[insert local Trust Logo]

SATURN – Stimulant medication for ADHD and Tics – Understanding Response versus Non-stimulants

Information Sheet for parents/carers

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1. You are invited to take part in our research study

The aim of the SATURN study is to understand whether stimulant (modified-release methylphenidate) or non-stimulant (guanfacine extended-release) medication is most effective for treating children and young people who are experiencing both ADHD and tics.

This information sheet is to help you understand why the research is being carried out and what it will involve for you if you and your child/young person decide to take part.

Please take time to read this information and ask us if there is anything that is not clear to you or that you would like more information about.

It is entirely your decision whether to take part in this study. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will continue in the normal way.

2. A summary of the study

Approximately 3-5% of children and young people (CYP) in the UK have Attention Deficit Hyperactivity Disorder (ADHD). Some of these CYP also experience tics.

Stimulant medication (such as modified-release methylphenidate) is often prescribed to children and young people (CYP) with ADHD.

However, some doctors are concerned that stimulants may increase tics and therefore, they favour prescribing non-stimulant medication (such as guanfacine extended release)

to CYP with ADHD and tics. Non-stimulant medication, however, may be less effective in treating the symptoms of ADHD.

With the SATURN study, we want to find out which one of these two medications, modified-release methylphenidate (stimulant medication) or guanfacine extended-release (non-stimulant medication) is better for treating CYP with both ADHD and tics.

If you and your child/young person (age 6-16) are eligible to take part in the study following the initial screening, you will be asked to complete the following:

- Baseline data collection (this may be split over multiple visits and take place face to face at a clinic or some of it may take place online)
- 12 Weekly visits (face to face, online, or via phone)
- 6-month visit (online or via phone)
- 12-month visit (online or via phone)

All information collected during the study will be kept safe and confidential.

3. What is the purpose of the study?

The SATURN study will compare modified-release methylphenidate (usually prescribed for ADHD) with guanfacine extended-release (usually prescribed for tics) to identify the best treatment for children and young people with both ADHD and tics.

4. Why have I been invited to take part?

We are asking parents/carers who have a child or young person (aged between 6 and 16 years old) with ADHD and suspected tics to take part. Both the child/young person AND one parent/carer need to take part.

Your child/young person will either be already taking medication and is being considered for a **medication change** or they will be about to **start medication for the first time** for their ADHD.

If you are unsure whether your child/young person needs to be taking medication or have their medication changed, please speak to their usual care team before expressing an interest in this study.

We are looking for 314 children / young people to take part throughout England.

5. Do I have to take part?

No. It is up to you and your child/young person whether or not you take part in this study. You can take as much time as you need to discuss with your family whether you would like

to be considered for this study. If you decide to take part, you will need to complete a form called the **Consent to Contact** form. Once completed, the information on this form will be shared with us (the research team).

Even if you complete the Consent to Contact form, you can withdraw interest at any point without giving a reason. Taking part is entirely voluntary and declining to take part in the study will not affect your child/young person's current or subsequent care or treatment.

If you agree to take part and are eligible, we will ask you to sign a consent form.
We will also ask your child/young person (if under 16) to sign an assent form (this is a child/young person's agreement to take part in the study, where they are not legally able to give consent) to indicate they are happy to take part in the study.

If age 16, they will sign a consent form. 15 year olds who turn 16 during the study will be asked to sign a consent form as their assent will no longer cover their participation from their 16th birthday onwards.

6. What would taking part involve?

Consent to Contact Form & DAWBA Online Screening Questionnaire

Following completion of the Consent to Contact form, you will be asked to complete an **online assessment questionnaire** called the DAWBA (Development and Well-Being Assessment).

If we find that the study is not suitable for your child/young person from the information provided on the DAWBA, we will contact you to let you know and inform your child/young person's usual care team

Screening Call

If your child/young person is suitable to take part following review of the DAWBA, a member of the research team will arrange to have a conversation **(screening call)** with you at a suitable time (via phone or Microsoft Teams – your choice). During the screening call, the research team member will provide more information about the study, answer questions you have and further assess your child/young person's suitability to take part in SATURN. If you would like to take part and the researcher thinks your child/young person may be eligible, they will book your **baseline visit(s).** The study will cover your travel expenses.

As with most medication, when a change is advised by the usual care doctor, a tapering off/washout period is needed. This is a period when the dose may need to be gradually reduced and stopped before the person is asked to take a new medication. The length of time varies depending on medication and is advised by the usual care doctor.

If your child/young person is already taking medication for ADHD, which their usual care doctor is in the process of tapering off or has advised that a tapering off/washout period is imminent, **this will need to be completed, before your family's eligibility for SATURN can be assessed at the face-to-face clinic visit (it does not to be completed before any virtual baseline visits).** Your usual care doctor will advise the SATURN team when this period is over and your clinic visit can be booked.

Baseline Visit

Depending on where you are located your baseline visit **may be split** across multiple visits with at least one occurring face to face at a clinic. The others may take place via phone or video conferencing (Microsoft Teams). Your local team will make it very clear how your baseline data visits will take place.

During the baseline visit(s), **informed consent** will be obtained from you and assent will be obtained from your child/young person if they are aged under 16. Consent will be obtained from young people aged 16. Both the parent/carer and child/young person need to agree to take part and sign the relevant forms (consent/assent) for the child/young person to be enrolled in the study.

Following consent, eligibility will be confirmed, and the first set of questionnaires will be completed. Your child's/young person's blood pressure, pulse, height and weight measurements will also be collected at the face-to-face appointment. They will then be **allocated to their treatment randomly** by computer software. Children/young people in one group will receive modified-release methylphenidate once daily tablet or capsule, while those in the other group will receive guanfacine extended-release tablet once daily. Your child/young person will have an equal chance of being in either group.

The research team will confirm with you when your next appointment will be. For most people, these follow-up appointments will be done remotely (via phone or Microsoft Teams – this is up to you, unless a tic assessment needs to be completed. In this case, a video conference is required. This is to allow the researcher to be able to see and interact with your child/young person in order to complete the assessment accurately). A small number of participants may be asked to be seen in person at the clinic or have their blood pressure and pulse taken and shared with the research team frequently – it will be up to the research doctor to decide if this may be needed and when.

Please note: Female participants who are, or are planning, to become pregnant will be not be able to take part in the study. Those who are sexually active will be required to use contraception (assessed at the baseline visit) and continue to use this method for the duration of the study. Acceptable methods of contraception include hormonal contraception (which may be in the form of tablets, injection, patch or implant) or not being sexually active. The research doctor will discuss the risk of pregnancy and study medications. If the research doctor thinks there is a chance that a participant could be

pregnant, they will ask them to do a pregnancy test during the baseline visit before they are able to give consent to take part. If a study participant plans to or does become pregnant after agreeing to take part (if they miss a period and/or thinks they may be pregnant, they should take a pregnancy test and inform the study team of the result), they and/or their parent/carer should inform the study team and they will be withdrawn from the study. In these circumstances following withdrawal from the study, the decision whether to stop or change the study medication will be made between the participant, their parent/carer and usual care team/treating clinician.

Follow-up research contacts

Children/young people will be in the trial for 12 months from the initial clinic visit. Following the clinic visit**, parents/carers of children/young people (and children/young people 11-16 who wish to contribute) will be contacted weekly for 12 weeks** (approximately 3 months), with additional email and/or text reminders to complete questionnaires online (or on paper if required) when appropriate **and** two more times **at 6 months and 12 months** following the visit. During these visits, parents/carers will be asked to answer a few questions (e.g., any changes in their child's treatment/symptoms) and have their child/young person's dose checked and changed if needed. Any other current treatment your child/young person is receiving, e.g. psychotherapy, will continue as normal throughout the study unless it is a contraindication to their study treatment – your child/young person's usual care doctor will advise.

7. What are the possible benefits of taking part?

Taking part in the study may not have any more direct benefits to you and your child/young person, but the information we collect from this study may help to determine the best treatment for children and young people with ADHD and tics. This will inform national and international clinical guidelines, and as a result, influence future clinical practice.

Children/young people taking part in the study will be monitored regularly (weekly in the first three months of their participation in the study followed by two more contacts at six and twelve months) by the researcher(s) and research doctor.

Your family will be offered a total of £30 in e-vouchers as a thank you for your participation. Your family will also be entered into a number of prize draws (e.g. for an electronic tablet) as a thank you for taking part in SATURN.

8. What are the possible disadvantages and risks of taking part?

The questionnaires we will ask you to complete will ask some questions about your child/young person's mood and feelings. Some people can find it hard when they are

asked to think about the difficulties their child/young person and family are experiencing. If you are concerned by any of the issues raised in the SATURN study, there are some organisations that can offer support and advice:

[ADD LINK TO SIGNPOSTING INFO]

Both study medications are licenced for and regularly prescribed in clinical practice in this age group, but there is a small chance your child/young person may experience some side effects from the medication they take; **please tell your child/young person's usual care doctor if this is the case.**

Some of the most common side effects are listed in the Table below.

Potential side effects of study medications		
Frequency	Modified-release Methylphenidate	Guanfacine extended-release
Common or Very Common	Aggression; hair loss; anxiety; decreased appetite; irregular heartbeat; joint stiffness; cough; depression; diarrhoea; dizziness; tiredness; dry mouth; fever; tummy pain; growth retardation; headaches; high blood pressure; difficulty swallowing; change in mood; movement disorders; common cold; nausea; sleep disorders; vomiting; weight loss.	Anxiety; loss of appetite; irregular heartbeat; body weakness; constipation; depression; diarrhoea; dizziness; tiredness; dry mouth; tummy pain; headache; low blood pressure; change in mood; nausea; skin rash; sleep disorders; urinary disorders; vomiting; weight loss

For further information on the medication, including less common side-effects, please see the accompanying package leaflet, or click the links below:

- **Modified-release Methylphenidate** - https://www.medicines.org.uk/emc/product/6872/smpc#about-medicine
- **Guanfacine extended-release -** https://www.medicines.org.uk/emc/files/pil.5099.pdf

Specific information on the different types of methylphenidate tablets and capsules can be found here: https://bnfc.nice.org.uk/drugs/methylphenidate-hydrochloride/

Important Note: Your child/young person may feel dizzy, particularly, at the start of their treatment. They should **not** cycle or drive if they are learning to, or use any machines, tools etc. that could cause injury.

9.What is there is a problem?

If you have any concerns or questions between research appointments, please contact your child/young person's usual care team <insert local care team details>. They will be able to forward any study related queries to the SATURN research doctor.

If you have concerns or questions about any aspect of this study, you should ask to speak to the researchers. Their contact details are at the end of this information sheet.

If any questions remain, they will contact the study coordinating centre at the Nottingham Clinical Trials Unit.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via your local Patient Advisory and Liaison Service (PALS) <insert Local PALS details>.

In the event that something does go wrong, and you or your child/young person are harmed during the study, there are no special compensation arrangements. If you/they are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and **without your child/young person's care and legal rights being affected**.

If you withdraw, we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you withdraw the information collected will not be erased and this information will still be used in the final study analysis.

Important Note: Please ensure that your child/young person does not stop taking their medication without seeking advice from their usual care doctor first. If you stop taking your medication suddenly, you may develop withdrawal symptoms.

11. Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your child/young person and their medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and restricted-access office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Professor Chris Hollis) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The DAWBA questionnaire will be completed on a secure encrypted online platform. As access is restricted by user accounts, a unique ID number and password will be needed to access each individual account. Each DAWBA respondent will be sent their own unique logins by the study team. The link between participants' unique trial IDs and their DAWBA logins (ID and password) will only be known to the study team, which includes the local hub research teams. Neither the DAWBA platform team nor anyone else outside the study team will have access to this information. Personal information collected on the DAWBA are the child/young person's age, gender and their first name (should the parent/carer wish to provide it). Full name, contract address, IP address or any other sensitive data is not collected on the platform. Forms will be locked once the DAWBA has been completed so the information cannot be modified or re-entered at a later date. Data storage will comply with the UK Data Protection Act 2018 and any amended laws in relation to data protection in the UK and Europe.

Your personal contact details will be available to the Nottingham Clinical Trials Unit (NCTU) and the <insert Lead Trust/Hub Name here> so they can contact you during the study and send you the questionnaires.

Your name and telephone number will be shared with Esendex, our text messaging provider and their sub processors, and will be used to send you text message reminders about the study and study questionnaires whilst you and your child/young person are participating in the study. Essendex will keep the information shared with them for two years or until the end of the study before it is destroyed.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham and the research team based at <insert Trust name> who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you and your child/young person which leaves the [site] will have the name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your child/young person's medical records so in these instances we will need to know their name and date of birth.

Your contact information will be kept by the University of Nottingham for up to 12 months after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years from the first publication. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. Even if your child/young person is not eligible for the study, we may use your anonymised data in reports we write to explain reasons why patients did not take part in the study. The data used in any reports or academic articles will always be written in a way to maintain your anonymity.

With your permission, we will inform your child/young person's GP about your participation in this study and we will share with them a copy of your child/young person's agreement to take part (consent/assent).

12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, and this may be used in the final study analysis.

We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with your child/young person's condition that you may be interested in taking part in. You will also have the option to take part in future research using your data saved from this study.

If you do not wish for your contact details to be kept for a copy of the study results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the study. After 7 years, your questionnaire data collected during the study will be disposed of securely.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at **www.hra.nhs.uk/information-about-patients/** and **www.hra.nhs.uk/patientdataandresearch**
- at **http://www.nctu.ac.uk/data-protection/data-protection.aspx**
- by asking one of the research team: <insert email address and phone number(s) of Hub Research team>

14. Who is organising and funding this study? How has it been approved?

The study is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the study is provided by the research arm of the NHS, the National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) Programme (Ref No NIHR128472). All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by <insert REC name when known> Research Ethics Committee.

Patients who have previously been treated for ADHD and/or tics and their parents have helped us plan and design this study. Patient representatives are also involved in the teams that oversee the running of the study.

This study has also been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK and ensuring they meet applicable standards of safety, quality, and effectiveness.

15. What if relevant new information becomes available?

Sometimes we get new information about conditions and treatments during the study. If this happens, your research doctor will tell you about this new information and discuss whether you should continue in the study.

If you decide not to carry on, your research doctor will arrange for your child/young person's care to continue as normal. If you decide to continue in the study, they may ask you to sign a new Informed Consent Form.

16. What happens at the end of the study?

Your participation in the study will end after 12 months from your face-to-face clinic visit. When your participation ends, your child/young person's care and treatment will continue as normal.

If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication.

At the end of the study, a summary of the results will be published on the study website and you will be given information on how to access them unless you ask us not to.

17. How to contact us:

- Contact details of your local care team: <insert details here>
- Contact details of your SATURN research team: <insert contact details of Main Research Contact(s) at Hub here>

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Thank you for reading this leaflet.