知情同意书

尊敬的受试者：

我们邀请您参加南京医科大学病原生物学系、生殖医学国家重点实验室自闭症研究中心资助开展的“ 基于代谢组学的自闭症早期诊断方案实现”课题研究。本研究将在南京医科大学开展，估计将有 15 名受试者自愿参加。本研究已经得到南京医科大学伦理委员会的审查和批准。

为什么要开展本项研究？

自闭症是一组由神经发育失调导致的广泛性发育障碍疾病，以男性多见，起病于婴幼儿期，其主要表现为不同程度的社会沟通交往障碍、以及行为方式刻板和兴趣狭窄等；其致病机制复杂，包括遗传易感性，免疫失调，神经递质紊乱，过度氧化应激等。目前儿童自闭症谱系障碍的诊断主要是基于美国精神障碍诊断与统计手册 DSM-5（Diagnostic and Statistical Manual of Mental Disorders, 5th Edition）中的自闭症诊断标准，仅包括社交障碍和刻板行为两方面，敏感性低，不易应用于筛查工作。

5-羟色胺（5-HT）是大脑发育过程中最早出现的神经递质之一，在大脑发育过程中充当着神经营养因子的作用。现有大量的研究证实 5-HT 系统紊乱与合成障碍与自闭症的发生发展有着密切的联系，自闭症患者体内 5-HT 水平存在异常。为了研究及评价 5-HT 作为自闭症筛查标志物的合理性，本临床课题将对来自南京市江宁区海之星自闭症儿童康复中心的 3-9 岁自闭症患者共 15 位，收集尿液样本 15 毫升并测定其中 5-HT 含量，研究该代谢物作为自闭症患者筛查标志物的合理性。

南京医科大学伦理委员会已经审议此项研究是遵从赫尔辛基宣言原则，符合医疗道德的。

本研究受试人群的纳入标准为

年龄 3-9 岁的自闭症患者（CARS 评分＞30 分）；

饮食正常；

自愿参加本实验，家属签署知情同意书。

如果参加研究，需要做什么？

1. 您将在指导下留取约15毫升清洁中段尿液样本；

2. 您的尿液样本将按以下步骤进行实验：

本研究将使用多种方法测量样本 5-HT 等代谢物含量，并进行后续对比分析。

哪些人不宜参加研究?

1. 儿童服用影响体内代谢物含量的特殊药物；

2. 儿童同时患有其他神经系统疾病者及其他原因所致的严重影响生存质量的疾病；

3. 儿童的家属不能配合；

4 儿童者正在参加其他课题研究；

参加研究有哪些好处？

参加本项研究，您将可能从本项研究中受益。此种受益包括您将获得免费的尿液代谢物水平检测及报告。参与本次研究将不会给您任何报酬。

个人信息是保密的吗？

您的研究记录将保存在实验室中，研究者、研究主管部门、伦理委员会将被允许查阅您的研究记录。任何有关本项研究结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您个人研究资料的隐私。

我必须参加研究吗？

是否接受本项研究完全取决于您的自愿。您可以拒绝参加此项研究，或在研究过程中的任何时间退出本研究，不会影响对您的医疗或有其他方面利益的损失。

研究者出于对您的最大利益考虑，可能会随时中止您参加本项研究。

如果您因为任何原因从中退出，您可能被询问有关您接受此项研究的情况。如果研究者认为需要，您也可能被要求进行实验室检查和体格检查。这对保护您的健康十分有利。

受试者声明：我已经阅读了上述有关本研究的介绍，对参加本研究可能产生的风险和受益充分了解。我自愿参加本研究。

受试者法定监护人签名：_____ 日期：__ __ __ 年 __ __ 月 __ __ 日

受试者法定监护人的联系电话：_____

研究者声明：我确认已向受试者解释了本研究的详细情况，特别是参加本研究可能产生的风险和受益。

研究者签名：_____　　日期：__ __ __ 年 __ __ 月 __ __ 日

研究者的联系电话：_____

Consent Form

Dear Sir/Madam:

We invite you to participate in the research project of “the Early Diagnosis of Autism based on Metabolomics" sponsored by the Department of Pathogen Biology and the Autism Research Center of the State Key Laboratory of Reproductive Medicine, Nanjing Medical University. This study will be conducted at Nanjing Medical University and it is estimated that 15 subjects will participate voluntarily. The study has been reviewed and approved by the Ethics Committee of Nanjing Medical University.

Why do we want to carry out the research?

Autism is a group of pervasive developmental disorders caused by neurodevelopmental disorders. It is more common in males. It starts in infancy, the main performances are varying degrees of social communication barriers, as well as stereotyped behavior, narrow interests, and so on. Its pathogenic mechanism is complex, including genetic susceptibility, immune disorder, neurotransmitter disorder, excessive oxidative stress. The current diagnostic criteria of autism spectrum disorders in children are mainly based on the Diagnostic and Statistical Manual of Mental Disorders 5th Edition, which includes only two aspects: social dysfunction and behavioral stereotyping. The low sensitivity makes it difficult to apply to the screen.

5-hydroxytryptamine(5-HT) is one of the earliest neurotransmitters that appear during brain development, which acts as a neurotrophic factor. A large number of studies have confirmed that 5-HT system disorders and synthetic disorders are closely related to the occurrence and development of autism. People with autism have abnormal levels of 5-HT. To investigate and evaluate the rationality of 5-HT as a screening biomarker for autism, this clinical project will focus on 15 autistic children aged 3-9 years from Haizhixing Autism Children rehabilitation Center in Jiangning District, Nanjing. We will collect 15 ml of urine samples and determine the 5-HT content in order to investigate the rationality of 5-HT as a screening marker for autistic patients.

The Ethics Committee of Nanjing Medical University has considered that our study complies with the Principles of the Declaration of Helsinki and medical ethics.

The inclusion criteria for the study population are autistic children aged 3-9 years (CARS score > 30), normal diet, and volunteer to participate in this experiment. Family members signed informed consent forms in advance.

If you participate in the study, what do you need to do?

1. You will be instructed to take a 15 ml clean midsection urine sample.
2. Your urine sample will be tested in the following steps: the study will use a variety of methods to measure the content of metabolites such as 5-HT in the sample and conduct subsequent comparative analysis.

Who are not suitable for the study?

1. Children take special drugs that affect the content of metabolites in the body.
2. Children with order neurological diseases and other causes that seriously affect the quality of life.
3. The children's family couldn't cooperate.
4. The children are participating in other studies.

What are the benefits of participating in this study?

You may benefit from participating in this study. This benefit includes free urine metabolite level testing and reporting. You will not be paid to participate in this study.

Is personal information confidential?

Your research records will be kept in the laboratory, the researchers, research authority, and Ethics Committee will be allowed access to your research records. Any public report on the results of this study will not disclose your identity, and we will make every effort to protect the privacy of your research data within the scope permitted by law.

Do I have to take part in the study?

Acceptance of the study is entirely up to you. You can refuse to participate in the study or withdraw from the study at any time during the study process without prejudice to your medical or other benefits. The researchers may terminate your participation in this study at any time for the best interest of you. If you withdraw from the study for any reason, you may be asked about your acceptance of the study. If researchers deem it necessary, you may be required to undergo laboratory and physical examination, which is of great benefit to your health protection.

Subject statement: I have read the above introduction of this study and fully understand the possible risks and benefits that may arise from participating in this study. I am willing to participate in the study.

Signature of the subject's legal guardian: _____ Date: _____
The contact number of the subject's legal guardian: _____

Researcher statement: I confirm that I have explained to the subjects the details of this study, especially the possible risks and benefits of participating in this study.

Investigator's signature: _____ Date: _____
The contact number of researcher:_____
The contact number of Ethics Committee, Nanjing Medical University: _____