中山大学附属口腔医院医学伦理委员会
MEDICAL ETHICS COMMITTEE OF HOSPITAL
OF STOMATOLOGY SUN YAT-SEN UNIVERSITY

伦理审查意见 Ethical Review Comments

意见号 No.	KQEC-2020-77-01		
项目名称 Protocol Title	不同类型磨牙症患者口颌系统功能研究分析 Analysis of stomatognathic system function in patients with different forms of bruxism		
申办者 Sponsor	不适用 NA		
研究科室 Research Department	口腔修复科 Department of prosthodontics		
主要研究者 Principal Investigator	阎英 Yan Ying		
审查类别 Review Category	初始审查 Initial Review	审查方式 Review Mode	快速审查 Expedited Review
审查日期 Review Date	2020年12月10日 December 10, 2020	审查地点 Review Place	不适用 NA
审查文件 Documents	（1）送审文件清单 Submission letter （2）初始审查申请 Initial Review Application （3）临床研究方案（版本号：1.0，日期：2020年11月9日） Protocol (Ver.1.0; Date:November 9, 2020) （4）知情同意书（版本号：1.0，日期：2020年11月9日） Informed consent application (Ver.1.0; November 9, 2020) （5）主要研究者简历 Resume of Principal Investigator （6）主要研究者责任声明 Responsibility Statement of Principal Investigator （7）项目分工 Project Division of Labor （8）病例报告表及其附件 Case report form and its attachments （9）受试者招募广告 Recruitment advertisements for subjects （10）使用仪器及系统说明书 Instrument and system specification （11）临床研究立项通知 Approval notice of clinical study		
审查意见 Comments	同意 Agree		
年度/定期跟踪审查频率 Frequency of Annual Follow-Up Review	初始审查及初始审查后的复审：12个月 Initial review and review after initial review 12 months 跟踪审查及跟踪审查后的复审：不适用 Follow-up review and review after follow-up review NA		
意见有效期 Valid Period of Approval Letter	一年 One year	截止日期 Expiration Date	2021年12月10日 December 10, 2021

主任委员签名：
Signature of the Chairman

中山大学附属口腔医院医学伦理委员会（盖章）
Medical Ethics Committee of Hospital of Stomatology,
Sun Yat-sen University (Seal)

日期：2020.12.11
Date

注意事项
Notes

一、如为非肯定性意见

按审查意见修改后的文件，或对审查意见不同观点的陈诉，请提交“复审申请”，方案/知情同意书请注明新的版本号和版本日期，并以阴影和(或)下划线方式标注修改部分，报伦理委员会审查，经批准后执行。

Please submit the revised documents or different opinions on the review opinions in the form of "re-review application". Please indicate the new version number and date of the protocol
/informed consent form, and mark the revised part with shading and/or underline. Execute after review and approval by the ethics committee.

二、 如为肯定性意见

1. 本意见可能在其他中心机构及其伦理委员会备案。如果对方案在贵机构的可行性（包括研究者的资格与经验、设备与条件等）有不同意见，请及时与本伦理委员会联系。

This approval may be filed with other institution and their ethics committees. If you have different opinions about the feasibility of the protocol in your institution (including the qualification and experience of the investigator, equipment and conditions, etc.), please contact us in time.

2. 请遵循CFDA/GCP（2020）、《涉及人的生物医学研究伦理审查办法（2016）》
《医疗器械临床试验质量管理规范（2016）》和《赫尔辛基宣言》的原则，遵循伦理委员会批准的方案开展临床研究，保障受试者的权利、安全和健康。

A trial should be conducted in compliance with the principles of CFDA/GCP(2020), Methods for Ethical Review of Biomedical Research Involving Humans(2016), Standard for Quality Management of Clinical Trials of Medical Devices(2016), and the Declaration of Helsinki. A trial should be conducted in compliance with the protocol that has received prior ethics committee approved/favourable opinion. The rights, safety, and well-being of the trial subjects are the most important considerations.

3. 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请研究者提交修正案审查申请。

The investigator is requested to submit an application for amendment review during the investigate process in these cases: the principal investigator is changed, any changes to the trial protocol, informed consent form, recruitment materials, etc.

4. 发生严重不良事件，请研究者及时提交严重不良事件报告。

The investigator is requested to submit a report of SAE timely when SAE occurred.

5. 请按照伦理委员会规定的年度定期跟踪审查频率，研究者在截止日期前1个月提交年度定期跟踪审查报告；研究者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请研究者及时向伦理委员会提交书面报告。
The investigator is requested to submit written reports of Annual Follow-Up Review One month before the deadline requested by the ethics committee. The investigator is requested to submit a summary progress report of each institution to the ethics committee of the leading site. The investigator should promptly provide written reports to ethics committee on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

6 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益健康以及研究的科学性造成不良影响等违背GCP原则的情况，请申办者/监查员/研究者提交违背方案报告。
The sponsor/monitor/investigator should submit reports of protocol deviation to the ethics committee in these cases: the trial enrolled subjects that didn't meet include criteria or meet exclude criteria; Subject who met discontinuation criteria but didn't withdraw from the study; Subject was given incorrect treatment or dosage; Subject was treated with prohibited drug combination or study was conducted that violated given protocol; Situations that might adversely affect the rights and health of the subject and the scientific nature of the research or other condition that might jeopardize GCP principle.

7 研究者提前终止或暂停临床研究，请及时提交暂停/终止研究报告。
If the trial is prematurely terminated or suspended, the investigator should submit a suspension/termination report in time.

8 完成临床研究，请研究者提交结题报告。
The investigator should submit a final report when completed the clinical research.

声明：本伦理委员会按照中国GCP、ICH GCP和有关法规组成和工作，其审查和工作过程不受任何组织及个人的影响。

Announcement:

This ethics committee is composed and working in compliance with the Chinese GCP, ICH GCP and relevant regulations. The review and work process is not affected by any organization or individual.

联系方式：广州市陵园西路56号
Contact: No. 56, Lingyuan West Road, Guangzhou
电话/传真：020-83700609
Telephone / Fax: 020-83700609
邮箱：ghkqec@126.com
Email Address: ghkqec@126.com