

LonDownS Research Consortium (LonDownS) – An Integrated Study of Cognition and Risk for Alzheimer’s Disease in Down’s Syndrome.

Parent Consent for Child Form

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Purpose of this form

We are inviting your child to take part in a research study. The purpose of this form is to give you the information you will need to help you decide whether you would like your child to participate. Please read the form carefully, and feel free to ask any questions about the purpose of the study, what we would like your child to do, the possible risks and benefits, your child’s rights as a volunteer and anything else that you feel is not clear. When all your questions have been answered, you can decide if you want your child to be in the study or not.

Purpose of the study

As you probably know, adults with Down’s syndrome are more likely than the general population to develop Alzheimer’s Disease in adulthood. With teams of geneticists, psychiatrists and neuroscientists, we at Birkbeck’s Centre for Brain and Cognitive Development aim to better understand the links between Down’s syndrome and Alzheimer’s disease. Our collaborators will be studying young and older adults to understand why do some individuals with Down’s syndrome go on to get dementia and others do not, despite having Alzheimer’s brain pathology. We at Birkbeck will focus on infants and toddlers and address some of the following questions: how do learning disabilities develop in young children with Down’s syndrome?; are there differences in memory early on in development?; does sleep play a role in learning?; apart from Trisomy 21, are there other genetic differences? We will look for risk and protection markers that can differentiate individuals with Down’s syndrome who may go on to develop dementia and those who may not. We particularly aim to identify such markers during early development, which may subsequently help us to target preventative treatment.

What does participating in the study involve?

We can be very flexible about when and where we carry out the testing sessions with your child, and we leave the choice entirely to you. One solution is for a researcher to come to your home for the first visit, which will also serve the purpose of getting to know your child so that s/he is more at ease during the subsequent visit to Birkbeck. The home visit would be followed by a visit to our research centre. Alternatively, we can run the whole session at Birkbeck. The testing session at Birkbeck can take place over one day (morning and afternoon, with lots of breaks, of course), or over two days (one afternoon, a night in a nearby hotel, and resume testing the following morning). Such choices are up to you and will depend on the distance you need to travel and what you find the most convenient. The entire testing will be divided into three parts. In the first part we will ask questions about your child’s medical history, early development, leisure activities, sleep routines, eating habits, social interaction, likes and dislikes. We will then do some assessments of your child’s behaviour, her/his communication skills and cognitive abilities by administering memory and other simple problem-solving tasks such as reaching for objects or putting shapes together. These are always

presented as fun games that infants and toddlers really enjoy. In the second part, we will make recordings of your child's brain waves using EEG (electroencephalogram). We will place a light damp cap on your child's head. It's a bit like wearing a hairnet with tiny sponges that measure the natural electrophysiological activity of the brain. Nothing goes into the brain. The sponge-covered sensors are held together with a plastic net. You and your child will of course have the opportunity to inspect the cap prior to the session. While your child wears the cap, we will present videos on a television/computer monitor, and your child will be asked to watch the videos. In the third part we will make a recording of your child's eye movements from a table-mounted eye-tracker, as they watch fun displays on a television/computer monitor. During all testing your child will sit on your lap, and you will remain with your child at all times.

We will also ask both parents whether they would be happy to complete a simple and short online task of verbal and spatial memory, either during this session or later from home. Such parental measures will help us fully analyse the data. This is of course optional, and your child can still participate in the study if you yourself prefer not to do the memory tasks.

We will take a digital photograph of your child during the visit, and these photographs will be associated with a unique study ID number, not your child's name. Any photos will be stored securely in electronic format, and will only be seen by researchers involved with the study. If you wish, you can choose for your child not to be photographed but still take part in the study. We will also videotape the session. These videos will only be used for research and data analysis purposes/consultation. The videos will be kept in a secure location.

Your child will also have his/her head circumference, height and weight measured.

#### *Saliva sample*

We would like to collect a saliva sample from your child during the visit. This will be used for obtaining genetic material (DNA) from white cells.

#### *Optional blood draw*

If your child needs to have blood drawn for some medical reason by your GP, we would like to request that additional blood be collected from your child. The blood sample will be used for the same purposes as the saliva sample, but is less prone to degrade than saliva samples. If you agree, we will inform your GP of your enrolment in our study and provide you with a pouch for your doctor to collect the blood on our behalf. You can choose for your child not to give a blood sample and still remain in the study.

#### *Optional for male participants only*

If your son will be having a circumcision around the time of the study, and if you agree, we would like to ask that your doctor collect the foreskin sample in a pouch (that we will provide). The skin will be used for the same purposes as the blood sample, to gather cellular material from your child.

#### *Hair sample*

If you agree, a trained member of our research team will painlessly pluck 10 strands of hair to send to researchers at Queen Mary, University of London, who will use the hair sample to conduct tests on your child's cell biology.

Any samples that we collect from your child will be number coded, and not identified by your child's or family's name. You can of course stop us doing anything you would prefer us not to do.

#### Risks, Stress and Discomfort

There are no known psychological risks associated with any of the test procedures. However there is the possibility of minor stress, frustration or boredom associated with participation in these tasks.

Wearing the sensor cap may be uncomfortable for some individuals, but is completely painless. You will be given another opportunity to ask questions at the end of the experiment.

#### Benefits of the study

We hope that our insights will lead to novel treatments for early Alzheimer's diagnosis, and intervention/ treatments that will benefit individuals diagnosed with Down's syndrome as well as their family members. We also hope that future generations may benefit if we increase our scientific understanding of these disorders.

All hotel and travel expenses within Great Britain will be reimbursed. This will include all expenses for parents and child to travel into our research centre in London and back home, where necessary an overnight stay at a local hotel, meals, and travel from the hotel to our research centre and back by taxi. We regret that our grant does not allow us to cover fares from overseas.

#### How the data will be used

Your child's data will have a unique study ID number associated with them rather than a name. The study ID number will be linked to your child's name and identifying information (name, address, phone number) on a list that we will keep confidential and separate from the data. Only members of the research team will have access to the list. The only exception to this is if we think that a child may be at risk of harm.

Your and your child's involvement in the study will remain confidential except in the highly unlikely event that the researcher has a serious concern regarding a child protection issue.

If your child participated in a previous study at Birkbeck, University of London, we may combine the data gathered from that project with this project.

#### Is my participation voluntary? What happens if I change my mind?

Your child does not have to take part in the study should you wish for him/her not to. You may withdraw from this study at any point, and for any reason. If during the study procedure your child wishes to stop, he/she can at any time without penalty, or you needing to provide a reason. You/your child may skip any questions/tasks he/she does not want to participate in, without penalty.

Thank you very much in advance, for your and your child's time and participation in the study.

*If you have any questions or concerns, or need to report a problem associated with your child's participation in the study, please contact the Project Coordinator for the study, Dr. Esha Massand on 020 7079 0778 or [e.massand@bbk.ac.uk](mailto:e.massand@bbk.ac.uk). Alternatively, you could contact the Chief Investigator, Professor Annette Karmiloff-Smith, preferably by emailing her ([a.karmiloff-smith@bbk.ac.uk](mailto:a.karmiloff-smith@bbk.ac.uk)) or, if you prefer, by telephone (07903 701136).*