

内分心

佛山市南海区人民医院临床研究伦理审查表

课题名称	病案报道：18 号染色体短臂缺失综合征自身免疫性甲状腺炎和垂体瘤 1 例		
项目负责人	叶静文	联系电话	15919076083
项目起止时间	2023-5 至		
请求审查类型	☒ 申请项目 ☐ 批准后项目 ☐ 延续项目 ☐ 委托项目		
涉及人体研究的内容	本研究回顾性分析 1 例成年的 18 号染色体短臂缺失患者，该患者除了表现为常见的智力减退、认知障碍之外，还合并比较少见的自身免疫性甲状腺炎和罕见的正常身高和垂体瘤。		
可能涉及的不良反应、危害及防治措施	本研究为回顾性病案报道，不公开患者的私人信息，无涉及患者的不良反应和危害。		
申请人（项目负责人）承诺： 以上所填内容属实，如获批准，我将严格遵守《南海区人民医院医学伦理委员会章程》，并按照提供的方案进行项目研究。 申请人签名：_____ 时间：2023.6.15			
伦理委员会审查意见： 1、同意开展 ☒； 2、不同意开展 ☐； 理由：_____ 3、做必要修正后重审 ☐； 修改意见：_____ 4、做必要的修正后同意 ☐； 修改意见：_____ 主任签名：_____ 佛山市南海区人民医院医学伦理委员会（公章）			
伦理批件号	2023115		

注释：本表一式两份，分别用于项目和伦理委员会备案一份。

Clinical Research Ethics Review Form of Nanhai District People's Hospital of Foshan

Project Name	A Case of Chromosome 18p Deletion Syndrome Complicated by Autoimmune Thyroiditis and Pituitary Adenoma		
Principal Investigator	Ye Jingwen	Contact Number	15919076083
Project Duration	2023-5 to		
Type of Review Requested	☒ New Application ☐ Post-Approval ☐ Continuation ☐ Delegated Project		
Description of Human Subjects Research Involved	This study involves a retrospective analysis of an adult patient with Chromosome 18p Deletion Syndrome. In addition to exhibiting common manifestations such as intellectual decline and cognitive impairment, the patient also presents with the less common occurrence of autoimmune thyroiditis and the rare features of normal stature and pituitary adenoma.		
Potential Adverse Reactions, Harms, and Mitigation Measures	This is a retrospective case report. Patient private information will not be disclosed. There are no anticipated adverse reactions or risks to the patient.		
Applicant (Principal Investigator) Certification: I certify that the information provided above is accurate. If approved, I will strictly adhere to the <i>Medical Ethics Committee Bylaws of Nanhai District People's Hospital</i> and conduct the project research in accordance with the submitted protocol. Applicant Signature: <u>[Signature]</u> Date: <u>2023.6.5</u>			
Ethics Committee Review Decision: 1. Approved for Implementation ☒ ; 2. Not Approved ☐ ; Reason(s): _____ 3. Resubmit after Necessary Revisions ☐ ; Revision Requirements: _____ 4. Approved Pending Minor Modifications ☐ ; Revision Requirements: _____ Chairperson Signature: <u>[Signature]</u> Medical Ethics Committee, Nanhai District People's Hospital of Foshan (Official Seal) 2023.6.5			
Ethics Approval Number: _____			

Note: This form shall be prepared in duplicate copies, one for the project file and one for the Ethics Committee records.

I confirm this is an accurate translation of the original document.

Translator: Wang Haidong, Qualification: CATI 2020110093400000056

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