, and increased behavioural responses by the child.

These aims will be realised through 5 different work packages (WPs). The current ethics application focuses on the work described in the first work package, WP1, which will be conducted on children here in the UK and with our Serbian partners, in Belgrade. Subsequent applications will be submitted for the work described in the remaining WPs.

The main objective of WP1 is to collect and annotate facial, bodily, vocal and verbal recordings of interactions between autistic children and (a) the robot, (b) the researcher and (c) their parent made in structured teaching settings. These annotated recordings are key for gaining an understanding of the degree and nature of autistic children’s production, recognition and use of social and emotional behaviours (in the UK and in Serbia), and are critical for the subsequent development of the DE-ENIGMA robot. Furthermore, accurately labeled/annotated real-world data such as these are key for designing algorithms to sense, track and interpret human behaviour in naturalistic settings. With appropriate consent (see below), these recordings will therefore also form the first online research database of dyadic interactions with autistic children.

METHOD

In year 1 of the project, we will recruit 64 children on the autism spectrum, 32 aged between 5 and 8 years and 32 aged between 9 and 12 years, from London and the South East of the UK to take part. There will be more boys than girls with autism given that current prevalence estimates suggest that the gender ratio is at least 4:1 (Fombonne, 2009). Half of the children from each age group (n=16) will be involved in robot-led teaching and the other half will be involved in research-led teaching (see below for more details). An identical arm of the project will take place with researchers and clinicians in Serbia. Ethical approval for this arm is not sought here but will be subject to ethical processes within Serbia, which are internationally validated and recognized by the European Council.

This research focuses on autistic children with an additional (mild-to-moderate) learning disability, who are now
under-represented in research (Pellicano et al., 2014). These children are likely to be educated within specialist
provision in the UK and have difficulties with verbal communication. Some may have fluent speech but many
will have limited or no speech and will use other forms of communication (e.g., pictures).

Children will each have an independent clinical diagnosis of an autism spectrum condition according to ICD-10,
DSM-IV or DSM-5 criteria and will meet the threshold for autism on standard assessments of autistic
symptomatology, the Social Responsiveness Scale – 2nd edition (SRS-2) (Constantino, 2003) and the Childhood
Autism Rating Scale – 2nd edition (CARS-2) (Schopler et al. 2010).

Between April 2015 and March 2016, UCL IOE-based DE-ENIGMA researchers and students will conduct the
following assessments and sessions:

**PRE-INTERVENTION: initial assessments**

Prior to the initial testing session, parents will receive a series of questionnaires (by post), including

- **Background information questionnaire**, which asks questions about the child’s diagnostic, medical and
  educational history, as well as information on their education level and ethnicity.
- **Social Responsiveness Scale** (SRS), a 65-item tool for assessing autistic traits.
- **Vineland Adaptive Behaviour Scales – 2nd edition**, which measures the child’s everyday adaptive
  behaviours, including their daily living and social skills.
- **Strengths and Difficulties Questionnaire (SDQ)**, a brief behavioural screening questionnaire about 3-16
  year olds.
- **MacArthur-Bates Communicative Developmental Inventories**, a parent checklist on children’s spoken
  language skills.

The child’s class teacher will be asked to complete the **Childhood Autism Rating Scale – 2nd edition (CARS-2)**, an
observational behavioural rating scale to determine where children lie along the autism spectrum. During the
testing period (see below), children will receive the **Matrices subtest from the Wechsler Abbreviated Scales of
Intelligence (WASI)**, to measure children’s nonverbal reasoning ability (15 minutes).

**DURING INTERVENTION: robot-/researcher-led teaching sessions with children**

Children within each age group (5-to-8 year-olds; 9-to-12 year-olds) will be randomly allocated to receive either
the (a) robot-led or (b) researcher-led structured teaching intervention, which will then be implemented across
multiple different short sessions (10-15 minutes each session) every 1-2 days for a maximum period of 3 weeks.
We will follow Howlin et al.’s (1998) approach to teaching perception, expression, understanding, and social
imagination related to four affective states: surprise, happiness, anger and sadness. All four groups will be
administered (and recorded) during Howlin et al.’s 6 Phases of teaching, which become progressively more
challenging, moving from simple matching to identification to more complex social understanding. Feedback will
be given to children – either by the robot or the researcher (depending on which intervention programme they
have been allocated to).

Children will work through the 6 Phases (below) at their own pace. The exact duration of each phase (and
therefore the entire teaching session) will differ for each child, depending on his/her individual learning rates –
that is, some children might successfully get through the first 3 phases within a single teaching session, while
others could take 3 or more sessions to complete 3 phases. Children will move on to the next phase once they
have reached criterion and is maintained across at least 2 sessions. In case a child cannot reach criterion, the
intervention will cease. The first three phases listed below will be trialed for all children enrolled in the study.

**Phase 1:** Matching across same static emotional images: researcher shows face-and-body images (robot
displays facial and bodily expressions) of target affective states and the child is asked to choose
Phase 2: Matching across different static emotional images: researcher shows face-and-body images (robot displays facial and bodily expressions) of target affective states and the child is asked to choose appropriate emoticons;

Phase 3: Matching from dynamic ‘real’ emotional displays to static images: researcher/robot displays an affective state using facial, bodily and vocal expressions and the child is asked to choose appropriate emoticons;

Phase 4: Identifying dynamic ‘real’ emotional displays and expressing that emotion: researcher/robot displays an affective state using facial, bodily and vocal expressions and the child is asked to identify the affective state and to display the same affective state in the way s/he usually displays that affective state;

Phase 5: Identifying dynamic ‘real’ emotional displays and expressing that emotion in the same way: researcher/robot displays an affective state using facial, bodily and vocal expressions and the child is asked to identify the affective state and to display the same affective state in the way researcher/robot displayed that affective state;

Phase 6: Understanding own/others’ emotional states: researcher/robot tells the child a series of stories to examine their understanding of their own and others’ affective states (e.g., Sam wanted a special iPad for Christmas but Father Christmas did not bring it to him. How does Sam feel?)

POST INTERVENTION: Parent-led teaching sessions with children
Once children have reached their threshold on the teaching intervention (which may be Phase 3 for some children and Phase 6 for others), children will then take part in two teaching sessions with their parents. Parent-led sessions will occur once, immediately following the last robot/researcher-led teaching session, and again one month later. These sessions will be in the same format as the earlier sessions with the robot/researcher, take place in school and will be recorded. These additional sessions will allow us to examine whether the child has retained the skills learned during the intervention and generalized such skills across instructional partners (in this case, parents).

All sessions during and post-intervention will be recorded by three sets of High Definition (HD) and Kinect cameras (one set recording the child, one recording child’s counterpart (robot/researcher, parent) and one recording both). Kinect cameras will be used for acquisition of both audio and three-dimensional visual data and sensors mounted on the robot will also record all interactions of children with the robot. Children will also wear a wearable sensor on their wrists – like a sports watch or Fitbit – during the teaching sessions (during and post-intervention) to gain a measure of their physical response.

All sessions (pre-, during and post-intervention) will take place in a quiet room located in the school. For robot-led sessions, the child will not be left alone with the robot; a researcher will always be present. The robot is not meant to ‘replace’ the researcher in these teaching sessions but to act as a tool with which to help teach sociocommunicative skills. For researcher-led sessions, however, the robot will not be present.

Once the teaching intervention has ceased, children who received the researcher-led teaching sessions will have an opportunity to interact with the robot with the researcher and/or with their parents.

### Section 3 Research Participants (tick all that apply)

- [ ] Early years/pre-school
- [x] Ages 5-11
- [x] Ages 12-16
- [x] Adults please specify below
- [ ] Unknown – specify below
- [ ] No participants

March 2015
NB: Ensure that you check the guidelines carefully as research with some participants will require ethical approval from a different ethics committee such as the National Research Ethics Service (NRES) or Social Care Research Ethics Committee (SCREC).

### Section 4 Security-sensitive material

Security sensitive research includes: commissioned by the military; commissioned under an EU security call; involves the acquisition of security clearances; concerns terrorist or extreme groups.

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<tbody>
<tr>
<td>a.</td>
<td>Will your project consider or encounter security-sensitive material?</td>
<td>Yes ☑️ No ☒</td>
</tr>
<tr>
<td>b.</td>
<td>Will you be visiting websites associated with extreme or terrorist organisations?</td>
<td>Yes ☑️ No ☒</td>
</tr>
<tr>
<td>c.</td>
<td>Will you be storing or transmitting any materials that could be interpreted as promoting or endorsing terrorist acts?</td>
<td>Yes ☑️ No ☒</td>
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* Give further details in Section 8 Ethical Issues

### Section 5 Systematic reviews of research

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<tbody>
<tr>
<td>a.</td>
<td>Will you be collecting any new data from participants?</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>b.</td>
<td>Will you be analysing any secondary data?</td>
<td>Yes ☑ No ☐</td>
</tr>
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</table>

* Give further details in Section 8 Ethical Issues

If your methods do not involve engagement with participants (e.g. systematic review, literature review) and if you have answered No to both questions, please go to Section 8 Attachments.

### Section 6 Secondary data analysis

Complete for all secondary analysis

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<thead>
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<tbody>
<tr>
<td>a.</td>
<td>Name of dataset/s</td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td>Owner of dataset/s</td>
<td></td>
</tr>
</tbody>
</table>
| c. | Are the data in the public domain? | Yes ☐ No ☐  
* If no, do you have the owner’s permission/license? Yes ☐ No* ☐ |
| d. | Are the data anonymised? | Yes ☐ No ☐  
* Do you plan to anonymise the data? Yes ☐ No* ☐  
* Do you plan to use individual level data? Yes* ☐ No ☐  
* Will you be linking data to individuals? Yes* ☐ No ☐ |
| e. | Are the data sensitive (DPA 1998 definition)? | Yes* ☐ No ☐ |
| f. | Will you be conducting analysis within the remit it was originally collected for? | Yes ☒ No* ☒ |
| g. | If no, was consent gained from participants for subsequent/future analysis? | Yes ☐ No* ☐ |
h. If no, was data collected prior to ethics approval process?  

* Give further details in Section 8 Ethical Issues

If secondary analysis is only method used and no answers with asterisks are ticked, go to Section 9 Attachments.

Section 7 Data Storage and Security

Please ensure that you include all hard and electronic data when completing this section.

<table>
<thead>
<tr>
<th>a. Confirm that all personal data will be stored and processed in compliance with the Data Protection Act 1998 (DPA 1998). (See the Guidelines and the Institute’s Data Protection &amp; Records Management Policy for more detail.)</th>
<th>Yes ☒</th>
</tr>
</thead>
<tbody>
<tr>
<td>b. Will personal data be processed or be sent outside the European Economic Area?</td>
<td>Yes ☐ * No ☒</td>
</tr>
</tbody>
</table>

* If yes, please confirm that there are adequate levels of protections in compliance with the DPA 1998 and state what these arrangements are below.

Who will have access to the data and personal information, including advisory/consultation groups and during transcription? Members of the research team will have access to participants’ personal information. The data itself will be anonymised and, once it is annotated, will be made available to recognized researchers (see below for details).

**During the research**

Where will the data be stored? Data from hard-copy questionnaires will be de-identified and stored in locked filing cabinets at CRAE, UCL IOE and on secure UCL IOE computers. The recordings will be stored on firewall-protected data servers that are not directly connected to the Internet, and they will be protected by SSL (Secure Sockets Layer) with an encryption key when transferred to the authorised users via the Internet.

e. Will mobile devices such as USB storage and laptops be used?  

* If yes, state what mobile devices:  

* If yes, will they be encrypted?:  

**After the research**

Where will the data be stored? Electronic data files will be kept on UCL IOE shared disk space accessible only by members of the CRAE team and hard copies of assessment data will be de-identified and filed at UCL IOE. The recordings will be stored on firewall-protected data servers that are not directly connected to the Internet, and they will be protected by SSL (Secure Sockets Layer) with an encryption key when transferred to the authorised users via the Internet.

How long will the data and records be kept for and in what format? The assessment data will be stored for 10 years. The anonymised DE-ENIGMA database will remain active for the foreseeable future.

Will data be archived for use by other researchers?  

* If yes, please provide details. The anonymised recordings will become the first database of behavioural recordings of autistic children interacting with a robot/researcher and his/her parent.
Section 8 Ethical issues

Please state clearly the ethical issues which may arise in the course of this research and how they will be addressed.

All issues that may apply should be addressed. Some examples are given below, further information can be found in the guidelines. Minimum 150 words required.

<table>
<thead>
<tr>
<th>Methods</th>
<th>International research</th>
</tr>
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<tbody>
<tr>
<td>Sampling</td>
<td>Risks to participants and/or researchers</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Confidentiality/Anonymity</td>
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<td>Gatekeepers</td>
<td>Disclosures/limits to confidentiality</td>
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<tr>
<td>Informed consent</td>
<td>Data storage and security both during and after the research</td>
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<tr>
<td>Potentially vulnerable participants</td>
<td>including transfer, sharing, encryption, protection</td>
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<tr>
<td>Safeguarding/child protection</td>
<td>Reporting</td>
</tr>
<tr>
<td>Sensitive topics</td>
<td>Dissemination and use of findings</td>
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</table>

This research raises several ethical issues, each of which are discussed in turn below.

Recruitment and testing

Children will be recruited through the Centre for Research in Autism and Education’s (CRAE) extensive community contacts, including the National Autistic Society, parental organisations in London and surrounding areas, and through mainstream and (mostly) special schools in the greater London area. Head teachers, programme coordinators, or other authorised persons, will be approached to gain permission to recruit. After permission to recruit has been received, initial contact with participants will be made by distributing information sheets and consent forms to parents (see attached). Interested parents return the consent forms or contact the investigator for more information.

All of the testing will be performed in schools. All UK children will be seen by researchers who have valid Enhanced Disclosure and Barring Service (DBS) (i.e., police check) clearance. Prof. Pellicano is an experienced educational and developmental psychologist and has worked for many years with autistic children and their families.

Informed consent

Potential participants and their parents/guardians will be sent a letter inviting them and their child to participate in the research. The letter will include the information letter (see attached), which describes the goals of the study and the type of testing that will take place, and a consent form (see attached), which parents/guardians are to complete to indicate their willingness to participate. Participants will have up to 6 weeks to decide whether to participate in the study.

Parents/guardians will have the opportunity to ask any questions before consent is obtained. It will be made clear to parents and children (if appropriate) that they are free to refuse to participate or to withdraw from the study at any time, without having to provide justification and without prejudice. Given the potentially limited communicative abilities of these children, children’s assent will be managed by monitoring their behaviour and responses towards the researchers throughout each session. Testing will cease immediately if children become disengaged or agitated. On the very rare occasions that children refuse to take part, or express explicit or implicit desire to withdraw from the study at any time, no further attempts will be made to ensure their cooperation.

After the teaching intervention has ceased, the child’s parents will be offered to review the acquired recordings of his/her behaviour. They have the right to withdraw their child’s data in part or completely without

March 2015
explanation. Parents will be informed that s/he can withdraw their child’s data at any point, including from the DE-ENIGMA database.

Exactly the same procedure will be followed in Serbia and organised by the project partner (the Serbian Society for Autism).

**Sensitivity to children’s needs**
Extensive efforts will be made to ensure that the research is sensitive to children’s needs. In all of our research, we go to great lengths to ensure that our tasks and methods are enjoyable and developmentally appropriate for the age range of children being assessed. In all previous studies, children and young people have shown great enthusiasm in taking part and have enjoyed the one-to-one attention they receive during the testing session. We will ensure that the same care is taken with the assessment sessions in the current project.

Researchers will monitor closely participants’ well-being and breaks will be taken if deemed necessary by the researcher, or if they are requested by the participant. Children will be given as many breaks as necessary during the testing session. All children will be given positive reinforcement throughout the various parts of the sessions.

One innovative aspect of this particular project is the use of biofeedback measures to gain a direct index of children’s physical response, including their heart-rate and movement levels. We will use wearable biometric wristbands – just like a sports watch or Fitbit, which have been used previously (and successfully) with autistic children and young people. We are, however, aware that some autistic children have tactile sensitivities and so many not be comfortable with wearing such a device. We will work with teachers and teaching assistants with mock versions of the wristbands to determine the feasibility of this item and we will closely monitor children’s responses. If individual children do not feel comfortable wearing the device, we will not take these biofeedback measurements from these children.

**Confidentiality**
Participants will be assigned anonymous ID numbers and these numbers will be used on all questionnaires, test forms and recordings. In line with the UK’s Data Protection Act, all data will be kept in a secure location at UCL IOE and data will be stored in a separate location from the one containing the name-ID number associations.

Data protection is a particular issue for this study because participants will be recorded with the intention of including the recordings in a DE-ENIGMA database, which will made available to the research community. We will deal with this issue by ensuring that all parents provide written informed consent to allow their and their child’s data to form part of the database. The procedures are well established in this consortium’s previous projects, which have included the collection of similar recordings of hundreds of people and the release of these datasets for research purposes (e.g., Bilakhia et al., 2015; Schuller et al., 2009). In brief, children’s recordings will be anonymised prior to the inclusion into the DE-ENIGMA database. The process of anonymising participants includes deletion of any personal data such as the name, birthdate, the country of residence, etc., related to the participants’ recordings. The recordings will be stored in the database with labels (e.g., ‘participant N’), where N will be a random number unique for the DE-ENIGMA database. The recordings will be stored on firewall-protected data servers that are not directly connected to the Internet, and they will be protected by SSL (Secure Sockets Layer) with an encryption key when transferred to the authorised users via the Internet. These servers are managed by PI Pantic and researchers at Imperial College London.

**Access to data by third parties**
One of the important benefits that the DE-ENIGMA project brings is that the collected data will be released to the research community to facilitate investigations on the topic beyond the DE-ENIGMA project. Critically, only
anonymised data will be shared (i.e., no link to the identity of the participants will exist) and only if participants (parents of the recorded children) have given their written informed consent. The sharing will be governed by a restrictive license agreement (limited duration of use; allows use only for research purposes). To ensure that the data are used in accordance to participants’ wishes, all researchers that wish to use the DE-ENIGMA database for their research will be required to sign the End User Licence Agreement (EULA). A draft version of the EULA is attached to this application form.

Participants will be assured that there shall be no financial gain from the recordings. We will carefully maintain a database of partners with whom the data have been shared and parents whose children's recordings are to be included in the DE-ENIGMA database will always have the right to know with whom the data has been shared and request deletion of their data at any time.

Risks to participants
This project and the nature of the tasks have been designed to be enjoyable and entertaining for children. Although existing studies have repeatedly shown that autistic children generally enjoy interacting with a human-like robot, probably because its behaviour is predictable and interpretable, it is nevertheless possible that some children might experience the robot’s behaviour as unexpected, which could cause some discomfort. Should children show an unusual level of unease during the interaction with the robot, our researchers will stop the session, switch into a fun, unrelated activity and consider whether testing can be resumed later on.

In terms of debriefing, the nature of the proposed research means that it is not appropriate to debrief participants directly. It is common practice at CRAE, however, that anyone involved in the research (e.g., teachers and parents) are debriefed in the form of an accessible newsletter outlining the results of the study, which will be sent out in a timely manner once the results have been analysed and interpreted (we expect to send these out twice yearly for the duration of the DE-ENIGMA project).

Reimbursement
Parents and participating schools will be given gift tokens as a reimbursement and ‘thank you’ for their time and effort but these will not be used as an incentive for participation.

<table>
<thead>
<tr>
<th>Section 9 Attachments</th>
<th>Please attach the following items to this form, or explain if not attached</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Information sheets, consent forms and other materials to be used to inform potential participants about the research</td>
<td>List attachments below</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If applicable/appropriate:</th>
</tr>
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<tbody>
<tr>
<td>b. Approval letter from external Research Ethics Committee</td>
</tr>
<tr>
<td>c. The proposal (‘case for support’) for the project</td>
</tr>
<tr>
<td>d. Full risk assessment</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Section 10 Declaration</th>
</tr>
</thead>
<tbody>
<tr>
<td>I confirm that to the best of my knowledge the information in this form is correct and that this is a full description of the ethical issues that may arise in the course of this project.</td>
</tr>
</tbody>
</table>

March 2015
Please submit your completed ethics forms to the Research Ethics and Governance Administrator researchethics@ioe.ac.uk.

**Timescales** for receiving the Committee’s decision following submission are as follows:

- Standard – 20 working days
- Expedited – 10 working days

*Please note* that the above are guidelines for response times which will vary depending on the quality of the application and the number of applications being processed. All applications are assessed prior to forwarding to the Research Ethics Committee and *incomplete* applications will be returned for further detail.

**Decisions:**

- **Approved:** The research is fully approved and can commence immediately.
- **Provisionally approved:** The application is incomplete and/or raises concerns so further information and/or changes need to be made and submitted before full approval can be granted.
- **Extensive revision required:** The application raises considerable concerns and needs extensive revision before resubmission.
- **Rejected:** The application is considered to raise fundamental concerns that means it cannot be approved by the committee.
3. SSA clearance: Ethical clearance from the Serbian Institute of Mental Health in Serbian and the official translation

Институт за ментално здравље
Institute of Mental Health

ETIČKI ODBOR
Broj: 30/66
Datum: 1.3.2016.
Beograd, Palmotićeva broj 37

Na osnovu odredaba Zakona o proizvodnji i prometu lekova (Sl. glasnik RS br. 84/04), Poslovnika o radu Etičkog odbora Instituta za mentalno zdravlje br. 1529 od 14.09.2007. godine, postupajući u skladu sa Standardnim operativnim postupcima Etičkog odbora za medicinska ispitivanja lekova na ljudima, Etički odbor Instituta za mentalno zdravlje je na svojoj II sednici održanoj dana 1.3.2016. godine primio, razmotrio i jednoglasno

Odobrio istraživanje

Naslov: DE-ENIGMA: multimodalna ljudska-robot interakcija za učenje i proširenje društvene
imaginacije kod autistične dece
Istraživač: Sunčica Petrović, Savez udruženja Srbije za pomoć osobama sa autizmom

Etičkom odboru je uz molbu podneta sledeća dokumentacija:
1. Saglasnost Stručnog kolegu Instituta
2. Protokol istraživanja
3. Popunjena Prijava za odobrenje istraživačkog projekta u Institutu

Na sednici su bili prisutni sledeći članovi Etičkog odbora koji su činili kvorum i koji su diskutovali i
izjasnili se o odobrenju gore navedenog istraživanja:
1. Dr Nenad Rudić, spec. psihijatar, Šef Dnevne bolnice za decu, predsednik Etičkog odbora,
Institut za mentalno zdravlje
2. Dr Vlada Radivojević, spec. neuropsihijatar, Odsek za epilepsije i kliničku neurofiziologiju,
potpredsednik Etičkog odbora, Institut za mentalno zdravlje
3. Dr Vladan Jugović, specijalista psihijatrije, Šef Dnevne bolnice za bolesti zavisnosti i Dnevne
bolnice za bolesti zavisnosti u adolescenciji, Institut za mentalno zdravlje
4. Dr Marko Vuković, specijalista psihijatrije, Kliničko odeljenje za krizna stanja i afektivne
poremećaje, Klinika za odrasle, Institut za mentalno zdravlje
5. Dr Biljana Lukić, specijalista psihijatrije, Šef Dnevne bolnice za psihotične poremećaje, Institut
za mentalno zdravlje

Iz diskusije o odobrenju izuzeta je Vesna Petrović, Predsednica Saveza, Savez udruženja Srbije za
pomoć osobama sa autizmom.

Etički odbor Instituta za mentalno zdravlje je osnovan i radi u skladu sa smernicama ICH/GCP.

1.3.2016.

Palmotićeva 37, 11000 Beograd, Srbija
Tel. +381 11 3238 160 • Fax: +381 11 3235 333
www.imh.org.rs • imz@imh.org.rs

DE-ENIGMA – H2020-ICT-2015 no. 688835
Deliverable: D1.1 – Ethical clearances

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INSTITUTE OF MENTAL HEALTH
Palmotičeva 37, 11000 Belgrade
Tel. +381 11 3238 160
www.imh.org.rs
E-mail: imz@imh.org.rs

ETHICS COMMITTEE
No. 30/66
Date: 01.03.2016
Belgrade, Palmotičeva 37

Pursuant to provisions of the Law on Production and Distribution of Medicines ("Official Gazette of RS", No. 84/04), Rule Book of the Ethics Committee of the Institute of Mental Health No. 1529 dated 14.09.2007, acting in accordance with the Standard Operations Procedure of the Ethics Committee for Medical Testing of Medicines on Humans, the Ethics Committee, at the Second Meeting held on 01.03.2016, admitted, examined and unanimously

Approved the following research

Title: DE-ENIGMA: Multi-Modal Human-Robot Interaction for Teaching and Expanding Social Imagination in Autistic Children

Researcher: Sunčica Petrović, Serbian Society of Autism

The Ethics Committee received the request and the following documentation:

1. Approval of the Expert Committee of the Institute of Mental Health
2. Research Protocol
3. Filled in Application for Approval of the Research Project

The following members were present in the meeting of the Ethics Committee, who established presence of the quorum and discussed and voted on the proposed research:

1. Dr. Nenad Rudić, Specialist in Psychiatry, Head of the Day Hospital for Children, President of the Ethics Committee, Institute of Mental Health
2. Dr. Vlada Radivojević, Specialist in Neuropsychiatry, Department for Epilepsy and Clinical Nerophysiology, Vice-President of the Ethics Committee, Institute of Mental Health
3. Dr. Vladan Jugović, Specialist in Psychiatry, Head of the Day Hospital for Addiction and the Day Hospital for Adolescence, Institute of Mental Health
4. Dr. Marko Vuković, Specialist in Psychiatry, Clinical Department for Critical Conditions and Affective Disorders, Clinic for Adults, Institute of Mental Health
5. Dr. Biljana Lukić, Specialist in Psychiatry, Head of the Day Hospital for Psychotic Disorders, Institute of Mental Health

Vesna Petrović, President of the Society, Serbian Society of Autism, was exempted from discussion of this approval.
The Ethics Committee of the Institute of Mental Health is established and operates in accordance with the ICH/GCP guidelines.

01.03.2016

President of the Ethics Committee
DR. Nenad Rudić: sgd.

OFFICIAL SEAL
(Institute of Mental Health - Belgrade)

------------------------------------END OF TRANSLATION------------------------------------

Belgrade, 14.03.2016
N° 05/A-1

I HEREBY CERTIFY THAT THE ABOVE IS A TRUE TRANSLATION INTO ENGLISH OF THE DOCUMENT COMPOSED IN SERBIAN LANGUAGE.

VESNA BILJAN LONČARIĆ

The Sworn Court Interpreter for English Language approved by
The Decision of the Republic Secretary of Justice & Public Administration
Dated at Belgrade under N°74-10/74-03 on 18th September 1974.
4. SSA Letter of Support: Letter of support from the Serbian Ministry of Social Policy and the official translation


Република Србија
МИНИСТАРСТВО ЗА РАД,
ЗАПОШЉАВАЊЕ,
БОРАЧКА И СОЦИЈАЛНА ПИТАЊА
Број: 07-00-00366/2016-15
Датум: 25. марта 2016. године
Београд, Немањина 22-26

САВЕЗ УДРУЖЕЊА СРБИЈЕ ЗА ПОМОЋ ОСОБАМА СА АУТИЗМОМ

БЕОГРАД
Гундулићев венац 38

Поштовањи,

Најзначајнији правац сарадње Министарства за рад, запошљавање, борачка и социјална питања - Сектор за заштиту особа са инвалидитетом и удружења особа са инвалидитетом, огледа се у стручној и финансијској подршци коју пружа удружењима која спроводе програме у циљу заштите права и унапређења положаја особа са инвалидитетом. Подршка је усмерена на програме које реализују удружења на целој територији земље, а посебно у области спречавања дискриминације, развоја сервиса на локалном нивоу кроз увођење нових услуга које као пружаоци спроводе удружења у циљу пружања подршке особама са инвалидитетом што за резултат има већи степен њихове укључености у социјални и економски живот друштва.

На наведени начин већ дуги низ година ово министарство има партнерски однос и са Савезом удружења Србије за помоћ особама са аутизмом и поздравља њихово учешће у истраживању „ДЕ-ЕНИГМА: мултимодална људска-робот интеракција за учење и проширење друштвене имагинације код аутистичне деце”.

С поштовањем,

[Signature]
Dear Lady or Gentleman,

The most important form of cooperation of the Ministry of Labour, Employment, Veteran and Social Policy – Sector for Protection of Persons with Disability and Societies of the Persons with Disability, is expert and financial support to societies which carry out programmes aiming to protect the rights and improve the position of persons with disability. This support is directed towards programmes realized by these societies throughout the country, especially those pertaining to prevention of discrimination and development of local services introduced by these societies for the purpose of providing support for the persons with disability, resulting in the higher level of their involvement in the social and economic life of the society.

On these grounds this Ministry has had an excellent partnership relationship with the Serbian Society of Autism for many years now and it strongly supports their participation in the research programme: „DE-ENIGMA: Multi-Modal Human-Robot Interaction for Teaching and Expanding Social Imagination in Autistic Children”.

Sincerely Yours,

Acting Assistant Minister
Vladimir Pešić: sgd.

OFFICIAL SEAL
(Republic of Serbia - Ministry of Labour, Employment, Veteran and Social Policy)

Belgrade, 29.03.2016
N° 05/O-I

I HEREBY CERTIFY THAT THE ABOVE IS A TRUE TRANSLATION INTO ENGLISH OF THE DOCUMENT COMPOSED IN SERBIAN LANGUAGE.

VESNA BILJAN LONČARIĆ

The Sworn Court Interpreter for English Language appointed by
The Decision of the Republic, Secretary of Judicial and General Administration.
Dated at Belgrade under N°74-1074-02 on 19th September 1974.