
关于“基于合成生物学原理对孤独症患者尿液五羟色胺等神经递质水平进行筛查”项目
涉及（非干预性）临床研究的伦理审查意见

南京医科大学基础医学院刘星吟教授领导的iGEM 团队申请的“基于合成生物学原理对孤独症患者尿液五羟色胺等神经递质水平进行筛查”项目需要收集患者的尿液进行方法学评估，所涉及的临床研究研究内容属于非干预性研究，经南京医科大学伦理委员会审查，符合国际医学科学组织理事会与世界卫生组织发布的《人体生物医学研究国际伦理指南》、国家卫生健康委员会科技教育司发布的《涉及人的生物医学研究伦理审查办法（试行）》、国家药品监督管理局发布的《体外诊断试剂临床研究技术指导原则》以及南京医科大学伦理委员会有关规程，一旦项目被批准，可以在符合临床研究法规要求及伦理的条件下实施。

南京医科大学伦理委员会

2020年 9 月 11 日

**Ethical Review Opinions about the (Non-
Interventional) Clinical Research in Project:
"Screening of ASD Patients Based on Urinary
Serotonin (or Other Neurotransmitters) Levels based
on synthetic biology"**

Ethical reviews about the (non-interventional) clinical research in project from iGEM team "Screening of Autism Patients Based on Urinary Serotonin (or Other Neurotransmitters) Levels based on synthetic biology" was requested by Prof. Xingyin Liu from School of Basic Medical Sciences, Nanjing Medical University. The project needs to collect urine from Autism patients for methodological evaluation. The content, reviewed by the Ethics Committee of Nanjing Medical University, is in compliance with the "International Ethical Guidelines for Human Biomedical Research" issued by the Council of International Medical Science Organizations and the World Health Organization, the "Biomedical Research Ethics Involving Humans (for Trial)" issued by the National Health Commission, the "Technical Guidelines for Clinical Research of In Vitro Diagnostic Reagents" issued by the National Medical Products Administration, and relevant procedures released by the Ethics Committee of Nanjing Medical University. Once the project is approved, it can be in compliance with clinical research regulations and ethical conditions Implement.

Ethics Committee of Nanjing Medical University

Time: 9/11/2020