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Information Sheet for Parents and Guardians

Assessing the impact of children with ADHD on the health and well-being of families. Part B.

We would like to invite you to take part in the second part of this research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully.

Ask me if there is anything that is not clear or if you would like more information. You can take your time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of the study is to understand in greater detail of how living with a child who has ADHD affects your mood across a typical week. From the first part of this study we will have gained an understanding of the quality of life of families who have a child with ADHD. However, we also want to understand what life is like for you on a daily basis and be able to compare the daily life of someone who looks after a child with ADHD to someone who looks after a similar aged child without ADHD.

Why has my child been chosen?

We are asking some of those people who took part in the first part of the study if they would like to be involved in the second part.

What will be involved if I agree to take part in the study?

We will give you a small digital recorder which you will use to tell us how you are feeling at random points throughout the day (7.30am to 9.30pm). The study will run for one week and the digital recorder will 'beeb' about 10 times a day. At each 'beep' point the recorder will ask 5 questions about how you are feeling. The digital recorder does not need to be attended to at times when doing so could be dangerous, e.g. while driving. We appreciate that the research may make a significant demand on your time over the week.

Do we have to take part?

No, you do not have to take part. If you don't want to, you do not need to do anything.

What are the possible benefits of taking part?

There will be no direct benefit to you or your child in taking part in the study. However, the results of the study may help research into ADHD and the impact this condition has upon families. On completion of the weeks mood

assessment, and return of the digital recorder we would like to give you £20 high street voucher as a 'thank you'.

What are the possible risks of taking part?

There are no risks for you in taking part in the study. Your child's treatment and care at the ADHD clinic will not be affected whether you take part in the study or not.

Is the study confidential?

The information collected in the study will be kept completely confidential. Any information about you or your children will not be stored with your name or address so that you cannot be recognised. If it emerges that there is any possibility of harm to yourself or others from the information you provide then we will inform an appropriate person, for example your GP.

Who will have access to the data and where will it be held?

The data will be sent to the University of Sheffield where it will be stored in a secure area and also kept as a password-protected computer file, both of which can only be accessed by the research team and regulatory authorities. Any personal details will be kept separately to your questionnaire responses and linked only by a research study number.

An anonymous (with any details that might identify you removed) computer file will be retained and made available to other researchers for use in future studies. The anonymous copy of the data will also be retained by the funders, Shire Pharmaceuticals, and may be used in further research studies.

Will my GP be informed?

Yes, with your permission we will inform your GP that you are taking part in this research.

What if I change my mind?

You may change your mind at any point.

What will happen to the results of this study?

The results of this study will be used to help understand the impact on health and well-being of living with a child with ADHD. This may provide useful information health researchers in the future when considering the possible benefits of treatments for ADHD. The results will be presented both nationally and internationally.

Who is funding the study?

This study is being funded by Shire, who are a global pharmaceutical company that makes some treatments for ADHD. This study is not about their products. The study is being run independently by the University of Sheffield.

Has the study been approved?

Yes. The study has been approved by a Research Ethics Committee. The Research Ethics Committee is completely independent from anyone organising the study.

What if there is a problem?

If you have any problems or are worried about anything to do with this study, you should ask to speak to the research nurse who will do their best to answer your questions (contact name and number TBA).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The University of Sheffield, NHS Trust **NAME**, or **CLINIC NAME** but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. Please contact **THE LOCAL COMPLAINTS MANAGER on LOCAL NUMBER** for more details.

Who should I contact for further information?

If you have any questions about the study or would like any further information, please feel free to ask **THE RESEARCH NURSE** who can be contacted on **LOCAL NUMBER**.

Thank you for taking the time to read this.