

河南工业大学科研伦理审查批准函

Approval Letter for Scientific Research Ethics Review of Henan

University of Technology

编号：HAUTEC-2024-68

No. : HAUTEC-2024-68

项目名称 Project Title	阿克曼氏菌 Akk11 对超重志愿者体脂的改善作用的有效性和安全性评价：一项交叉验证研究 Evaluation of the efficacy and safety of the ameliorative effect of Akkermansia muciniphila Akk11 on body fat in overweight volunteers: a cross-validation study		项目计划起止时间 Project Duration	2024-06-28 至 2025-06-28 June 28, 2024 to June 28, 2025			
项目类别 Project Category	____A____ A. 涉及人体研究 B. 涉及动物研究 C. 涉及生物信息安全 D. 涉及病原微生物/病毒 E. 其他（请注明）：_____ ____A____ A. Involving Human Research B. Involving Animal Research C. Involving Biosafety D. Involving Pathogenic Microorganisms/Viruses E. Others (Specify): _____						
申请人（项目负责人）简要信息 Applicant (Principal Investigator) Information							
姓名 Name	许飞 Xu Fei	性别 Gender	男 Male	学历 Education	博士 Ph.D.	职称 Position	副教授 Associate Professor
办公电话 Office Phone	无 None	传真 Fax	无 None	移动电话 Mobile Phone	18623716648	电子邮箱 Email	xu.fei@haut.edu.cn
目前主要研究方向 Current Research Focus	粮油食品加工与制造 Grain and Oil Food Processing and Manufacturing						
科研活动经费来源： ☐ 政府 ☐ 基金会 ☒ 公司 ☐ 国际组织 ☐ 其他 Funding Source: ☐ Government ☐ Foundation ☒ Company ☐ International Organization ☐ Others							
主要研究内容及涉及的伦理问题： Main Research Content and Ethical Considerations:							
对甲方提供的阿克曼氏菌 Akk11 对超重志愿者体脂的改善作用的有效性和安全性等功能进行临床试验并探究其干预机制。通过测序、相关性分析等对其生理调节机制进行解析。 Conduct clinical trials to evaluate the efficacy and safety of the Akkermansia muciniphila Akk11 strain provided by Wecare Probiotics in improving the body fat of overweight volunteers, and explore its intervention mechanism. The physiological regulatory mechanisms were analyzed through sequencing and correlation analysis. 益生菌菌株安全性前期已通过认证，并获得市售许可。每日服用剂量均远低于行业推荐最大食用量，对受试者无食用风险。实验开始前会让受试者签订实验知情表格和自愿参加表格，实验过程中如有任何不适，可随时无条件退出实验。 The safety of the probiotic strains has been pre-certified and approved for commercial sale. The daily dosage is far below the industry-recommended maximum intake, posing no risk to participants. Prior to the experiment, participants will sign informed consent and voluntary participation forms. Participants may withdraw unconditionally at any time if discomfort occurs during the study.							

申请人（项目负责人）承诺：

Applicant (Principal Investigator) Declaration:

以上所填内容均属实，如获批准，我将严格按照提供的方案进行研究，并遵守河南工业大学伦理委员会的相关规定。

I confirm that the above information is accurate. If approved, I will strictly adhere to the proposed research protocol and comply with the regulations of the Ethics Committee of Henan University of Technology.

申请人（项目负责人）签字：

Applicant (Principal Investigator) Signature:

日期：

Date:

2024.04.28

学院学术委员会审查意见：

Review Opinion of the College Academic Committee:

经粮油食品学院学术委员会审查，该项目设计规范，研究内容和过程符合国家颁布的有关生物医学研究的伦理要求，同意该项目按计划执行。

After review by the Academic Committee of the College of Food Science and Engineering, the project design is standardized, and the research content and procedures comply with national ethical requirements for biomedical studies. The project is approved for execution as planned.

粮油食品学术委员会（盖章）

College of Food Science and Engineering Academic Committee (Seal)



日期：2024.05.26

Date: