**INSTITUTE OF COGNITIVE NEUROSCIENCE**

Participant information sheet for parents of
children with or without autism

Title of study: Sensory reactivity in genetic syndromes and autism

This study has been approved by the UCL Research Ethics Committee as Project ID19157/001

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We would like to invite you and your child to participate in this research project being conducted by University College London. Before you decide whether to take part, it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please do also discuss the study with your child in whatever way you feel is most appropriate. Ask us if there is anything that is not clear, or you would like more information.

**Our research:** Our research focuses on sensory processing and physiological responsivity in autistic children, how this differs from typical development, and whether this is similar in other developmental disorders and related conditions. This research is funded by University College London.

**This study:** Previous research suggests that autistic children show differences in sensory processing difficulties compared to children without autism. In the current study, we are interested in whether autistic children show different physiological responses (e.g. heart rate variability) in response to social and non-social situations and whether these responses are different from other developmental disorders and neurotypical children. We are also interested in whether children’s physiological responses are related to behaviours such as social skills, autistic traits, mood and anxiety. Therefore, we are looking for both autistic children and typically developing children aged four to eight (4-8) years to take part.

Your child has been selected to take part as he/she/they may fit the criteria above to be included in the study. If your child currently attends a school or community centre, and they have provided your with our study and contact information, the leaders of the school or community centre have agreed to assist us with recruitment by sharing our flyer and information sheet/consent form.

**What your child will be asked to do:** Your child will be asked to wear a wristband with sensors (Empatica E4 wristband) that will measure their physiological responses. The wristband is a bit like a smart watch and will not hurt your child. Your child will wear this wristband whilst they take part in some play-based activities with you at you home, which will be recorded on video using Microsoft Teams.

**What you will be asked to do:** We will ask you to complete some questionnaires online and an interview over the phone about your child’s abilities and preferences. The questions you will be asked will relate to your child’s overall adaptive behaviour (Vineland-3), social experiences, sensory experiences, and anxiety levels. We will also collect demographic information required for the study (your e-mail/phone number for contact, your address for sending the materials, your child’s name, date of birth and diagnosis) and this personal information will be stored separately from the rest of the data (see **Your data** section below). During the study, we will also ask you to complete some play-based activities with your child whilst they wear the wristband described above. You will be given further written and verbal instructions on how to access the video platform (Microsoft Teams), how to place the watch on your child, and how to carry out the play-based activities with your child before the test session. During the test session, the experimenter will be present via a video-link in order to support you and answer any questions you may have. Before the scheduled date for the study, we will send you the wristband. You will be asked to place the wristband on your child’s wrist at the start of the test session and then remove it when the test session has ended. We will also send you some toys for the session. We will ask you to post the equipment back to a member of the research team. We will prepay the costs of the postage so that you are not out of pocket.

**When and where:** The test session will take approximately 1-2 hours and will take place in your home, while on video teleconference with the experimenter. The experimenter will schedule a time convenient for you and your child. You will be able to take breaks as needed.

**Video recordings:** With your permission, we would like to record the play sessions. This will help us to understand your child’s behaviour in detail. These recordings will then be used only for analysis. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings. The recordings will be deleted from our database after 15 years.

**Your data:** Your responses will be assigned an identifying code, and stored separately from your identity. All data will be secured in our laboratory or on GDPR compliant platforms and accessed only by our research staff. Pseudoanonymised data collected via the wristband will be initially uploaded onto Empatica’s E4 connect cloud-based repository hosted by Amazon web services before being transferred to UCL servers. Your data will be anonymised to Empatica and Amazon, meaning that they will not have access to any of your or your child’s personal information, and they will not use this data in any way.

Data resulting from these experiments will be composite data from multiple participants. Your or your child will not be identified in any report or publication.

**Benefits**: You will receive £7.50 per hour (pro rata) in cash or vouchers for your time and participation. It is hoped that this research will help improve our understanding of how to support individuals who experience sensory processing difficulties, such as individuals with genetic syndromes and autism. We also hope that results from this study will help shape future research into sensory processing within genetic syndromes, autism, and other related populations.

**Risks:** There are no known risks associated with wearing the wristwatch. Although we know that children with hypersensitivities may find it difficult to tolerate wearing things on their wrists, these methods have been successfully used in previous studies with children with neurodevelopmental disorders. Nevertheless, we will not ask your child to participate in any assessment that you feel may potentially cause a level of distress that is unreasonable given the aims of the study and the best interests of your child.

The play-based conditions will mean that some social demands will be placed upon your child. We know that some children find social situations difficult and this may be particularly so for children with certain neurodevelopmental disorders. If you or your child’s distress should become too great at any point, we will suspend the session to give you and your child the opportunity to decide whether you want to withdraw from the study. We will not ask your child to participate in an assessment that we have not previously discussed with you.

**Confidentiality:** Confidentiality will always be respected except where the researcher has a duty of care to report to the relevant authorities possible harm/danger to the participant or others.

**Complaints:** If you wish to raise a complaint relating to the project, please contact Dr. Sarah White (details at the top of this sheet) in the first instance. Should you feel your complaint has not been handled to your satisfaction, you should then contact the Chair of the UCL Research Ethics Committee on ethics@ucl.ac.uk

**After the study:** Following your participation in the study, we will give you a chance to discuss the study and to ask any further questions you may have, and you may contact the experimenters if you desire more information at any time (contact details at the top of this sheet). If you would like, we can provide feedback on the results of some of the assessments that you and your child took part in. If you give us your email address, we will send you a copy of our 6-monthly newsletter containing short reports of all our findings. It is expected that this research will be published in a scientific journal within the next 3 years; please contact us if you would like a copy.

**Your decision:** It is up to you and your child to decide whether or not to take part. If you choose not to participate, this will not disadvantage you in any way. If you do decide to take part, you will be given this information sheet to keep and asked to sign an online consent form. **Even after agreeing to take part, you and your child can still withdraw at any time and without giving a reason.**

**Data Protection Privacy Notice:**The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. UCL’s Data Protection Officer is Alexandra Potts data-protection@ucl.ac.uk

This ‘local’ privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our ‘general’ privacy notice:

 For participants in health and care research studies, click [here](https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies)

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the ‘local’ and ‘general’ privacy notices.

The lawful basis that will be used to process your personal data are: ‘Public task’ for personal data and’ Research purposes’ for special category data.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible. If you are concerned about how your personal data is being processed, please contact UCL in the first instance at data-protection@ucl.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner’s Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protectionreform/overview-of-the-gdpr/individuals-rights

**Thank you for reading this information sheet and for considering participating in this research**.

**INSTITUTE OF COGNITIVE NEUROSCIENCE**

Consent form for parents of children with or without autism

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of study: Sensory reactivity in genetic syndromes and autism

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Isabel Power

Isabel.power.20@ucl.ac.uk

UCL Data Protection Officer: Alexandra Potts data-protection@ucl.ac.uk

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You may save a copy of this Consent Form to keep and refer to at any time.

**I confirm that I understand that by ticking each box below I am consenting to this element of the study. I understand that it will be assumed that unticked boxes means that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element that I may be deemed ineligible for the study. *(Please click on the boxes to give us your consent.)***

[ ] I confirm that I have read and understood the Information Sheet for the above study. My child has also had the opportunity to review the ‘Information and consent forms for young participants’ with me. We have had an opportunity to consider the information and what will be expected of us. We have also had the opportunity to ask questions which have been answered to our satisfaction.

[ ] I consent to the processing of my child’s and my personal information for the purposes explained to me. I understand that such information will be handled in accordance with all applicable data protection legislation.

[ ] I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified. I understand that my data will be associated with an identifying code, kept separate from my and my child’s identities, and stored securely. It will not be possible to identify me or my child in any publications.

[ ] I consent to my test session being video recorded and understand that the recordings will be stored pseudonymously, encrypted and only accessed by the research team for data analysis and specific research purposes.

[ ] I understand that my child’s and my information may be subject to review by responsible individuals from the University (to include sponsors and funders) for monitoring and audit purposes.

[ ] I understand that my child’s and my participation is voluntary and that we are free to withdraw at any time without giving a reason. I understand that if I or my child decides to withdraw, any personal data I have provided up to that point will be deleted unless I agree otherwise.

[ ] I understand the potential risks of participating and the support that will be available should my child become distressed during the course of the research.

[ ] I understand the indirect benefits of participating.

[ ] I understand that the data will not be made available to any commercial organisations but is solely the responsibility of the researcher(s) undertaking this study.

[ ] I understand that I will not benefit financially from this study or from any possible outcome it may result in in the future.

[ ] I understand that I will be reimbursed for my time at the rate of £7.50/hour *pro rata* in cash or vouchers.

[ ] I agree that my child’s and my anonymised research data may be used by others for future research.

[ ] I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. Yes/No

[ ] I am aware of who I should contact if I wish to lodge a complaint.

[ ] I voluntarily agree to take part in this study and I provide consent on behalf of my child to take part in this study.

Optional consent items:

[ ]  I consent to the use of images and video recordings from my test session for presentations to academic and non-academic audiences, for training, quality control, and specific research purposes. I understand that neither my child’s nor my name will be identified and that these images/recordings will be stored pseudonymously, using password-protected software.

[ ] I agree to be contacted in the future by UCL researchers who would like to invite me and my child to participate in follow-up studies or studies of a similar nature

[ ] I wish to be sent a copy of any research published in scientific journals of findings from this study

***By ticking below, you are agreeing to take part in the study.***

[ ]  I,       *(insert name)*, voluntarily agree to take part in this study, and I provide consent on behalf of my child to participate in this study.