Participant Information Sheet

Parent/Guardian

GENETIC AND ENVIRONMENTAL INFLUENCES ON RECOVERY OF SEVERE PAEDIATRIC BRAIN INJURY

ADAPT Genetics UK

Chief Investigator: Professor Anna Adlam, University of Exeter, U.K.

Invitation and brief summary:

In this research study we want to learn more about how genes and the environment may affect how children and adolescents recover from a Traumatic Brain Injury (TBI). We are asking young people with TBI who have completed taking part in the ADAPT study to be in this research study. We are also asking their parent/guardian to take part in the study.

We are asking you to be in this research study so that we can learn new information that may help other young people with TBI. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study.

Please take time to consider the information carefully and to discuss it with your child. If you want to ask any questions about the research, telephone, email and postal contact details are listed at the bottom of this sheet.

This research is funded by the National Institutes of Health (NIH).

Purpose of the research:

In this research study we want to learn more about how genes and the environment may affect how children and adolescents recover from a Traumatic Brain Injury (TBI). Genes are inside of our cells and direct how our bodies respond to things. The environment that we live in, including how we are raised and the people we have around us, can also affect how we respond to events. There is a lot of variation in how young people recovery from a TBI and we want to learn more about what causes this. Understanding how genes and the environment affect recovery from a TBI may help to improve how people recover from these injuries.

Why have I been approached?

You and your child have been invited to take part in this research because you previously took part in the ADAPT research study. We are inviting all families who took part in the ADAPT study to take part in this new study looking at how genes and the environment affect recovery from TBI.

This research is led by Professor Brad Kurowski and his team at Cincinnati Children's Hospital Medical Centre and involves children and families from lots of different countries. In England, the lead researcher is Professor Anna Adlam, a Senior Lecturer/Clinical Psychologist at the University of Exeter. This study is being done along with the ADAPT study, which is being conducted by researchers at the University of Pittsburgh.

What would taking part involve?

If you qualify and you decide that you want to be in the study, the following things will happen:

(1) Questionnaires: The questionnaires will provide environmental information for the study.

We will post you 3 short questionnaires along with instructions for how to complete these. The questionnaires will ask you about parenting practices and your home and neighbourhood environment. Answering these questions usually takes about 20 minutes. We will give you a freepost envelope to send them back to us. If you would prefer, you can answer the questions over the telephone.

(2) Saliva sample: The DNA in saliva sample will provide genetic information for the study.

We will post you a kit with instructions and ask your child to use this to spit into a cup or use a sponge to collect a saliva sample, and a freepost envelope to send them back to us. We will also give you a telephone number in case you have any questions and a link to a video guide to completing the sample saliva.

We will also ask your permission to send a letter to your child's GP to inform them that they are participating in this research. This is so that clinicians involved in their future health care can be aware of this.

Completed questionnaires and saliva samples will be sent to the University of Exeter. We will use a unique number to identify your child's saliva samples and

questionnaires, and will not include you or your child's name when we send these to Cincinnati Children's Hospital in America to be analyzed. With your permission, findings from this study will be looked at along with information collected about you as part of the previous ADAPT study.

Left over saliva samples will be stored in a biorepository, the Cincinnati Biobank in America, to be used for future studies about traumatic brain injury. Only Cincinnati Biobank staff have access to client sample data.

What are the possible benefits of taking part?

Being in this study may not help you/your child right now. When we finish the study, we hope that we will know more about ways to improve care for people who have had a traumatic brain injury. This may help other children with TBI later on.

What are the possible disadvantages and risks of taking part?

There are known and potential risks and discomforts to being in this study. They are:

- Questionnaires: Answering questions and sharing information about yourself and your family may be uncomfortable, cause stress, or make you nervous. You do not have to answer any question that makes you nervous. For this study, all information that identifies you will be removed from the questionnaire data before it is used.

- Saliva collection: There are no known risks from collecting saliva.

- Genetic Testing: Some people in genetic studies feel anxious if they think they might have a gene that puts them at risk or that may be passed on to children. If you have these feelings at any time during the study, you should talk with the lead researcher (Professor Anna Adlam: a.r.adlam@exeter.ac.uk; 01392 722209) or your local clinician.

The results of genetic testing will not be given to you. We use a research lab, not a clinical lab with certified procedures for reporting results. We will not understand the meaning of most of the differences in this information until there is more research in the future.

There may be other risks that we do not know about yet.

What will happen if I don't want to carry on with the study?

Instead of being in this study, you can choose not to be in it.

If you do take part in the study, you can change your mind and decide to withdraw from being in this research at any time and you do not need to give any reason for choosing to do this.

If you decide to withdraw from the research and you would like us to destroy the data (questionnaires and saliva sample) you or your child have provided please inform us of this. We will be able to fulfil this request up until the point that your anonymized data has been sent to America. At that point, we will be able to destroy you or your child's personal data (retained only in the U.K.) but not you or your child's anonymized research data. If you have any questions about this please contact a member of the research team and we will be happy to discuss it with you.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation, GDPR, 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this.

If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection. If you have any concerns about how the data are controlled and managed for this study then you can also contact the Sponsor Representative, Pam Baxter, Senior Research Governance Officer, whose details are at the end of the information sheet.

Making sure that information about you remains private is important to us. To protect your confidentiality in this research study we will do the following:

- You will be allocated a unique study identifier that will be used to label research samples and documents. This number will ensure that the information from your samples and documents will be protected and cannot be identified by anyone else.

- You and your child's personal details (name, telephone number, home address, email address, and your child's date of birth) will be stored at the

University of Exeter and only accessed by the research team. Paper copies of the consent to contact and consent/assent forms will be held in locked filing cabinets in a locked room. These copies of the forms will be scanned and stored electronically and encrypted in a password protected format. The details will be held following consent in order to post the correct questionnaires and saliva sample kit. These details will be stored separately from the research data (i.e., your answers to the questionnaires and the saliva sample). We will not send any of these personal details to America with the research data.

When you complete the consent form, we will ask your permission to be contacted about other related research projects. If so, we shall hold on file your details indefinitely for the purposes of contacting you about future research, unless you withdraw consent at a later date. You can choose to participate in this research but not to be contacted about other research if you prefer. If so, we will keep you/your child's personal details for 7 years only, and will be securely destroyed after this period.

- We will only send your study identifier with your research data. This identifier will be used to link your child's saliva sample and answers to the questionnaires with information you provided when you took part in the ADAPT study.

- Information that links you to the study identifier will be stored separately and securely in an encrypted password protected form, which can only be accessed by the research team at the University of Exeter. We will keep this for 7 years and will be securely destroyed after this period.

- Research data from the study will be provided to a data repository and will not include information that can be used to identify you or your child. This will be stored indefinitely.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

De-identifiable information (information that cannot be linked to you or your child) will be made available to other members of the research team (including the ADAPT research team) for an indefinite period of time.

De-identified information will be shared with other groups, including authorized officials from the National Institutes of Health agency (the agency paying for this study) and possibly other agencies.

To share this information with the National Institutes of Health and/or other agencies, a specialized number will be generated for you to ensure your privacy. This number will be able to link the de-identified information that is generated from this study with other studies you may decide to join in the future. This number will not be linked to you or your child's medical records.

Will your medical care be impacted?

Your child's rights concerning medical care and treatment will not be affected. We will ask your permission to contact your child's general practitioner (GP) to let them know that you are taking part in the study. No results from the research will be shared with their GP or other professionals. The only time we would disclose any information given to us is if we believe that you or someone else may be at risk of serious harm, or if criminal behaviour that we are required by law to disclose was made known to us. Should this happen, wherever possible, we would always talk to you first.

Will I receive any payment for taking part?

You will be reimbursed £20 of gift vouchers for your time, effort and travel for participating in this research study. Specifically, your family will receive £10 for completing the questionnaires, and £10 for providing the saliva sample. If we find that your saliva sample has been damaged then we will to ask you to help your child provide a second sample and your family will receive a further £5 for this.

There will be no additional costs to you to participate in this study.

What will happen to the results of this study?

We would like to send you a newsletter informing you of the research findings when the study has finished. We will ask your permission to use your contact details to do this when we ask for your consent to take part in the research. If you would prefer not to receive the newsletter then please let us know. The research findings will also be published on the University of Exeter study website https://psychology.exeter.ac.uk/adapt

Who is organising and funding this study?

This research is funded by the National Institutes of Health https://www.nih.gov/ Cincinnati Children's Hospital Medical Centre are being paid to conduct this research.

Who has reviewed this study?

This project has been reviewed by the South West – Central Bristol Research Ethics Committee.

Your rights under the GDPR

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Who do you call if you have any questions or problems?

For questions or concerns about this research study you can contact the Chief Investigator, Professor Anna Adlam:

Email: a.r.adlam@exeter.ac.uk, or adapt-genetics-uk@exeter.ac.uk; Telephone: 01392 72 2209

Sir Henry Wellcome Building for Mood Disorders Research, University of Exeter, Queen's Drive, Exeter, Devon, EX4 4QQ

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or complaints about the research, you can call the Patient Advice and Liaison service (PALS). To find your nearest, click here: https://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363

If you are not happy with any aspect of the project and wish to complain to a member of the University of Exeter you can contact Gail Seymour, Research Ethics and Governance Manager g.m.seymour@exeter.ac.uk, Telephone: 01392 726621.

If you are not satisfied with their response or believe they are processing your personal data in a way that is not lawful you can complain to the Information

Commissioner's Office (ICO): please visit https://ico.org.uk/ or call their helpline: 0303 123 1113.

For general support and advice regarding brain injury, we recommend contacting the Child Brain Injury Trust (national helpline: 0303 303 2248; email: info@cbituk.org, website: https://childbraininjurytrust.org.uk/

The study sponsor is the University of Exeter, and the representative is Pam Baxter. Email: p.r.baxter2@exeter.ac.uk, Telephone: 01392 723588, Address: Ms Pam Baxter, Senior Research Governance Officer, Research Ethics and Governance Office, Lafrowda House, St Germans Road, Exeter, Devon, EX4 6TL.

Thank you for your interest in this project.